



Medication Safety Committee

January 6, 2016

California Hospital Association

1215 K Street, Suite 800

Sacramento, CA 95814

Conference Call Option:

(800) 882-3610 Access Code: 4206832#

Medication Safety Committee

AGENDA

10:00	I. CALL TO ORDER/INTRODUCTIONS	Fong
	A. Roster - Page 5	
	B. Member Map - Page 9	
	C. Member Geographic - Page 10	
	D. Member Updates	
	E. Committee Guidelines and 2016 Goals and Objectives - Page 11	
10:10	II. MINUTES OF OCTOBER 7, 2015 MEETING	Fong
	A. Meeting Minutes - Page 12	
	III. OLD BUSINESS	
10:15	A. CHA 340b Advisory Committee Update	Fong / Paulsen
	i. 340b Article - Page 16	
	ii. 340b CHA Comment Letter - Page 18	
	iii. 340b Model Comment Letter - Page 31	
10:20	B. CURES 2.0 Browser	Bartleson
	i. Minutes - Page 35	
	ii. CURES 2.0 Browser Workgroup Roster - Page 37	
	C. Impact Act & CMS Drug Regime http://www.calhospital.org/cy2016-hh-pps-final	
10:25	D. Drug Quality and Security Act	Bartleson
	i. KP Track and Trace Policy - Page 39	
	ii. Track and Trace Job Aid - Page 48	
	iii. Track and Trace Law FAQs - Page 61	
10:40	E. Sterile Compounding	Fong
	i. Medication Safety Sterile Compounding Memo - Page 67	
	ii. CHA Draft Hazardous Sterile Compounding Webinar - Page 68	
	iii. Sterile Compounding FAQs - Page 70	
	iv. Medication Safety Committee Guidelines Matrix - Page 71	
11:10	F. CalOSHA Antineoplastic Regulations	Saiger
	i. AB 1202 - Page 75	
	ii. Antineoplastic Drug Handling Workgroup Roster - Page 77	
	iii. Draft Discussion as of 10-13-15 - Page 78	
11:15	G. Drug Take Back Programs	Gutierrez

	i. Board of Pharmacy Drug Take Back - Page 95	
	ii. Prescription Drug Take Back Matrix - Page 114	
11:20	H. Drug Reconciliation and Inventory Regulations	Fong
	i. CHA Board of Pharmacy Inventory Letter - Page 118	
	ii. CCR Section 1715.65 - Page 122	
11:25	I. CHA Medication Safety Tools - Page 133	Bartleson
11:35	J. Medication Reconciliation / Discharge Planning	Blaisdell
	i. Discharge Planning Article - Page 135	
	ii. CHA Summary Discharge Planning Proposal - Page 136	
11:50	IV. LUNCH	
	V. NEW BUSINESS	
12:00	A. Hazardous Waste Pharmaceuticals	Hummel
	i. CHA Comment Letter Regarding EPA Hazardous Waste Pharmaceuticals - Page 143	
	ii. Hazardous Disposal Article - Page 146	
	iii. EPA Waste Generator Proposed Rule - Page 147	
	iv. EPA Hazardous Waste Pharmaceuticals Proposed Rule - Page 243	
12:15	B. USP 797, USP 800 Update	Bartleson
12:30	C. CMS Regulations - Page 323	Paulsen
12:40	D. Small Bore Connectors	Jaffe
1:10	E. Proposed 2016 Guidelines for Prescribing Opioids for Chronic Pain - Page 368	Jaffe
1:45	VI. WORK GROUP REPORTS	
	A. Medication Technology	Jaffe
	B. Sterile Compounding	Fong
	C. CURES 2.0 Browser	Bartleson
	D. CHA Medication Safety Toolkit Plan	Bartleson
	VII. STANDING REPORTS	
	A. Board of Pharmacy	Herold
	B. CDPH	Woo
	C. CSHP	Sinclair
	D. CALNOC	Blankenship
	E. CAHF	Hall
	VIII. PHARMACY LEGISLATIVE UPDATES	Bartleson
	IX. OTHER BUSINESS	All

X. ARTICLES OF INTEREST

All

Hospitals Launch Specialty Pharmacies to Curb Drug Costs - Page 395

XI. NEXT MEETING

All

April 6, 2016

2:00

XII. ADJOURNMENT

Fong



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Medication Safety Committee Representation

Rev. January 2015



Denotes number of hospitals/health systems represented within that county.

**Medication Safety Committee
Member Geographics - July 2015**

HOSPITAL COMMITTEE MEMBERS

Candace Fong	Dignity Health	Sacramento/San Francisco
Doug O'Brien	Kaiser Foundation Hospitals	Sacramento
Sarah Stephens	Kaweah Delta Health Care District	Tulare
Carolyn Brown	Santa Clara Valley Medical Center	Santa Clara
Jeanenett Hanni	Sutter Health - West and South Bay Region	Santa Clara
Nasim Karmali	Kaiser Foundation Hospital	Alameda
Kevin Dorsey-Tyler	Enloe Medical Center	Butte
Sue Reed	Adventist Health	Placer
Christine Low	Scripps System	San Diego
Eddie Avedikian	Providence Holy Cross Medical Center	Santa Barbara
Edna DeLeon	Huntington Memorial Hospital	Los Angeles
Nancy Blake	Childrens Hospital Los Angeles	Los Angeles
Lori Nolan	Providence Holy Cross Medical Center	Los Angeles
Richard Rabens	The Permanente Medical Group, Inc.	Alameda
Diane Schultz	Palomar Medical Center	Los Angeles
Theresa Vidals	Tri-City Medical Center	San Diego
Amy Gutierrez	LA County Department of Public Health	Los Angeles

NON-HOSPITAL COMMITTEE MEMBER:

Dan Ross	California Society of Health System	Sacramento
Jocelyn Montgomery	California Association of Health Faciliteis	Sacramento
Patricia McFarland	Association of California Nurse Leaders	Sacramento
Randy Kajioka	California Correctional Health Care	Sacramento
Robert Menet	California Department of Public Health	Sacramento
Roy Jaffe	California Hospital Patient Safety	Sacramento
Virginia Herold	California Board of Pharmacy	Sacramento
Art Woo	California Department of Public Health	Contra Costa
Cari Lee	California Department of Public Health	San Mateo
Jacalynn Blankenship	CALNOC	Contra Costa
Jenna Fisher	Hospital Council of Northern and Central	Contra Costa
Katie Choy	Washington Hospital Health Care System	Alameda
Lynn Paulsen	University of California	San Francisco
Mary Foley	Center for Nursing and Innovation	San Francisco
Alicia Munoz	Hospital Association of San Diego	San Diego
Christy Sinclair	California Society of Health System	Sacramento
Julie Slininger	Hospital Association of Southern California	Los Angeles

CHA Medication Safety Committee, Mission, Purpose and 2016 Objectives

Mission:

The mission of the CHA Medication Safety Committee is to provide leadership within the health care community to promote the highest standards related to the safe and effective use of medication.

Purpose:

The purpose of the Medication Safety Committee is to provide a forum for diverse multi-disciplinary health care organizations, which includes health care delivery organizations, patient safety organizations, discipline specific professional associations/organizations and regulatory agencies, to promote safe medication practices in the state of California. The Committee will focus on acting as a source of medication safety expertise, providing a venue for the coordination of medication safety activities and making recommendations related to medication safety legislation and regulations.

2016 Goals and Objectives

- 1) Develop guidance, tools, information and strategies for hospitals and pharmacists involved in medication safety to enhance quality care and patient safety.
 - a) Implement workgroups where members can apply their expertise to explore, plan and suggest strategies
 - i) 2016 Workgroups: Sterile Compounding , Medication Technology, CURES 2.0 Browser Workgroup, Inventory and Reconciliation, Drug Quality and Security , Antineoplastic Regulations
 - ii) Finalize the Sterile Compounding Matrix Tools, disseminate and implement an informational webinar to assist members with compliance
- 2) Advise the CHA Board of Trustees on issues relevant to medication safety, particularly under health care reform and projected care model changes.
 - a) Develop an issue brief that describes the challenges of the present environment and make strategic recommendations for the pharmacy of the future
 - b) Work with CHA Finance staff to assist with regulatory advocacy on pricing issues such as the 340B Drug Pricing Program Omnibus Guidance.
- 3) Develop new strategies for CHA Medication Safety Tools to be disseminated and distributed among California hospitals and stakeholders.
 - a) Publish the CHA Medication Safety Tool Compendium that includes the numerous tools developed by the committee and disseminate to members.

**MEDICATION SAFETY COMMITTEE
MEETING MINUTES**
October 7, 2015 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Alicia Munoz, Amy Gutierrez, Art Woo, Candace Fong, Cari Lee, Carolyn Brown, Christine Low, Dan Ross, Diana Schultz, Doug O'Brien, Eddie Avedikian, Enda DeLeon, Jacalynn Blankenship, Jeannette Hanni, Kevin Dorsey-Tyler, Lori Nolan-Mullenhour, Lynn Paulsen, Richard Rabens, Robert Menet, Sarah Stephens, Terri Vidals, Virginia Herold,

Members Absent: Jeanna Fischer, Jocelyn Montgomery, Julia Slininger, Katie Choy, Mary Foley, Nancy Blake, Nasim Karmali, Patricia McFarland, Randy Kajoioika, Sue Reed

Invited Guests: Mike Small, Chris Patty, Murooj Shukey, Kathy Ghomeshi

CHA Staff: BJ Bartleson, Ronda Fricke, Amber Ott, Pat Blaisdell

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Jeannette Hanni at 10:05 AM.

A. Member Updates

Ms. Hanni reviewed/discussed membership items included in the meeting book.

Action: CHA Staff to update member roster and membership geographics to update membership information

B. Member Updates – New Members

Mr. Hanni welcomed Christy Sinclair to the group. Introductions were by the committee.

C. Committee Guidelines

Ms. Bartleson reviewed the 2015 draft goals and objectives. The proposed goals and objectives reflect the committee discussions, work activity and ongoing conversations. Ms. Bartleson discussed the importance of this committee, not only to CHA hospital members, but to the CHA and Regional Association Boards, relative to their knowledge on current topics and issues affecting hospital pharmacies and medication safety in their hospitals.

Action: Ms. Bartleson will update the 2015 draft goals and objectives.

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the July 8, 2015, Medication Safety Committee meeting were reviewed as submitted.

IT WAS MOVED, SECONDED AND CARRIED:

- To approve the minutes of the July 8, 2015, Medication Safety Committee meeting.

CHA 340b Advisory Committee Update

Ms. Amber Ott presented the 340B Omnibus Guidance presentation. She provided a high level overview and answered questions from the committee regarding 340B. She added that CHA would be making several comments and asked the committee to assist by providing additional comments to her.

III. OLD BUSINESS

A. CURES Webinar

Mr. Mike Small presented on CURES 2.0 Prescription Drug Monitoring Program. He provided background information by sharing that California has the oldest prescription drug monitoring program that originated in 1939. Mr. Small noted he is custodian of reports but doesn't touch or change the data that is submitted. He added that an extension to extend the registration date to July 1, 2016 is awaiting the Governor's signature.

Mr. Small discussed improvements made to the CURES website and provided some examples to the committee. He suggested that users download the User Manual prior to logging in for the first time.

Sterile Compounding Advisory Committee

Ms. Bartleson discussed that the workgroup has been meeting to determine the most appropriate time and method to deploy an educational webinar in 2016 and working on FAQs. Once completed the group will disseminate.

Action: Ms. Bartleson will work with Ms. Paulsen and others to provide FAQs.

IV. LUNCH

V. NEW BUSINESS

A. Impact Act and CMS Drug Regime Measure

Ms. Pat Blaisdell provided some history on the Post-Acute Care Center for the committee. She discussed the four specific provider levels (1) Inpatient

Rehabilitation Facility (2) Long Term Acute Hospital, (3) Skilled Nursing and (4) Home Health Agencies. She touched on the individuals who are eligible to receive 340B drugs as well as covered entity responsibilities. She also touched base on contract pharmacy arrangements and the AIDS drug assistance program.

Ms. Blaisdell mentioned the Improving Medicare Post-Acute Care Transformation Act of 2014 and that she has been working on it for the last 2 years. She told the committee this is their opportunity to make comments and provide input and encouraged them to send those to her.

B. The Drug Quality and Security Act

Ms. Jeannette Hanni discussed the Act and mentioned it had been withdrawn from California legislation in lieu of federal legislation. She mentioned that all information collected needs to be kept for a 6 year period. She added that there are several software programs that could help with tracking including Tracelink.

ACTION: Ms. Hanni suggested CHA create a subgroup that could compose and disseminate FAQs for this action. The following individuals volunteered to work on the subgroup: Doug O'Brien, Amy Gutierrez, Jeannette Hanni and Christine Low.

C. Double Verification of SQ Insulin

Mr. Chris Patty presented "Prescription for Success Medication Administration Accuracy". He discussed discontinuing mandatory double verification of SQ Insulin and stated his facility has not required double checking SQ insulin for two years and the error rate has remained the same. He shared how this process improves patient safety and nurse satisfaction.

VI. STANDING REPORTS

- A. Board of Pharmacy – Ms. Amy Gutierrez provided an update on the Pharma Take Back Initiative. She discussed that some counties are trying to mandate a hospital pharmacy take back medications program for patients. She stated that a DEA registrant can participate in Drug Take Back Program. She added that more information is available on the Board of Pharmacy website.
- B. CDPH – Ms. Cari Lee updated the committee on finishing the MERP surveys and that six additional surveys will be conducted by the end of the year. The projected full implementation date is March 16 but subject to change. Mr. Art Wood discussed repetitive pharmacy findings and how they change over time.
- C. CSHP – Ms. Christy Sinclair reminded the committee that 50% of the staff is new and that since the association transition, things are starting to improve.

D. CALNOC – Ms. Jacalynn Blankenship provided a brief overview.

E. CAFH –Ms. Lisa Hall provided an update on the pending lawsuit.

VII. WORKGROUP REPORTS

A. Medication Technology – No update was provided.

B. Sterile Compounding – Ms. Hanni discussed what the group is currently working on.

C. CURES 2.0 Browser – Ms. Bartleson reviewed the CURES workgroup minutes and discussed next steps in relation to browser compatibility and registration date regulations.

D. CHA Medication Safety Toolkit Plan – Ms. Bartleson discussed the work occurring with the sterile compounding matrix and tools, and developing the content for a future webinar.

VIII. PHARMACY LEGISLATE UPDATE

Ms. Bartleson discussed the comments and provided a copy of the letter that were provided to the California Board of Pharmacy for the Compounding Regulations, Notice of Proposed Modifications, Article 4.5, 7 and 7.5 of Division 17 of Title 16 California Code of Regulations, Section 1735 et seq., 1751 et seq., 1752, 1753 and 1754.

IX. OTHER BUSINESS

The committee was made aware of the Scope of Pain Safe and Competent Opioid Prescribing Education opportunity on November 6, 2015, in San Diego.

X. ARTICLES OF INTEREST

XI. NEXT MEETING

January 6, 2016, California Hospital Association Boardroom.

XII. ADJOURNMENT

Having no further business, the committee adjourned at 1:50 PM.

CHA Advocacy Alert: Members Urged to Submit Comments on 340B Omnibus Guidance

Comments are due Oct. 27



OCTOBER 21, 2015 AMBER OTT

Action needed: CHA urges hospital executives to submit comments to the Health Resources and Services Administration (HRSA) on the 340B Drug Pricing Program Omnibus Guidance. Comments can be submitted at www.regulations.gov by searching for Regulatory Information Number (RIN) 0906-AB08, or by email at 340BGuidelines@hrsa.gov, including RIN 0906-AB08 in the subject line of the message.

Timing: Submit comments before 2 p.m. (PT) Oct. 27.

CHA has prepared the attached comment letter on the 340B Drug Pricing Program Omnibus Guidance, published Aug. 28 by HRSA. In the letter, CHA urges HRSA to consider several important changes to the proposed guidance so hospitals can continue to stretch scarce federal resources as far as possible to provide necessary access to the most vulnerable populations.

Specifically, CHA urges HRSA to change the proposed definition of an eligible patient and an eligible drug; accept alternative forms of documentation to show that a clinic is an integral part of the hospital; reduce the burdensome audit requirements associated with contract pharmacy arrangements; and limit all disclosures to those that rise to the level of being material.

CHA's detailed comments are the result of a robust dialogue with CHA member hospitals that participate on the 340B work group. CHA urges members to use the attached comment letter as a model in writing their own comments. CHA also encourages members

who have not done so to review the **proposed guidance summary**.



October 26, 2015

Commander Krista Pedley
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RE: RIN 0906-AB08, 340B Drug Pricing Program Omnibus Guidance; August 28, 2015.

Dear Commander Pedley:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) is pleased to submit comments on the 340B Drug Pricing Program Omnibus Guidance, published by the Health Resources and Services Administration (HRSA) August 28. Over the past 60 days, CHA gathered members from across the state to solicit input and feedback on the guidance. It was a robust dialogue that engaged disproportionate share hospitals, children's hospitals, critical access hospitals, cancer centers and sole community hospitals.

CHA shares HRSA's goal of ensuring that the 340B Drug Pricing Program remains strong and that covered entities are good stewards of the program. Since its inception, California's hospitals have upheld high standards of 340B program integrity and remain fully committed to improving the program by supporting the administration's ongoing audits and annual recertification process.

According to HRSA, the intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients. After careful consideration of the stated intent of the 340B program and the operational realities of implementing some of the changes outlined in the guidance, we urge HRSA to consider several important changes to the guidance so that hospitals can continue to provide necessary access to our most vulnerable population, while fulfilling our shared goal of the triple aim.

In summary, CHA urges HRSA to:

- **Remove the employment and independent contract language from the definition of an eligible patient.** CHA is concerned that the policies HRSA has proposed with regard to the eligible patient definition are too restrictive and, if finalized, will inhibit the ability of facilities in California to meaningfully participate in the 340B program.
- **Withdraw the proposal that a patient receiving only infusion services would not be an eligible 340B patient.** The covered entity is responsible for the patient and his or her

care while administering the infusion drug. Therefore, it seems arbitrary to deem infusion treatment of patients from another facility as ineligible for 340B.

- **Continue to allow 340B drug discount pricing to apply to discharge prescriptions, to the extent that the drugs are for outpatient use.**
- **Reconsider many of the proposed changes detailed below that will result in significant costs and administrative burdens within a program designed to generate cost savings for safety-net hospitals.**

Individuals Eligible to Receive 340B Drugs

HRSA proposes to add additional conditions to the definition of a patient eligible to receive 340B drugs to better ensure that covered entities are not able to resell or transfer a 340B drug to a person who is not a patient of the entity. Current guidance provides for a three-part test to determine if an individual is a patient of a covered entity. In this guidance, HRSA proposes that an individual will be considered a patient of a covered entity on a prescription-by-prescription or order-by-order basis and extends the conditions to a six-part test.

CHA acknowledges a need for greater clarity around the current patient definition. However, the proposed definition is very problematic for California's hospitals, as it leads to more questions than answers.

1. The individual receives a health care service at a covered entity site that is registered for the 340B program and listed on the public 340B database.

HRSA proposes that the patient must receive a health care service from the covered entity, and the covered entity is medically responsible for the care provided to the individual. The guidance also notes that an individual will not be considered a patient of the covered entity if the individual's health care is provided by another health care organization.

CHA recognizes that HRSA wants to ensure that the covered entity maintains full responsibility for care. However, CHA is concerned that this provision could impact California hospitals' home care programs, which provide critical support services to vulnerable patients who are often too fragile to travel. For example, a hospital may have a neonatologist prescribe Synagis, a drug to help prevent serious lower respiratory tract disease in children at high risk for respiratory syncytial virus disease, which will then be administered by a nurse to the baby in the home. This important service ensures that the patient gets the right care in the right place, as it keeps the baby out of the hospital or clinic where s/he would be at greater risk for illness or infection. The preamble notes that HRSA interprets the statute to mean that a 340B eligible patient is one who receives health care services from the covered entity, and the covered entity is medically responsible for the care provided to the individual. In this case, the order is from the entity's provider, but the care is provided in the home as part of the covered entity's home care program. We request that HRSA clarify whether this type of service, which is

provided by the covered entity, would qualify since the home is obviously not registered in the 340B database. **CHA believes these types of programs are consistent with the current 340B program guidelines and we ask HRSA to confirm that these types of home care services would remain eligible under the 340B Drug Pricing Program.**

2. The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.

CHA appreciates and supports HRSA's efforts to provide additional clarification and guidance with respect to which patients are eligible to receive prescription medications purchased at 340B prices. **As discussed in more detail below, CHA is concerned that the policies HRSA has proposed with regard to the eligible patient definition are too restrictive and, if finalized, will inhibit the ability of facilities in California (and possibly elsewhere) to meaningfully participate in the 340B program.** Specifically, the proposed guidance poses problems for covered entities that are restricted by state law in the types of relationships they can establish with health care practitioners such as physicians. **CHA urges HRSA to remove this language from the proposed patient definition for a number of reasons detailed below.**

In the proposed guidance, HRSA indicates that, among other requirements, a patient will only be considered eligible to receive 340B drugs if that individual "receives health care services by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider." HRSA then goes on to state that "[s]imply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by a privileged provider is a patient of the covered entity for 340B program purposes." **This element of the proposed definition of eligible patient is too narrow in light of the fact that some states, including California, prohibit hospitals from employing physicians.**

Many states have statutes or regulations codifying what is commonly known as the "corporate practice of medicine doctrine" (CPM). The CPM broadly articulates the principle that physicians must be able to make decisions autonomously, without undue influence from a business corporation for which the physician works. Though the details of its application vary by location, roughly 30 states now follow some form of the CPM and prohibit corporations from practicing medicine and/or employing physicians. This is a complex and varied set of state statutes that varies from state to state. California is widely regarded as the state with the most aggressive version of the CPM.

California's CPM arises from two provisions of the state's Medical Practice Act, as codified in the California Business and Professions Code. Specifically, Section 2052 of the code makes it unlawful for any person or entity to practice medicine without a valid license, and Section 2400 states that "[c]orporations and other artificial entities shall have no professional rights, privileges or powers." California courts, as well as the California

Attorney General, interpret the two statutes together to mean that corporations and other business entities are prohibited from employing physicians. California law significantly restricts the kind of relationships hospitals, including 340B covered entities, can establish with physicians.

Further, judicial and agency interpretations of the CPM have established that it is permissible in California for physicians to enter into independent contractor relationships with hospitals, but such relationships often are not practically desirable or feasible when the physician will only be providing medical services to hospital patients, as opposed to also taking on additional administrative responsibilities akin to a medical directorship. For that reason, it is fairly common in California (as well as other CPM states) for physicians to have no formal relationship with the hospitals in which they work other than being members of the medical staff. **Given this fact, the proposed guidance clearly presents problems for California's hospitals by establishing that a patient of a covered entity is only eligible to receive a 340B drug if that patient receives services from a hospital employee or independent contractor.**

If the patient definition set forth in the proposed guidance is finalized to require a service rendered by an employed or contracted physician, it would significantly decrease the number of 340B prescriptions California covered entity hospitals can dispense to their patients and have devastating consequences for our patients. The proposed eligible patient definition leaves California facilities with few options for creating the kind of relationships with physicians that meet the standard for use of 340B drugs. Forcing safety net hospitals to scale back 340B dispensing because of the currently proposed patient definition would effectively defeat the statutory purpose of the 340B program, which is to increase the accessibility of outpatient prescription drugs to safety net providers. CHA urges HRSA to remove this problematic definition from the patient definition.

HRSA has commented in previous guidance that the purpose of the language in the patient definition calling for an individual to receive care from a health care professional who is employed by, or working under a contractual or other arrangement with, the covered entity is to provide an indication that the hospital remains responsible for the patient's care, as such responsibility may not be present unless the health care provider is bound by some kind of reciprocal obligations to the hospital. CHA believes binding reciprocal obligations can be established between a hospital and practitioner by other means than employment or direct contracts. For example, many hospitals in California and elsewhere now follow a foundation model, whereby the hospital contracts with a medical foundation. The foundation, in turn, contracts with physicians who provide services to the hospital's patients. Under this model, the physicians are not under a direct contractual relationship with the hospital but nevertheless have obligations to the facility arising from the foundation's relationship with the hospital. However, it is not clear whether this type of relationship would satisfy the eligible patient definition in the proposed guidance. Further, state laws vary and the challenges of ensuring that every physician integration model is fully addressed in guidance may be a challenge for the agency.

We believe, depending on the specific conditions attached to medical staff membership, medical staff privileges can impose enough obligations on a practitioner to rise to the level of a contract between the practitioner and the facility, as in *Smith v. Adventist Health System/West* (2010) 182 Cal. App.4th 729, 753, which held that medical staff bylaws can create a contract between a physician and a hospital if the bylaws state expressly that they form a contract. Further, even if they do not expressly establish a contract, California statutory requirements may view medical staff bylaws as imposing reciprocal binding, enforceable obligations on both the hospital and medical staff members. See, e.g. 22 California Code of Regulations (CCR) § 70703 (imposing a requirement on hospitals that the medical staff must adopt bylaws, including a means of enforcement of those bylaws); see also *Janda v. Madera Comm. Hosp.* (E.D. Cal. 1998) 16 F. Supp.2d 1181, 1183. In light of these factors, **CHA urges HRSA to adopt a blanket policy that medical staff privileges alone establish a sufficiently strong relationship between a covered entity and its doctors to satisfy the eligible patient definition.**

Finally, the restrictive policy HRSA proposes is unnecessary in light of the other elements of the definition of an eligible patient, as well as other existing 340B policies. In our view, other requirements within the guidance create sufficient safeguards to ensure that 340B drugs are only dispensed to covered entity patients. Among other things, the proposed guidance specifically requires: (1) that the patient obtain a service within the covered entity itself (including home care services, as described above) or a properly registered off-site clinic; (2) that the patient either be registered as a hospital outpatient or the hospital bills a third-party payer for the services as outpatient care; and (3) that the hospital maintain records showing it is responsible for the patient care. In this regard, it would appear that hospitals can adequately demonstrate responsibility for care of a patient, even if that care is provided by a physician who only has medical staff privileges at the hospital. Regardless of the relationship between the hospital and physician providing a service to a patient, if that service is furnished by the 340B covered entity, the hospital would maintain the records for the patient's care and bear responsibility for the care. **A number of factors, including the CPM ban, either outright prohibit or make it difficult for California hospitals to employ or directly contract with physicians. Other requirements within the guidance create sufficient safeguards to ensure that 340B drugs are only dispensed to covered entity patients and we urge the agency to remove the employment and independent contract language.**

3. An individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the service described in 2.

Under this provision, HRSA modifies the current guidance from “the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements” to “an individual receives a drug that is ordered or prescribed by the covered entity as a result of the services described in step 2.” The proposed guidance specifically mentions that an individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion or dispensing of a drug,

meaning the guidance would prohibit 340B use in connection with infusion drugs unless the order for infusion was written by a hospital provider as a result of a service provided at the hospital.

This proposed change to the patient definition would cause significant access issues for patients, particularly in rural areas and at sole community hospitals. For example, if an oncologist writes an order for infusion therapy, the patient can go to the local 340B hospital to receive the infusion therapy service; under the current guidance, 340B drugs can be used. However, the new guidance would not allow that hospital to use 340B drugs and, therefore, it may not be able to maintain the infusion therapy services. Rather, those patients would have to travel outside of their community to find a provider who is willing and able to provide such services. This new guidance would discourage hospitals from expanding infusion therapy centers, further limiting access for patients.

The infusion of a drug is more complex than the proposed guidance suggests, as it requires the administration of medication intravenously, under the management of a trained health care professional. CHA understands HRSA's attempt to ensure that patients of a covered entity are receiving health care services as opposed to simply a prescription. However, infusion treatment, regardless of the prescription's origin, requires substantial care from a health care provider at the time of the infusion. Individuals receiving infusion at a hospital are unquestionably hospital patients, even if the order is written outside the hospital. **In addition, the covered entity is responsible for the patient and his or her care while administering the infusion drug. Therefore, it seems arbitrary to deem infusion treatment of patients from another facility as ineligible for 340B, especially when the prescription meets all other criteria under the revised patient definition. CHA encourages HRSA to withdraw this proposal as it is harmful to patient care.**

4. The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient.

HRSA has proposed a new standard that a patient is considered eligible for 340B if the patient's health care service is billed as outpatient to the patient's insurer. CHA understands that the 340B program should only be used to furnish covered outpatient drugs. However, the proposed policy goes too far and seems to contradict the purpose of the 340B program — as well as the way care should be provided. For example, discharge prescription programs have been implemented by many institutions to facilitate the transition of care and improve compliance with medication therapy, in an effort to improve patient outcomes and reduce hospital readmissions. These types of programs help educate and remove some of the challenges related to medication compliance, but would be jeopardized if this policy is finalized. **Covered entities may instead be forced to have an individual make a second trip to the hospital just to have the physician prescribe or order a much-needed covered outpatient drug, wasting both time and resources.** Apexus notes in a frequently asked question (FAQ ID: 1563) that "340B drugs can be used for discharge prescriptions to the extent that the drugs are for

outpatient use.” This seems consistent with the intent of the program, and we urge HRSA to maintain the current interpretation.

In addition, it appears that under the proposed guidance patients receiving outpatient or emergency department (ED) treatment that leads to an inpatient admission would no longer qualify as an eligible patient, even if they receive drugs while in the outpatient setting. This seems to also include instances when someone goes to the ED for care (e.g., asthma attack), receives care and is sent home. Once home, the patient experiences another asthma-related issue within 72 hours and is admitted as an inpatient in the hospital. Under the Medicare 72-hour rule, that initial visit to the ED would no longer be eligible for 340B drugs since the ED charges would appear on the inpatient bill. Again, this proposed policy would change HRSA’s longstanding rules in this area and seems inconsistent with the intent of the program. Under current direction from Apexus (FAQ 1526), covered entities may determine inpatient vs. outpatient status such that the determination is in compliance with all 340B program requirements. CHA believes that drugs provided in the outpatient observation or the ED, prior to an individual being admitted as inpatient, are consistent with the 340B program. Complicating this with various payer billing rules is unnecessary and will be burdensome to implement.

Furthermore, tracking discharge prescriptions that tie to an inpatient service so they could be excluded from 340B would be operationally challenging and burdensome because hospitals generally do not track in their retail pharmacies whether a prescription resulted from an outpatient encounter. **Compliance with the proposed change would be very costly and require significant time and resources to develop. CHA does not support this proposal as all outpatient drugs should be considered for purposes of the 340B program, regardless of the payer and billing rules for which the drugs are billed and reimbursed. We believe the current documentation requirements are sufficient and we urge HRSA to reconsider this proposal.**

Drugs Eligible for Purchase Under 340B

CHA has concerns with the “limiting definition” for covered outpatient drugs, as well as the proposed requirement that a covered entity that receives a bundled payment by Medicaid and does not receive direct reimbursement for the drug would not qualify for 340B. The 340B program allows certain hospitals to participate only if the hospitals can demonstrate that they provide a disproportionate amount of care to Medicaid and low-income Medicare patients. It would be inconsistent with the purpose of the program to disallow 340B pricing for drugs dispensed to that population.

The proposed definition establishes a new standard for identifying 340B eligible drugs. As proposed, each state’s reimbursement methodology and Medicaid managed care plan’s reimbursement methodology will determine which drugs can be purchased under 340B. This will result in tremendous variability across states — and even within a state — as to which drugs a covered entity can purchase under the 340B program. If implemented as proposed, this provision would create significant administrative challenges and require new 340B tracking systems that do not exist today. Covered entities could no longer categorically classify certain drugs as “covered outpatient drugs” because the status of such drugs will vary by site and payer. As a

result, covered entities might be unable to determine the appropriate drug purchasing account to use in procuring such drugs until after the payer is determined, which could occur well after the drug is dispensed.

This proposal also changes the economics of providing care to Medicaid patients. Removing the ability to receive 340B pricing on Medicaid bundles eliminates the covered entity's savings on the very group of patients that are reimbursed significantly below the cost of care. This would be particularly problematic for California, since one in three (12 million) Californians are on Medi-Cal (California's Medicaid program), and California hospitals experience a \$7 billion payment shortfall annually by providing care to the Medi-Cal population. The 340B savings cover a small portion of these uncompensated costs.

This proposed policy is also contrary to the purpose of the program, which was created to help safety net providers "stretch scarce federal resources," like Medicaid, to provide more comprehensive health care services to more patients. Consequently, some California hospitals have noted that these changes would force them to carve-out the Medi-Cal managed care population, leading to significant increases in drug purchasing costs.

It's also worth mentioning that earlier this year CMS announced its goal to move 50 percent of Medicare fee-for-service payments to alternative payment models and population-based payments, such as accountable care organizations, bundled payments and the Medicare-Medicaid financial alignment initiative model. **As the health care industry continues to move toward bundled payments, it seems contradictory that HRSA would exclude drugs paid as part of a bundle from the 340B drug program. CHA does not support this proposal and urges HRSA to reconsider. If HRSA proceeds, CHA requests additional clarification regarding the application of this policy to both fee-for-service Medicaid and/or Medicaid managed care.**

Hospital Eligibility and Recertification

The guidance proposes a change to private nonprofit 340B hospitals that have contracts with state or local government by stating that the contracts "...should create enforceable expectations for the hospital for the provision of health services, including the provision of direct medical care." **It is not clear from the proposed guidance what HRSA means by the addition of the phrase "contract that should create enforceable expectations," and how it would affect nonprofit hospitals' eligibility. CHA requests that HRSA provide greater clarity in this area.** Specifically, how will HRSA evaluate the contract when hospitals apply or recertify for the program? How will the new language be used in HRSA's audit criteria for not-for-profit 340B hospitals?

The proposed guidance notes that child sites not located at the same physical address as the parent hospital covered entity will be listed on the public 340B database and are able to purchase and use 340B drugs for eligible patients, if the hospital covered entity provides its most recently filed Medicare cost report demonstrating that: 1) each of the facilities or clinics listed on a line of the cost report is reimbursable under Medicare; and 2) the services provided at each of the facilities or clinics have associated outpatient Medicare costs and charges.

Relying only on the most recently filed cost report can cause significant delays to registering child sites. If a hospital opens a new clinic just after the hospital filed its cost report, the hospital must wait another 17 months before filing a new cost report that includes the costs of the new clinic on a reimbursable line, and then may have to wait another six months before the hospital can register the clinic and have it appear in the OPA database. Meanwhile, Medicare will not require the hospital to wait until it files a new cost report for the clinic to bill for services as part of the hospital. **We urge HRSA to consider accepting alternative documentation to show that the clinic is an integral part of the hospital while the hospital waits to file a new cost report.** This could include the Medicare 855A enrollment form or a certification submitted to HRSA that: 1) the clinic will be listed on a reimbursable line of the cost report when the cost report is filed, 2) the hospital is currently billing for outpatient services at the clinic, and 3) the hospital agrees to repay manufacturers for 340B purchases made for the clinic if the clinic ends up not being billed on a reimbursable line of the cost report once it is filed.

In addition, the new requirement that a facility “have associated outpatient Medicare costs and charges” is concerning, especially for our children’s hospitals that operate pediatric clinics for low-income children, as well as our hospitals that operate outpatient AIDS clinics and free clinics for the uninsured homeless. A number of children’s hospitals have off-site outpatient facilities, and very few of them see Medicare patients — on average, Medicare represents less than 1 percent of children’s hospitals’ payer mix since the only pediatric population covered by Medicare is End Stage Renal Disease. Furthermore, some outpatient AIDS clinics and free clinics in low-income neighborhoods throughout our state do not have the Medicare volume necessary to meet this criterion. Consequently, this proposal could unintentionally eliminate child sites for many hospitals. **We believe that the guidance should be amended to more accurately reflect the population that these hospitals serve by removing the requirement for associated Medicare costs and charges on the Medicare cost report.**

Group Purchasing Organization Prohibition

The 340B statute prohibits the participation of DSH hospitals, children’s hospitals and freestanding cancer hospitals in the 340B program if they purchase drugs through group purchasing organizations (GPO). The proposed guidance clarifies three exceptions to the GPO prohibition: 1) an off-site outpatient facility of a 340B covered entity which is not participating in the 340B program; 2) GPO drugs provided to an inpatient whose status is subsequently changed to outpatient by a third party; and 3) hospitals that cannot access a drug at the 340B price or at wholesale acquisition cost to prevent disruptions in patient care. **CHA appreciates that HRSA clarified these exceptions to the GPO prohibition, in particular** the second scenario — when a GPO-purchased drug is provided to an inpatient that, upon subsequent review, is designated as an outpatient for payment purposes. California has experienced significant activity related to patient status reviews by the Medicare Recovery Audit Contractors (RACs), which primarily involves downgrading inpatient admissions to an outpatient level of care. While many of these denials are ultimately overturned after the hospital appeals, it is important that hospitals not be considered in violation of the GPO prohibition under these circumstances, especially considering the RACs can conduct audits on claims up to three years old.

Contract Pharmacy Arrangements

Existing guidance allows that a covered entity, regardless of the availability of an in-house pharmacy, may contract with one or more licensed pharmacies to dispense 340B drugs to eligible patients, provided the arrangement is in accordance with all other statutory 340B requirements and applicable laws. In the proposed guidance, HRSA proposes to add the expectation that the covered entity conduct oversight, including quarterly reviews and annual independent audits, of *each* contract pharmacy location. It is unreasonable to expect covered entities to conduct an annual independent audit and quarterly reviews of *each* contract pharmacy location. A covered entity should be able to conduct a single annual independent audit or quarterly review for each contract it has with a contract pharmacy provider, rather than at each site. Typically, sites subject to a single agreement use the same processes and software, maintained at a central location.

Requiring covered entities to audit each and every site is an unnecessary drain on resources that provides no added assurances of compliance.

The proposed guidance also states that *any program violation* detected through quarterly reviews or annual audits of a contract pharmacy should be disclosed to HRSA, and covered entities could be subject to applicable penalties for instances of duplicate discounts and diversion. The terms “any” and “violation” are not defined and we seek further explanation. Specifically, how will HRSA define “violation,” and is it the same as “discrepancy”? Given the large numbers of transactions, “any” violation could be interpreted to include any single transaction, which is neither reasonable nor practical and will create significant operational and financial burdens for covered entities. **HRSA should limit all disclosures to those that rise to level of being “material.”** Notifying HRSA of all program violations, no matter how minor, would be too burdensome for both HRSA and covered entities, and would not provide significant program integrity value.

Diversion

The proposed guidance includes an expectation that covered entities work with manufacturers to repay them for instances of diversion within 90 days of identifying a violation. Hospitals currently have safeguards in place to identify and correct cases of diversion, including timely manufacturer notification. Hospitals have noted that manufacturers rarely respond to their notification within sixty days. Given this lengthy response time, it is unreasonable to expect hospitals to repay manufacturers within 90 days of identification. **CHA recommends modifying this component of the guidance to instead require hospitals to notify the manufacturer within 90 days of identification, as opposed to requiring repayment within 90 days.**

The guidance also says covered entities “must notify HHS and each affected manufacturer of diversion and is expected to document notification attempts in auditable records.” This requirement appears to differ from HRSA’s current policy that only requires entities to report “material breaches” of program requirements to HHS. **Given the large number of transactions that occur under the 340B drug program, CHA seeks clarification from HRSA regarding the level of materiality that would be required.** In the absence of a materiality clause, this requirement could be interpreted to include any single transaction, which is neither reasonable nor practical and would create significant operational and financial burdens for covered entities.

It would also be a burden on HHS if it must receive reports on each of such violations. Therefore, HRSA should limit all disclosures to those that rise to level of being “material.”

Duplicate Discounts

The guidance outlines the 340B drug program’s standard that prohibits duplicate discounts whereby a state obtains a rebate on a drug provided to a Medicaid patient when the same drug was discounted under the 340B program. Under the proposed guidance, a covered entity will be listed on the public 340B database if it notifies HRSA at the time of registration whether it will purchase and dispense 340B drugs to its Medicaid FFS patients (carve-in) and bill the state, or whether it will purchase drugs for these patients through other mechanisms (carve-out).

For Medicaid managed care, HRSA has proposed that the covered entity may make a different determination regarding carve-in or carve-out status for MCO patients than it does for FFS patients. The guidance notes that an entity can make different decisions by covered entity site and by MCO, but must provide HRSA identifying information of the covered entity site, the associated MCO, and the decision to carve-in or carve-out. CHA is concerned that this proposal places too much of the burden on covered entities. **The Medicaid rebate statute maintains that states, not 340B covered entities, are legally responsible for protecting manufacturers from having to pay both a 340B discount and a Medicaid rebate on a managed care claim.** CMS reaffirmed this interpretation in the proposed managed care rule, released on May 26, 2015. CMS also proposed that, to ensure drug manufacturers will not be billed for rebates for drugs purchased and dispensed under the 340B drug pricing program, MCOs must have mechanisms in place to identify these drugs and exclude the reporting of this utilization data to the state as to avoid the manufacturer from incurring a duplicate discount on these products. **CHA urges HRSA to remain aligned with CMS in requiring that states and MCOs, not covered entities, are responsible for protecting manufacturers from duplicate discounts.**

Manufacturer Provisions

The proposed guidance says that HRSA expects manufacturers to issue refunds or credits for instances of overcharging within 90 days of the determination by the manufacturer or HRSA that an overcharge occurred, and that covered entities that fail to accept a refund within 90 days waive their right to repayment. CHA recommends that covered entities should have one year to accept a refund, not 90 days. There have been instances when a refund offer is sent to someone within the hospital who doesn’t have the authority to accept it and it takes time to get it to the correct person for review and approval. Time should also be given for entities to contest a repayment amount if they do not believe it was calculated correctly. **CHA recommends a one-year period to accept a refund in order to make sure the repayment is properly received and validated by the covered entity.**

CHA support HRSA’s expanded scope of what constitutes an overcharge, which includes errors, intentional overcharges and routine pricing adjustments. We appreciate HRSA recognizing that overcharges can occur due to miscalculation or retroactive readjustments, as well as intentional overcharging. We also support HRSA’s interest in knowing how an overcharge occurred. Specifically, the guidance states that manufacturers must submit to HHS the price recalculation

information, an explanation of why the overcharge occurred, how the refund will be calculated and to whom refunds or credits will be issued. **CHA appreciates HRSA's clarification that manufacturers may only calculate refunds on an NDC-by-NDC basis, not based on aggregated purchases, de minimis amounts, or netting purchases.** Refunds on an NDC-by-NDC basis are the fairest way of ensuring that entities receive the correct amount of a refund for each overcharge of a single type of drug.

Finally, CHA supports HRSA's proposal to conduct an annual recertification process for manufacturers. The proposed guidance says manufacturers should annually review and update their 340B database information as part of a recertification process. We support this proposed process because it will improve database accuracy and enhance program compliance. It is difficult for covered entities to communicate with manufacturers, either to report errors and make repayment or request refunds for overcharges, if manufacturer contact information in the database is not correct.

Maintenance of Auditable Records

HRSA proposes that a covered entity must maintain auditable records demonstrating compliance with all 340B program requirements for itself, any child site and any contract pharmacy for five years from the date the 340B drug was ordered or prescribed, regardless of whether the entity continues to participate in the 340B program. HRSA points out in the preamble, however, that if it finds a pattern of failure to comply with the program's requirements, it would not be precluded from accessing records prior to the five-year period. CHA agrees that a standard for record retention is important, especially in assisting covered entities in preparing for audits and understanding the time and scope limitations of 340B program audits. However, CHA asks HRSA to consider a three-year record retention requirement. This timeframe is consistent with the current look-back period for RACs and reasonably balances the need for a covered entity to document its compliance with 340B program requirements and the covered entity's effort and expense required to maintain records for an extended period of time.

Effective Date of Guidance

CHA recommends that the effective date of the 340B omnibus guidance be no less than 18 months after the date the final guidance is published in the Federal Register. In the proposed guidance, HRSA makes no mention of an effective date. An explicit effective date as recommended above would clarify when the guidance would apply, and it also would allow 340B hospitals sufficient time to make the appropriate internal policy and health information technology changes.

CHA and our 340B member hospitals appreciate the opportunity to share with you our concerns and questions. We share the common goal of ensuring that the 340B program can continue to help fulfill its original intent of helping hospitals stretch limited resources to expand and improve access to comprehensive health care services to low-income patients. The increasingly high cost of pharmaceuticals has continued to underscore the importance of the 340B program in helping achieve this goal. To that end, we encourage you to continue to strive for the right balance between requirements imposed on hospitals and those imposed on pharmaceutical

manufacturers. If you have any questions or require additional input, please do not hesitate to contact me at aott@calhospital.org or (916) 552-7669.

Sincerely,

/s/

Amber Ott
Vice President Finance

**PLACE LETTER ON HOSPITAL LETTER HEAD FOR
SUBMISSION TO HRSA BY NOT LATER THAN OCTOBER 27
at 2 pm PST**

October 27, 2015

Commander Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop 08W05A
Rockville, Maryland 20857

RE: RIN 0906-AB08, 340B Drug Pricing Program Omnibus Guidance; August 28, 2015.

Dear Commander Pedley:

On behalf of ***[insert name of your hospital and location]***, we are pleased to submit comments on the 340B Drug Pricing Program Omnibus Guidance, published by the Health Resources and Services Administration (HRSA) August 28.

We share HRSA's goal of ensuring that the 340B Drug Pricing Program remains strong and that covered entities are good stewards of the program. Since its inception, California's 340B hospitals including our hospital have upheld high standards of 340B program integrity and remain fully committed to improving the program by supporting the administration's ongoing audits and annual recertification process.

According to HRSA, the intent of the 340B program is to allow certain providers to stretch scarce federal resources as far as possible to provide more care to more patients. We are committed to those goals and have demonstrated such through various programs that have benefited our patients and our communities.

[Provide information about your hospital and the community you serve. Include detailed examples of how your hospital uses the 340B program to benefit your patients. Consider including examples such as providing free care to uninsured patients, medication management programs, free vaccines, lower priced prescription drugs and community health programs. If possible, include an example of a patient who has benefitted from the hospital's participation in the 340B program – patients who received access to cancer treatment closer to home; a low-income patient who received prescription drugs at a reduced rate or free of charge; a person who received free treatment at one of your clinics or who is enrolled in one of your community health programs.]

After careful consideration of the stated intent of the 340B program and the operational realities of implementing some of the changes outlined in the guidance, we urge HRSA to consider several important changes to the guidance so that hospitals can continue to provide necessary access to our most vulnerable population, while fulfilling our shared goal of the triple aim.

In summary, ***[insert name of your hospital]*** urges HRSA to:

1. **Remove the employment and independent contract language from the definition of an eligible patient.** We are concerned that the policies HRSA has proposed with regard to the eligible patient definition are too restrictive and, if finalized, will inhibit the ability of facilities in California to meaningfully participate in the 340B program.

In the proposed guidance, HRSA indicates that, among other requirements, a patient will only be considered eligible to receive 340B drugs if that individual “receives health care services by a covered entity provider who is either employed by the covered entity or who is an independent contractor for the covered entity, such that the covered entity may bill for services on behalf of the provider.” HRSA then goes on to state that “[s]imply having privileges or credentials at a covered entity is not sufficient to demonstrate that an individual treated by a privileged provider is a patient of the covered entity for 340B program purposes.” **This element of the proposed definition of eligible patient is too narrow in light of the fact that some states, including California, prohibit hospitals from employing physicians. Given this fact, the proposed guidance clearly presents problems for California’s hospitals by establishing that a patient of a covered entity is only eligible to receive a 340B drug if that patient receives services from a hospital employee or independent contractor.**

In our view, other requirements within the guidance create sufficient safeguards to ensure that 340B drugs are only dispensed to covered entity patients. Among other things, the proposed guidance specifically requires: (1) that the patient obtain a service within the covered entity itself (including home care services, as described above) or a properly registered off-site clinic; (2) that the patient either be registered as a hospital outpatient or the hospital bills a third-party payer for the services as outpatient care; and (3) that the hospital maintain records showing it is responsible for the patient care. In this regard, it would appear that hospitals can adequately demonstrate responsibility for care of a patient, even if that care is provided by a physician who only has medical staff privileges at the hospital. Regardless of the relationship between the hospital and physician providing a service to a patient, if that service is furnished by the 340B covered entity, the hospital would maintain the records for the patient's care and bear responsibility for the care. **Therefore we urge HRSA to remove the employment and independent contract language from the definition of an eligible patient**

[Insert detailed examples of arrangements you have with physicians that result in close ties to the hospital but that are not employment or independent contractor-base due to the ban on the corporate practice of medicine. Please feel free to also include information regarding the rational from CHA’s complete draft letter available at www.calhospital.org/regulatory-tracker. In addition, insert examples of barriers (complex financial and legal relationships) you face in attempting to form these types of relationships.]

2. **Withdraw the proposal that a patient receiving only infusion services would not be an eligible 340B patient.** The covered entity is responsible for the patient and his or her care while administering the infusion drug. Therefore, it seems arbitrary to deem infusion treatment of patients from another facility as ineligible for 340B.

Under this provision, HRSA modifies the current guidance from “the individual receives health care services from a health care professional who is either employed by the covered entity or

provides health care under contractual or other arrangements” to “an individual receives a drug that is ordered or prescribed by the covered entity as a result of the services described in step 2.” The proposed guidance specifically mentions that an individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion or dispensing of a drug, **meaning the guidance would prohibit 340B use in connection with infusion drugs unless the order for infusion was written by a hospital provider as a result of a service provided at the hospital. We urge HRSA to withdraw this proposal.**

[If appropriate for your hospital, give examples of how your infusion program benefits patients, such as providing patients cancer treatment closer to home.]

3. Continue to allow 340B drug discount pricing to apply to discharge prescriptions, to the extent that the drugs are for outpatient use.

HRSA has proposed a new standard that a patient is considered eligible for 340B if the patient’s health care service is billed as outpatient to the patient’s insurer. We appreciate that the 340B program should only be used to furnish covered outpatient drugs. However, the proposed policy goes too far and seems to contradict the purpose of the 340B program — as well as the way care should be provided. **For example, our hospital has implemented discharge prescription programs to facilitate the transition of care and improve compliance with medication therapy, in an effort to improve patient outcomes and reduce hospital readmissions. [Give examples to support this ask and detail how providing 340B prescriptions upon discharge has helped avoid readmissions and improved the care and health of your patients.]**

These types of programs help educate and remove some of the challenges related to medication compliance, but would be jeopardized if this policy is finalized. **Covered entities may instead be forced to have an individual make a second trip to the hospital just to have the physician prescribe or order a much-needed covered outpatient drug, wasting both time and resources.** Apexus notes in a frequently asked question (FAQ ID: 1563) that “340B drugs can be used for discharge prescriptions to the extent that the drugs are for outpatient use.” This seems consistent with the intent of the program, and we urge HRSA to maintain the current interpretation.

4. Reconsider many of the proposed changes that will result in significant costs and administrative burdens within a program designed to generate cost savings for safety-net hospitals.

In total, the new proposed guidance will impose significant administrative and regulatory burden on our hospital at a time when we are implementing electronic medical records, updating billing and clinical documentation tools in support of ICD-10. We urge HRSA to step back and consider alternative approaches that would reduce the financial and personnel resources needed to comply with many of the new changes.

This program serves **INSERT NUMBER OF BENEFICIARES** and is an essential component of our community safety net. **INSERT NAME OF HOSPITAL** asks HRSA to consider carefully the comments above as well as the detailed comments submitted by the California Hospital Association under separate cover and to make significant changes to the proposed guidance so that we can continue to achieve the stated goals of this program and maintain access to critical pharmacy services for our most vulnerable.

We appreciate the opportunity to comment on the 340B Drug Pricing Program Omnibus Guidance. If you have any questions or require additional input, please do not hesitate to contact **INSERT CONTACT AT HOSPITAL**.

Sincerely,

SIGNATORY

**CURES 2.0 BROWSER WORKGROUP
CALL MEETING MINUTES**

October 29, 2015 / 1:00 p.m. – 2:00 p.m.

California Hospital Association
Sacramento, CA

Members Present: Rachel Davids, Doug O'Brien, Edward Lee, Angelica Gonzalez, Dave Garrett, Eddie Avedikian, Mike Small

Members Absent: Candace Fong, Clara Evans, Shad Lappe, Bill King, Weip Chen, Michael Tou, Roneet Lev, Scott Fishman, Stephen Henry, Scott McDonald, Garen Wintemute

CHA Staff: BJ Bartleson, Ronda Fricke

I. WELCOME AND INTRODUCTIONS

The meeting was called to order at 1:04 p.m. Introductions were made. Ms. Bartleson provided background as to why the workgroup was created for new members. Ms. Bartleson also encouraged members to reach out to colleagues that may be interested in joining the workgroup.

➤ ***ACTION:*** *Reach out to colleagues who may be interested in joining the workgroup and ask that they contact Ms. Bartleson directly.*

II. REVIEW OF PREVIOUS MEETING MEETINGS

The Minutes of the September 2, 2015, CURES 2.0 Workgroup meeting were reviewed and approved as submitted.

III. CURES 2.0 UPDATES

The members discussed challenges and opportunities for the group.

Mr. Small discussed the 2.0 version and its design to be self-service. He also mentioned that the current browser may stay active for a year to allow users to update the current browser to one that is compatible.

Mr. Small mentioned the universal trial currently taking place. He stated it has been released to a limited number of users using only the one IP address on file. He also mentioned that once you register for the 2.0 version you will no longer have access to the 1.0 version.

Ms. Davids asked about the limited CURES staff and mentioned the difficulty in getting through to them. Mr. Small said he currently has staff on loan. He also said workgroup members can contact him directly.

Dr. Chen noted his familiarity with CURES through the ED use and agrees the CURES information imbedded within the EMR without having to go into another system, would assist physicians in rapidly accessing the patient care plan and applying the CURES information.

IV. CURES 2.0 UPDATE

Ms. Gonzalez stated that Kaiser is moving aggressively to update their system.

V. NEXT STEPS

Mr. Small encouraged the workgroup members to have their facilities upgrade to the compliant browser as quickly as possible in order to receive automated security updates.

VI. NEXT MEETING

To be announced.

IV. Call ended at 1:40 p.m.

DRAFT



CURES 2.0 BROWSER WORKGROUP 2015

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Policy Title: Drug Supply Chain Security Track and Trace	Policy Number: CAPHARM.1.4.10
Department Category: Pharmacy Operations General Policies, Inventory Management	Executive Owner: Vice-President, National Pharmacy Finance and Administration, Chief Finance Officer
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1.0 Policies

- 1.1 When Kaiser Permanente pharmacies receive medications from an external pharmaceutical trading partner, such as wholesaler AmerisourceBergen or a direct manufacturer, Transaction Information/Transaction History/Transaction Statement (TI/TH/TS) data has been identified as required under the Federal Drug Supply Chain Security Act (DSCSA).
- 1.2 Kaiser Permanente pharmacies will follow policies and procedures for "Suspect Product" or "Illegitimate Product" detection and TI/TH/TS data verification relative to the DSCSA law set forth by the Federal Government.

2.0 Purpose

The purpose of this California Pharmacy Policy Reference (PPR) is to establish the necessary policies and procedures to align with the Drug Supply Chain Security Act (DSCSA) which was passed on November 27th, 2013, in order to protect the drug supply chain and prevent illegitimate products from entering the chain. Kaiser Permanente Pharmacies will follow these policies and procedures to identify, investigate, report, quarantine and process any suspect and illegitimate products.

3.0 Scope/Coverage

This policy applies to all employees who are employed by the following entities:

- 3.1 Employees of all Kaiser Permanente Service Line Pharmacies in SCAL and NCAL.
- 3.2 DSCSA law is specific to the pharmacy supply chain only, and does not include Kaiser Permanente Materials Management employees.

4.0 Definitions

- 4.1 3T: Transaction Data (Transaction Information/Transaction History/Transaction Statement)
- 4.2 ABC: AmerisourceBergen, Kaiser Permanente's primary wholesale distributor
- 4.3 Dispensers:
 - 4.3.1 A pharmacy which dispenses legal drugs to patients, specifically including:
 - 4.3.1.1 All Kaiser Permanente Service Line Pharmacies across the organization, subject to DSCSA legislation effective 7/1/15.
 - 4.3.1.2 All service line pharmacies across the country, also subject to DSCSA legislation effective 7/1/15.
- 4.4 DSCSA: Drug Supply Chain Security Act
- 4.5 External On-Line 3T Provider: Vendors such as TraceLink and Axway, who house TI/TH/TS data (for select direct vendors who elect not to provide TI/TH/TS on their actual packing slip, but rather direct customers to an external website)
- 4.6 FDA: Food and Drug Administration



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- 4.7** KFH: Kaiser Foundation Hospitals, Inc.
- 4.8** KFHP: Kaiser Foundation Health Plan, Inc.
- 4.9** KP: Kaiser Permanente
- 4.10** Illegitimate Product: "Credible evidence showing" that the product is (i) counterfeit, diverted or stolen; (ii) intentionally adulterated so as to result in serious adverse health consequences or death; (iii) the subject of a fraudulent transaction; or (iv) otherwise unfit for distribution so as to result in serious adverse health consequences or death.
- 4.11** PIC: Pharmacist in Charge
- 4.12** Product Traceability: Manufacturers, wholesale distributors, dispensers and repackagers are required to pass, capture and maintain TI/TH/TS information with respect to each transaction. Product Traceability is triggered when the product changes ownership and TI/TH/TS information must be retained for 6 years either in paper or electronic format.
- 4.13** Suspect Product: Product for which there is reason to believe it is (i) potentially counterfeit, diverted, or stolen; (ii) potentially intentionally adulterated so as to result in serious adverse health consequences or death; (iii) potentially the subject of a fraudulent transaction; or (iv) otherwise unfit for distribution so as to result in serious adverse health consequences or death. FDA's Draft Guidance provides factors to consider for detecting and assessing a "suspect product."
- 4.14** Trading Partner: Authorized and licensed entities to distribute pharmaceutical product in the drug supply chain.
- 4.15** Transaction information (TI): Required element of product traceability. Commonly referred to as a packing slip. Must include the following key elements:
 - 4.15.1** Product Name, Strength and Dosage Form
 - 4.15.2** NDC
 - 4.15.3** Container size and number of containers
 - 4.15.4** Lot Number
 - 4.15.5** Transaction and shipment date (of more than 24 hours after transaction date)
 - 4.15.6** Business name and address of person(s) from and to whom ownership is transferred
- 4.16** Transaction History (TH): Required element of product traceability, identifying who has previously owned the product up the supply chain to the drug's point of origin. Commonly referred to as previous packing slips, when a change of ownership occurred. Must include a statement in paper or electronic format including the transaction information for each prior transaction going back to the original manufacturer of the product.

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4.17 Transaction Statement (TS): Required element of product traceability. Transaction statement in paper or electronic format stating that the entity transferring ownership in a transaction:

- 4.17.1 Is authorized as required under the DSCA,
- 4.17.2 Received the product, transaction information and statement from authorized person and prior owner,
- 4.17.3 Did not knowingly ship a suspect or illegitimate product,
- 4.17.4 Have systems and processes in place to comply with verification requirements.
- 4.17.5 Did not knowingly provide false transaction information and did not alter the transaction history.

5.0 Responsibilities/Procedures

- 5.1 Pharmacy Manager and Pharmacist in Charge (PIC)
 - 5.1.1 The Pharmacy Manager and PIC will be responsible for enforcement of the provisions outlined in this PPR, including:
 - 5.1.1.1 Ensuring procurement and receiving staff is adequately trained and fully understands the process as outlined in this PPR.
- 5.2 Shipping: The requirement to include Transaction Information/Transaction History/Transaction Statement data is dependent upon to which entity products are transferred.
 - 5.2.1 Internal Shipments - Transaction Information/Transaction History/Transaction Statement data is not required when products are transferred internally within Kaiser Permanente. Specifically, TI/TH/TS is not required for:
 - 5.2.1.1 Items sourced from local KP Distribution Center or KP Mail Order Center
 - 5.2.1.2 Items transferred from KP Pharmacy to KP Pharmacy
 - 5.2.1.3 Items transferred from KP Pharmacy to a KP Clinic/Hospital
 - 5.2.2 External Shipments - Transaction Information/Transaction History/Transaction Statement data is required when products are transferred externally to entities outside Kaiser Permanente (e.g. to a community hospital) except when:
 - 5.2.2.1 The DSCSA does not require dispensers to provide TI/TH/TS information in instances when a dispenser sells prescription drugs to another dispenser in order "to fulfill a specific patient need."

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dispenser, or at a Kaiser Permanente records retention facility.

- 5.4.1.3** For direct vendors who have elected to use the services of External On-Line 3T providers such as TraceLink and Axway, instead of printing TI/TH/TS data on their packing slips, said On-Line 3T providers will need to store TI/TH/TS data and have this data readily accessible to all Kaiser Permanente dispensers.

5.5 Escalation

- 5.5.1** If Transaction Information/Transaction History/Transaction Statement data is missing, the following contingency steps should be conducted by the receiver:

- 5.5.1.1** Reconfirm the item is missing TI/TH/TS data with the local pharmacy manager.
- 5.5.1.2** If there are still any issues with the TI/TH/TS data in question, contact the manufacturer/wholesaler directly to resolve the discrepancy and prevent reoccurrence.
- 5.5.1.3** Items without the appropriate TI/TH/TS data are to be quarantined until the appropriate documentation can be obtained.
- 5.5.1.4** If an operations manager determines that patient care is endangered, staff may receive the product in spite of missing TI/TH/TS data, as long as the product otherwise appears to be safe and compliant, and the pharmacy contacts the vendor directly to resolve the issue and prevent reoccurrence.

- 5.6** Inspection - Each shipment should be thoroughly inspected for signs of a suspect product. Signs include, but are not limited to the following.

- 5.6.1** Outer Packaging:

- 5.6.1.1** Appearance of package or container used for transport (i.e. case or tote) that seems suspicious (i.e. label contains misspellings or appears different than the standard label for that product),
- 5.6.1.2** Package that uses foreign terms such as a different drug identification number,
- 5.6.1.3** Package is missing information, such as TI/TH/TS, lot number or expiration date,
- 5.6.1.4** Tote, box has been compromised (i.e. opened, broken seals, damaged, repaired, altered).

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5.6.2 Paperwork:

- 5.6.2.1 Shipping labels, addresses, postmarks that appear to come from an unexpected foreign entity or source,
- 5.6.2.2 Product information or leaflets missing or do not correspond to the correct product.

5.6.3 Inner packaging:

- 5.6.3.1 Product has changed without explanation,
- 5.6.3.2 Missing information such as NDC or strength of the drug,
- 5.6.3.3 Smudged print or print that is difficult to read,
- 5.6.3.4 Finished dosage form seems suspicious (has different shape or color from the FDA approved product),
- 5.6.3.5 Has unusual odor,
- 5.6.3.6 Has signs of poor quality such as chips or cracks in the tablet coatings or smeared or unclear ink imprints,
- 5.6.3.7 Misspelled words,
- 5.6.3.8 Bubbling in the surface of the label,
- 5.6.3.9 Lack of an Rx symbol,
- 5.6.3.10 Foreign language with little or no English used,
- 5.6.3.11 Foreign language used to describe the lot number,
- 5.6.3.12 A product name that differs from the FDA approved product name,
- 5.6.3.13 A product name that is the product name for a foreign version of the drug,
- 5.6.3.14 A product that is transported in a case or tote, when not expected under the circumstances, and
- 5.6.3.15 Lot numbers and expiration dates on product don't match the lot number and expiration dates of its outer container.

5.7 Notification of FDA - Report must be filed with the FDA by the Pharmacy Manager or designee no later than 24 hours after a determination that an illegitimate product has been received.

5.7.1 Access the FDA website at:

www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm

5.7.2 Pharmacy Manager or designee follows the instructions on the webpage for accessing Form FDA 3911 and submits as indicated.

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5.8.2.3 Take reasonable and appropriate steps to assist a trading partner to disposition an illegitimate product not in the possession or control of the dispenser, and

5.8.2.4 Retain a sample of the product for further physical examination or laboratory analysis of the product by the manufacturer or FDA (or other appropriate Federal or State official), upon request by the manufacturer or FDA (or other appropriate Federal or State official), as necessary and appropriate.

5.9 Audit Requests for Data

5.9.1 The FDA may initiate an investigation into suspect or illegitimate products, or initiate an audit for TI/TH/TS information.

5.9.2 Requests made by the FDA must be responded to within 2 business days.

5.9.3 For items sourced from AmerisourceBergen, the dispenser should contact their local eProcurement specialist immediately to obtain TI/TH/TS information.

5.9.4 For all other items, refer to the stored paper packing slips to obtain the corresponding TI/TH/TS information.

5.9.5 CA State Board of Pharmacy inspectors can and may also audit a dispenser's compliance with the DSCSA during regulatory inspections and interactions.

5.10 Other Notifications - Once the FDA is notified after determination for an illegitimate product, or when a termination notice is approved by the FDA (of product previously reported as illegitimate), the Manager or designee will also notify:

5.10.1 Kaiser Permanente Departments:

5.10.1.1 National Pharmacy Compliance Office

5.10.1.2 Legal Department

5.10.1.3 National Pharmacy Contracting and Strategies (NPCS)

5.10.1.4 Facility Accreditation, Regulation, and Licensing Department

5.10.2 State Authorities

5.10.2.1 For Regional dispensers where state laws require suspect product reporting, the dispenser will follow the requirements of the state law.

5.11 Product Exemptions to TI/TH/TS Requirements

5.11.1 TI/TH/TS requirements do not apply to the following products, as per DSCSA law:

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- 5.11.1.1 Medical devices
- 5.11.1.2 Medical gases
- 5.11.1.3 Blood or blood products intended for transfusion
- 5.11.1.4 Product samples
- 5.11.1.5 Irrigating solutions and sterile water
- 5.11.1.6 IV drugs intended for replenishment of fluids and electrolytes
- 5.11.1.7 Medical convenience kits containing a drug product
- 5.11.1.8 Combination products consisting of a drug plus one of more devices and/or biologics
- 5.11.1.9 Dispensing of product pursuant to a prescription to a patient
- 5.11.1.10 Distribution for public health emergencies
- 5.11.1.11 Compounded products from approved Kaiser Permanente vendors
- 5.11.1.12 Over the Counter (OTC) items
- 5.11.1.13 Radioactive drugs or biologics (i.e., a biologic labeled with a radionuclide)
- 5.11.1.14 Imaging drugs
- 5.11.1.15 Homeopathic drugs

6.0 References/Attachments

- 6.1 Title II of the Drug Quality and Security Act, Sec. 201 Drug Supply Chain Security
- 6.2 White Paper: DSCSA Drug Supply Chain Security Act. Pharmaceutical Track and Trace Requirements, 2015.

7.0 Key Words

Track, trace, inventory, suspect, DSCSA, pharmacy, pharmaceutical, drug, supply, chain, security, act,

Track & Trace Pharmacy Job Aid

Drug Supply Chain Security Act (DSCSA)



I. Introduction: Track and Trace



 U.S. Food and Drug Administration

[back to Drug Supply Chain Integrity](#)

Drug Supply Chain Security Act (DSCSA)

Title II of the Drug Quality and Security Act of 2013

The Drug Quality and Security Act (DQSA), was signed into law by President Obama on November 27, 2013. [Title II of DQSA, the Drug Supply Chain Security Act](#), outlines critical steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.

The Drug Supply Chain Security Act (DSCSA), also known as ePedigree or Track and Trace, was signed into law on November 27, 2013 in order to protect the supply chain and prevent illegitimate products from entering the supply chain.

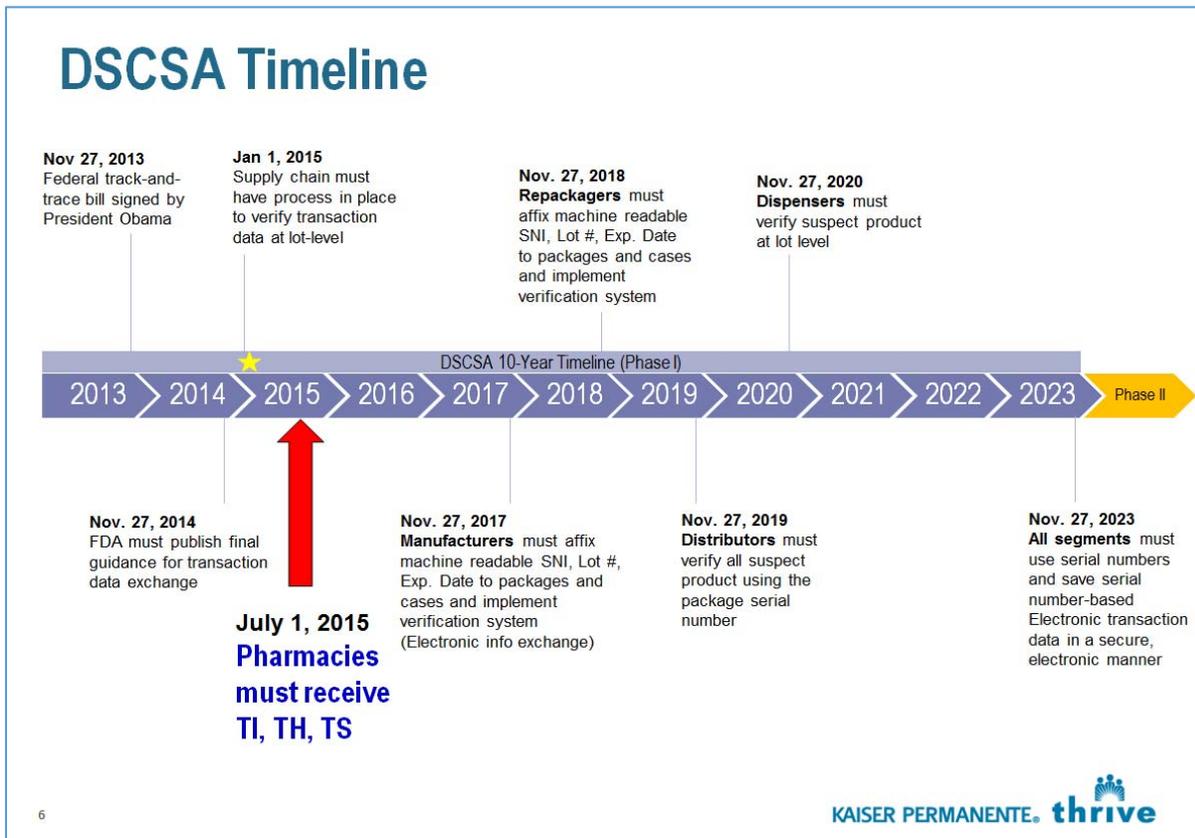
Track and Trace creates national requirements for tracing pharmaceuticals across the supply chain, and includes provisions for product identification, tracing and verification, detection and response, notification, wholesaler licensing, and third-party logistics provider licensing.

Track and Trace provides consistency of traceability on a national scale. Full implementation of DSCSA will occur within the next 10 years, and will result in standardized, unit-level traceability from the manufacturer to the dispensing pharmacy or practitioner.

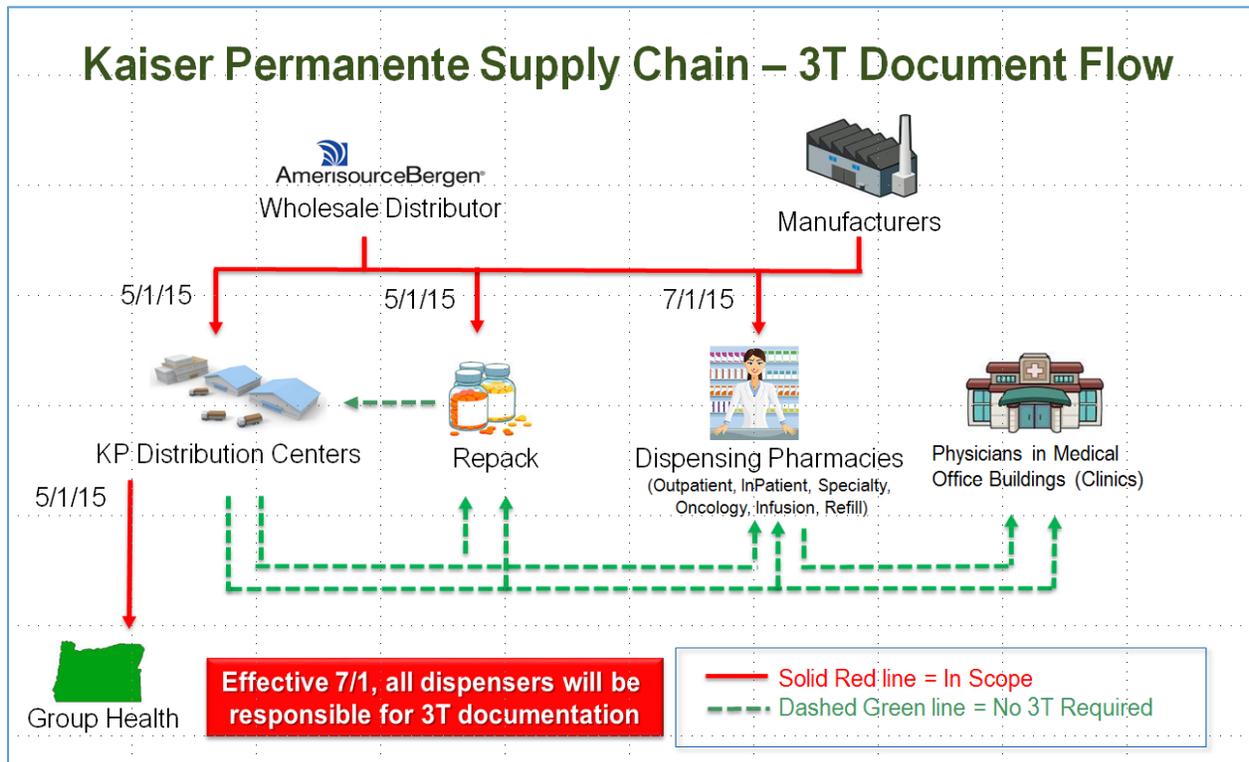
Effective July 1, 2015, all Kaiser Pharmacies (Dispensers) will be required to maintain and check for DSCSA “3T” information, either from AmerisourceBergen or Direct Vendors.

Note: As of May, 1, 2015, all KP Regional Warehouses are operating under the new Track and Trace, DSCSA regulation.

II. Track and Trace DSCSA Timeline



III. Track and Trace Scope Diagram



- A. **In Scope shown in RED Solid Lines** – Items from AmerisourceBergen and Direct Vendors/Manufacturers require Track and Trace DSCSA 3T information
- B. **Out of Scope shown in Dashed Green lines** – items Do NOT require Track and Trace DSCSA 3T information
1. Items sourced from Kaiser regional pharmacy distribution centers
 2. Items from Kaiser Pharmacy Repack
 3. Items transferred from KP Pharmacy to KP Pharmacy
 4. Items transferred from KP Pharmacy to KP Clinic. Physician or Hospitals.
 5. Dispensing to fulfill a “specific patient need” or prescription.
Note: DSCSA does not require dispensers to provide 3T data when dispensers “sells” prescription drugs to another dispenser in order to “fulfill a specific patient needs”.
 6. Return to Vendor – returning products to AmerisourceBergen or Direct Vendors

III. What is 3T Data?

Transaction Information	Transaction History	Transaction Statement
<ul style="list-style-type: none"> Product Name, Strength, and Dosage Form NDC Container size & # of containers Lot No. Transaction Date and Shipment Date (if more than 24 hours of transaction date) Business name and address of person(s) from and to whom ownership is being transferred 	<ul style="list-style-type: none"> Statement in paper or electronic format, including the transaction information for each prior transaction going back to the manufacturer of the product 	<ul style="list-style-type: none"> Transaction statement in paper or electronic format stating that the entity transferring ownership in a transaction: <ol style="list-style-type: none"> is authorized as required under the Drug Supply Chain Security Act; Received the product, transaction information and statement from authorized person and prior owner; Did not knowingly ship a suspect or illegitimate product; Have systems and processes in place to comply with verification requirements; Did not knowingly provide false transaction information and did not alter the transaction history

- A. Transaction Information (TI) is the information which describes the product, such as, product name, strength, dosage form, NDC, container size, number of containers, lot number, transaction date, shipment date, and the business name & address from and to who the ownership of the product is being transferred.
- B. Transaction History (TH) identifies who has previously owned the product up the supply chain to the drug’s point of origin, if applicable. Since Kaiser Pharmacies purchases products from only direct manufacturer/vendors or from AmerisourceBergen, KP pharmacy will rarely see the transaction history.
- C. Transaction Statement (TS) attests the transaction is compliant under the DSCSA law.

IV. What products Require DSCSA 3T Traceability?

In general, a “product” is a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as, capsules, tablets, and lyophilized products before reconstitution.

V. Products that are EXCLUDED from Tracking of 3T Information

There are categories of items that do not require Track and Trace, 3T information.

Here are few item categories that are **excluded**:

- A. Blood or blood component for transfusion
- B. Radioactive drug or biologic labeled with radionuclide.
- C. Imaging drugs
- D. Homeopathic and Over the Counter products
- E. Compounded drug, if compounded by a pharmacy (rather than produced by a manufacturer) that is either registered with FDA as an “outsourcing facility” or meets the FDA requirements for patient-specific compounding.
 - KP approved Compound Vendors are either 503A “Traditional Pharmacies”, or 503B

“Outsourced Facilities”; therefore, items from KP approved compound vendors are excluded from 3T.

- F. Intravenous products for hydration and replenishment, specifically one that is either:
 1. By its formulation, intended for the replenishment of fluids, electrolytes or calories.
 2. Used to maintain the equilibrium of water and minerals in the body, such as, dialysis solutions.
 3. Intended for irrigation or reconstitution, or sterile water for irrigation or injection.
 4. Medical gas, meaning a drug that is (a) is manufactured or stored in a liquefied, non-liquefied, or cryogenic state, and (b) is administered as a gas.

VI. Track and Trace 3T Item Identifier in OneLink Pharmacy Item Master

- A. Pharmacy Catalog team reviewed over 26,000 pharmaceutical items in the catalog to confirm if items require Track and Trace (DSCSA) 3T information.
- B. “Misc KP Pharmacy Attribute2” field in OneLink Item Master, “Pharm Misc” page is currently used to store the 3T flag.
 1. If the item required DSCSA 3T, Misc KP Pharmacy Attribute2 field will show “Y”.
 2. If the item does NOT need DSCSA 3T, Misc KP Pharmacy Attribute2 field will show “N”.
 3. Use the OneLink Query Name KP_RX_DSCSA_FLAG to validate 3T.

General | Inventory | Substitutes | Configuration | Custom | Audit | Supplemental Data | Legacy Sku | Pharm FDB | **Pharm Misc** | Preferred

SetID: PHARM Item ID: 00472162704 Standard Unit of Measure: ML
PROMETHAZINE/CODEINE SYRUP 118ML

Pharmacy Misc Attributes

Pharma Brand Name PROMETHAZINE-CODEINE
Brand Name Descr PROMETHAZINE-CODEINE
Generic Description PROMETHAZINE HCL
Pharma Label Name
Inner NDC
Pharmacy Item Class Non-Injectable Legend Drug
Misc KP Pharmacy Attribute1
Misc KP Pharmacy Attribute2 Y

Flags

ARCOS Flag Consigned Hazardous Quality Controlled Specialty Drug
 Bio/Immuno Flammable KP Compound Refrigerated
 Chemo Frozen Non-Controlled managed as Controlled Repack

DEA Control

DEA Controlled Item
Fed DEA Drug Schedule Schd V
CA DEA Schedule

Save | Return to Search | Previous in List | Next in List | Notify | Add | Update/Display | Include History

General | Inventory | Substitutes | Configuration | Custom | Audit | Supplemental Data | Legacy Sku | Pharm FDB | Pharm Misc | Preferred

VII. How does Track and Trace DSCSA law affect Kaiser Pharmacies?

A. Items Sourced from AmerisourceBergen (ABC)

1. AmerisourceBergen sends Advance Shipment Notification (ASN) electronically via electronic EDI 856 to Kaiser, and OneLink automatically creates ASN Receipts in OneLink.
2. Currently, Kaiser Pharmacies review the Receipt line by line and “Save” the Receipts.
3. Although there are no changes to the OneLink receiving process, pharmacy receiver must review the ASN Receipts daily before “putting away” or dispensing the products.

B. Items Sourced from Direct Vendor or Manufacturer

1. Direct manufacturer or vendor sends packing slip along with the shipment.
2. Packing slip contains the 3T information, or directions to an external website to obtain the 3T information. (See Appendix for website login information)

C. Items that are Drop Shipped – Items drop shipped from a vendor will include a packing slip including the 3T information, or directions to an external website to obtain the 3T information. (See Appendix for website login information)

Note: It is the responsibility of the drop shipping manufacturer/vendor to provide the DSCSA 3T information, not AmerisourceBergen.

D. Storage of 3T Information – FDA requires 3T documentation be stored for 6 years, either electronically or paper format.

E. Items “Borrowed” from Non-Kaiser Pharmacies – 3T documentation is not required if transferring or borrowing a product to & from a Non-KP pharmacy to fill a prescription for an identified patient. However, when KP pharmacy returns the product to the Non-Kaiser Pharmacy, KP pharmacy must provide the DSCSA 3T information in a paper format. Additionally, Non-KP pharmacy must provide the DSCSA 3T information when returning products to KP pharmacies.



External Shipment
Template.xlsx

1. External Shipment Template:

- a) External Shipment Template must be completed and printed when sending products to a Non-Kaiser Pharmacy for their inventory stock, not to fill a prescription for a specific patient.
- b) Attach the packing slip from direct vendor or AmerisourceBergen DSCSA 3T information along with the External Shipment Template.
- c) Provide the completed External Shipment Template and the DSCSA 3T information along with the product.



Return in Kind
Template.xlsx

2. **Return in Kind Template:**

- a) When sending “borrowed” drugs to a Non-Kaiser Pharmacy, complete and print the Return in Kind Template.
- b) Attach the packing slip from direct vendor or ABC DSCSA 3T information along with the Return in Kind Template.
- c) Provide the completed Return in Kind Template and the DSCSA 3T information along with the product to the Non-Kaiser Pharmacy.

F. **How to retrieve 3T information:**

1. Direct Vendor/Manufacturer DSCSA 3T information - Refer to stored direct vendor/manufacturer packing slip, or obtain 3T information from external website as instructed on packing slip.
2. AmerisourceBergen DSCSA 3T information – contact local eProcurement Specialist to download the 3T information from ABC Passport.



ABC_TS_Statement.
pdf

- a) ABC - TS letter: The following letter from ABC is also now arriving with their tote shipments. This letter simply serves as a value-add document, ensuring TS (Transaction Statement) information is truly arriving with the product. This letter does not need to be stored for 6 years.

VIII. Examples of Track and Trace 3T Information on Packing Slips

A. **Example 1** – from Valeant Pharmaceuticals

1. Transaction Information (TI) – this packing slip contains key TI elements, such as, product name, strength, dosage form, NDC, container size, shipment date, etc.
2. Transaction History (TH) – since this item is directly shipped by manufacturer, there are no previous owner of this product; therefore, no previous packing slips are attached nor required.
3. Transaction Statement (TS) – TS is found on the bottom left hand corner of the packing slip, stipulating that the seller has complied with each applicable subsection of the law, commonly referred to as Sec581 (27)(A-G) in Title II of the Drug Quality and Security Act.

VALEANT
Pharmaceutical North America, LLC

2723388 01/30/2015 02/02/2015
 Order Date Transaction Ship Date
 FedEx Priority 50.000
 Total Weight: 50.000
 DEB # WL24130
 Ship to License #

Master Packing List
 PAC207999
 Distributed by Specialty Pharmaceutical Services
 16 Ingram Blvd
 Lawrence, TN 37096
 USA
 SIC # 2800000000
 SLP # 1214

RECEIVED
 FEB 03 2015

Ship To: Saint Foundation Hospital
 6000 Pharmacy Dist. Dr.
 8600 Calumet Way
 Chicago, IL 60631-4012
 ID: 320847223

00001539

Item	Description Containers Form 228 Lot Date	Quantity	NDC # UOM	Shipped	Weight
AB10107	FLURATE 0.25% / 0.4% SOLN 9ML CARTON 4089923 - 9360024 Perigonal - store at 2-8 degrees Cent grade (2-46 degrees Fahrenheit) exp. 07/31/15 332351 July 31, 2015 1864	864	3430473005 EACH	864	45.930

864 x 1/16
 5/16
 2/3/15
 M. GLE
 2/04/2015

Checked & Verified
 FEB 03 2015
 Receiving Lead

See us online with our free mobile application at FDA Rec. M121(1) through (6)

Version 4.28 Date/Time 2/2/15 10:11 AM Page Page 1 of 1

Example 1: Valeant Pharmaceutical

B. **Example 2 – Jubilant Cadista**

1. Transaction Information (TI) – this packing slip contains key TI elements, such as, product name, strength, dosage form, NDC, container size, shipment date, etc.
2. Transaction History (TH) – since this item is directly shipped by manufacturer, there are no previous owner of this product; therefore, no previous packing slips are attached nor required.
3. Transaction Statement (TS) –on the bottom of Packing Slip (page 2) contains the TS information, but in this case the provision in SEC 581 (27)(A-G) are spelled out.

PACKING SLIP

JUBILANT CADISTA
 JUBILANT CADISTA PHARMACEUTICALS INC
 207 KILBY DRIVE,
 SALISBURY, MD 21801-2249
 Tel: (410)912-3779
 Fax: (410)912-3779
 CADISTA LIC # 5836

Ship To:
 SALSBER PHARMACEUTICALS,
 5850 COLISEUM WAY,
 OAKLAND, CA 94621
 Tel: (510) 434-5580
 Fax: (510) 434-5589
 LIC# RL84339
 DUNS 886285444

Ship To:
 SALSBER PHARMACEUTICALS,
 PO BOX 41906
 LOSANGELES, CA 90049
 Fax: (562) 401-2491

Page of Packing Slip No
 1 2 80272645

RECEIVED
 JAN 21 2015
 PHARM.DIST.CNTR

Shipment Date: 01/09/2015
 Bill of Lading: 04000018013102235

Customer	Ship Order Number	Sales Order Date	Customer P.O. Number	Customer P.O. Date	Center
12103	222060	01/09/2015	MCB02127	01/09/2015	

NO.	NDC NO.	ITEM	ITEM DESCRIPTION	LOT NO. & EXPIRY DATE	NO. OF UNITS	UOM	NO. OF CASES	Manufactured By
1	597483861	0	Tazosin Chewable USP 10 mg - 1000 ct	14P0880 08/2016	218.00	EA	18.00	JCI
2	597483861	0	Tazosin Chewable USP 10 mg - 1000 ct	14P0896 10/2016	38.00	EA	3.00	JCI
Total								

ORAL, 10/16 180X1000/1751.06

SHORTAGE
72ea

M. B. J. 1/21/2015
01/20/15
01/20/15
JV

Checked & Verified
 JAN 20 2015
 Receiving Lead 1

PACKING SLIP

JUBILANT CADISTA
 JUBILANT CADISTA PHARMACEUTICALS INC
 207 KILBY DRIVE,
 SALISBURY, MD 21801-2249
 Tel: (410)912-3779
 Fax: (410)912-3779
 CADISTA LIC # 5836

Page of Packing Slip No
 2 2 80272645

RECEIVED
 JAN 21 2015
 PHARM.DIST.CNTR

Jubilant Cadista Pharmaceutical Inc. (JCI) has complied with applicable subsection of the Federal Food, Drug and Cosmetic Act ("FDCA") section 582 and provides the information:

- As indicated below, the product(s) was (were):
 - Manufactured By: JCI, JUBILANT CADISTA PHARMACEUTICALS INC. 207 KILBY DRIVE SALISBURY - 21801 United States MD
- This change of ownership is authorized as required under the Drug Supply Chain Security Act.
- JCI received the product from a person that is authorized as required under the Drug Supply Chain Security Act.
- JCI received transaction information and a transaction statement from the prior owner of the product as required under section 582 of the FDCA.
- JCI did not knowingly ship a suspect or illegitimate product.
- JCI had systems and processes in place to comply with verification requirements under section 582 of the FDCA at the time of the shipment.
- JCI did not knowingly provide false transaction information.
- JCI did not knowingly alter the transaction history.

Customer represents and warrants that it is currently licensed as a pharmacy or wholesale distributor in its home state and as a non-resident wholesaler distributor in all other states where it is required to do so.

Verified by: *Katie Boica*
 Signature: *[Signature]*
 Date: 01/15/2015

Example 2: Jubilant Cadista

IX. Track and Trace DSCSA “3T Check” Receiving Best Practice

- A. In addition to existing Receiving processes, effective July 1, 2015, Track and Trace, DSCSA law requires receivers ensure DSCSA 3T information are obtained with the item. Review the “3T Check” best practice to ensure DSCSA 3T Compliance.
- B. **AmerisourceBergen (ABC) – Steps to “3T Check”**
 1. AmerisourceBergen will send the DSCSA Transaction Information (TI) and Transaction Statement (TS) electronically via EDI 856 (ASN). Note that Transaction History (TH) is not required for shipments from Wholesalers.
 2. AmerisourceBergen ASN Receipts must be reviewed line by line in OneLink, BEFORE dispensing or putting away the drug to the shelf.
 3. Receiving of ASN Receipts line by line complies with DSCSA law, as the required TI and TS information are sent by AmerisourceBergen electronically via ASN.
Note: Lot Numbers from ABC are currently out of scope, and not required.
 4. Receiving during OneLink outage, or if OneLink is unavailable.
 - a) Check in the shipment – keep a copy of the Manifest
 - b) Examine the items to determine if items are legitimate, and not counterfeit.
 - c) Record any shipment irregularity, such as, short ships, mis-ships, and damaged, and immediately notify the vendor.
 - d) Receive the OneLink ASN Receipt once OneLink is available.

C. **Direct Vendor/Manufacturer or Drop Ships**

1. Steps to “3T Check” for DSCSA 3T information on each Packing Slip:
 - a) Check **Transaction Information (TI)** – Does the packing slip contain item description, strength, dosage form, NDC, container size, transaction and shipment date, business name/address of from and to, and other required TI data?
 - b) Check **Transaction History (TH)** – If the item is from a third party, vendor should send packing slips from previous “owner” of each product. If the item is shipped directly from the manufacturer, there may NOT be any TH information since there are no previous “owner(s)” of the product.
 - c) Check **Transaction Statement (TS)** – Ensure the packing slip contains vendor attestation statement that the transaction is compliant under DSCSA law.
2. Packing slip with directions to an external website to obtain the DSCSA 3T information (**See Appendix “Accessing External Website”**)
3. Create on-line Receipts in OneLink for the shipments from direct vendor or manufacturer.

X. **What to do if Track and Trace DSCSA 3T Data is Missing**

A. **Conduct the following contingency steps:**

1. Confirm if item is in scope for DSCSA by checking the OneLink Item Master “Misc KP Pharmacy Attribute2” flag.
2. If the item is in scope for DSCSA, reconfirm the missing 3T information with your pharmacy manager.
3. If there are still issues with the 3T data in question, contact the manufacturer or wholesaler directly to resolve the discrepancy, and to prevent reoccurrence.
4. Items without 3T information must be quarantined until the appropriate 3T documentation can be obtained.

B. Kaiser Permanente Legal Department has provided guidance that if patient care is at risk as determined by a pharmacy manager, you may receive the product in spite of the currently missing 3T data, **as long as:**

1. The product appears to be safe and compliant and there are no factors that would lead you to believe otherwise;
2. Pharmacy calls the vendor directly to resolve the issue and prevent reoccurrence;
3. Pharmacy Materials Services team continues to work in parallel on a long-term Track and Trace DSCSA 3T electronic solution for the entire Kaiser Pharmacy Program.

XI. How to Handle Suspect Product Identification and Notification

- A. **Suspect Product by definition** is a product where there is a reason to believe that the product is potentially
1. Counterfeit, diverted, or stolen;
 2. Intentionally adulterated such that the product would result in a serious adverse health consequences or death;
 3. Subject of a fraudulent transaction;
 4. Appears otherwise unfit for distribution such that it would result in serious adverse health consequences or death.
- B. **Recommendations on determining whether the product is a counterfeit or suspect product**
1. Closely examine the package and transport container, and look for signs that it has been compromised or seems suspicious.
 2. Product labeling that contains misspelled words or looks different from the standard labeling.
 3. The finished product is a different shape or color from the standard product, or has an unusual odor.
 4. The Packaging is missing identifying information, such as, the lot number or expiration date, or does not match the outer container.
 5. Foreign language used to describe lot number, product name, etc.
 6. The original packaging seals have been opened, damaged, repaired or altered.
 7. Product inserts are missing or do not correspond to the product.

Examples of Counterfeit Product



- C. **Identification of Suspect Product and Illegitimate Product Notification**
1. Quarantine and reconfirm that the product is a suspect product with your pharmacy manager.
 2. Notify vendors (trading partners) and FDA of illegitimate product no later than 24 hours after a determination that an illegitimate product has been received.
 3. Access FDA's Webpage <http://www.accessdata.fda.gov/scripts/cder/email/drugnotification.cfm> to submit notification.

4. Follow the instruction on the Web page for accessing Form FDA 3911, and submit the form using the method provided in the form or on the Webpage.
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM400470.pdf>
5. FDA will review the request and consult with the trading partners.
6. FDA Form 3911: Drug Notifications
 - a) Initial Notification – first notification to the FDA of an illegitimate or product with a high risk of illegitimacy.
 - b) Follow-up Notification – subsequent notification to FDA, related to an initial notification already submitted to FDA
 - c) Request for Termination – request to FDA to terminate a notification of an illegitimate or product with a high risk of illegitimacy.

XII. What to do in the Event of an FDA Audit

- A. In the event of an FDA Audit, pharmacies must produce 3T information not later than 1 business day and not to exceed 48 hours.
Note: CA State Board of Pharmacy inspectors can and may also audit a dispenser's compliance with the DSCSA during regulatory inspections and interactions.
- B. AmerisourceBergen products:
 1. Contact your local eProcurement Specialist immediately.
 2. Pharmacy eProcurement Specialist will access ABC Passport system to obtain the DSCSA 3T information.
- C. All Direct Vendor and Manufacturer products:
 1. Refer to the paper packing slip containing the DSCSA 3T information.
 2. If DSCSA 3T information is not available in the packing slip, follow the direction on the packing slip to login to the website to obtain the DSCSA 3T information.
- D. Products from KP pharmacy distribution center:
 1. Contact your local pharmacy distribution center to obtain the DSCSA 3T information.

TRACK & TRACE



November 12th, 2015

DOCUMENT GUIDELINES:

PURPOSE:

PROVIDING "FREQUENTLY ASKED QUESTIONS" (FAQ) AND ANSWERS REGARDING NEW FEDERAL TRACK & TRACE LAW.

ATTENTION:

THIS DOCUMENT SHOULD BE DISTRIBUTED TO ALL EMPLOYEES WHO PROCURE, RECEIVE & HANDLE PHARMACEUTICAL PRODUCTS.

TABLE OF CONTENTS:

- SECTION 1: BRIEF HISTORY & OVERVIEW
- SECTION 2: POLICIES AND PROCEDURES
- SECTION 3: TRAINING REQUIREMENTS
- SECTION 4: SUPPORT
- SECTION 5: LONG-TERM SOLUTIONING
- SECTION 6: MORE FREQUENTLY ASKED QUESTIONS

Section 1: Brief History & Overview

A. What is Track and Trace?

Track and Trace is a Federal law signed by President Obama in November of 2013, not only affecting all Pharmacies, but all manufacturers, and wholesalers across the country.

Track and Trace is a 10-year program simply beginning at this stage, whose core objective is to prevent suspect or illegitimate pharmaceutical products from entering the U.S. pharmaceutical supply chain.

B. Are ePedigree, Track and Trace and DSCSA the same?

Yes, ePedigree, Track and Trace and the Drug Supply Chain Security Act (DSCSA) are the same. Originally known as ePedigree, the initiative is now commonly referred to as DSCSA or DQSA law, or simply Track and Trace.

C. Which main regulatory agency is most commonly associated with Track and Trace law-making and enforcement?

The FDA. Please find more information about the FDA, DSCSA law and updates at the following website:
<http://www.fda.gov/drugs/drugsafety/drugintegrityandsupplychainsecurity/drugsupplychainsecurityact/default.htm>

D. When does Track and Trace law take effect?

DSCSA law also went into effect for all Dispensers (aka - Pharmacies) on July 1st, 2015, although the FDA has stated that **enforcement will not officially begin for Dispensers until Tuesday, March 1st, 2016.**

E. Who can be contacted for Track and Trace questions or updates?

Please populate with your facility/organization-specific information

Section 2: Policies and Procedures

A. Have Policies and Procedures been developed to ensure alignment with new Track and Trace law?

Please populate with your facility/organization-specific information

It is also important to note these reference documents will be reviewed and updated iteratively, as Track and Trace spans a 10-year period and will continue to evolve and generate new legislative requirements.

Section 3: Training Requirements

A. Are there training requirements associated with Track and Trace?

Please populate with your facility/organization-specific information

Section 4: Track and Trace Support

A. Will Track and Trace support be provided to help answer questions from the field?

Please populate with your facility/organization-specific information

Section 5: Long-Term Solutioning

A. Looking beyond Nov 1st, 2015, what's next for Track and Trace?

Please populate with your facility/organization-specific information

Additional Federal regulations, spanning 2017 to 2023, will require product lot-level traceability and eventually item-level serialization throughout the entire supply chain. More information will be forthcoming.

Section 6: More Frequently Asked Questions:

Q1: Why do we need to implement Track and Trace?

Answer: To prevent suspect or illegitimate products from entering the pharmaceutical supply chain, by conducting business with "authorized trading partners" only.

One of the biggest problems affecting today's healthcare industry is the increase of counterfeit drug sales. Global counterfeit drug sales currently range between \$75 and \$200 billion dollars annually, meaning between 8 and 15% of all medicines sold around the world are counterfeit.

Secondly, Track and Trace is Federal law.

Q2: What is an "authorized trading partner?"

Answer: A distribution center or pharmacy is "authorized" if licensed under state law, and a manufacturer is "authorized" if it holds an FDA establishment registration.

Q3: Simply put, how do new Track and Trace requirements change things?

Answer: Presently there are no changes to receiving procedure for ABC sourced items.

The significant change is ensuring 3T data is found on packing slips sourced from direct vendors. Items that are delivered directly from the manufacturer or drop-shipped will include either a paper packing slip containing the 3T data, or directions to an external website to obtain 3T.

Q4: What does 3T information or data stand for?

Answer: 3T includes 1) Transaction Information, 2) Transaction History and 3) Transaction Statement data, commonly referred to as TI / TH / TS.

It is required and generated when there is a "change of ownership" transaction within the supply chain. The shipper assumes responsibility to provide 3T data with the product, and the receiver assumes responsibility to ensure 3T information is received with the product.

Q5: Do all drugs require 3T information?

Answer: No, certain drug categories are out-of-scope, including OTC drugs, compounding and intravenous drugs.

Q6: Does being compliant with “21 U.S.C. 360eee(27)” count as a Transaction Statement (TS)?

Answer: Yes, it is an acceptable Transaction Statement (TS).

Q7: Do pharmacy transfers to other internal pharmacies, or to clinics, require 3T information?

Answer: No, all internal transfers are out of scope at this time.

Q8: Is 3T data required when a pharmacy lends a product to an external hospital or pharmacy? Or for return-in-kind transactions?

Answer: First, check whether 3T data is required for the product.

Assuming 3T information is required for the product, then yes, the lending of product to an outside organization would be a “change of ownership” transaction requiring 3T data.

Per DSCSA law, there is one exception evident when lending product to an outside organization: 3T data is not required if the product is “fulfilling a specific patient need.”

3T data is required for all return-in-kind transactions. There is no “fulfilling a specific patient need” exemption clause here.

Q9: Do non-sellable product returns require 3T information?

Answer: No, 3T information is not required for items returned to a supplier due to shipping error, overstock or reverse distributor for destruction.

Q10: How do I handle suspect product identification and notification?

Answer: Each shipment should be thoroughly inspected for signs of suspect or illegitimate product. Any product concerns should be reported to the pharmacist-in-charge.

Q11: Are drug wholesalers, e.g. Amerisource Bergen (ABC) exempt from providing Lot # information, as part of the Transaction Information (TI) requirement?

Answer: Yes, ABC, along with all other wholesale distributors, are exempt from providing Lot # information at this time. All other direct vendors must produce Lot # info with their TI data, however.

Q12: How long does 3T data need to be stored for?

Answer: DSCSA law states that all 3T information must be stored for 6 years.

Q13: How long will the pharmacy have to produce 3T information in the event of an FDA audit?

Answer: According to DSCSA law, pharmacies will have 2 business days to produce the required 3T information in the event of an FDA audit or product recall.

Q14: Is 3T data required during drug shortages or public health emergencies?

Answer: 3T data is not required in the event of a public health emergency.

However, 3T data is still required during drug shortages, as DSCSA law states "a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason."

Q15: Do drugs administered at skilled nursing facilities (SNF's) require 3T information?

Answer: No, drugs administered at skilled nursing facilities do not require 3T information, as they are exempt under the DSCSA clause of being administered to "fulfill a specific patient need."

Q16: Do clinical trial or research drugs require 3T information?

Answer: No, at this time. Fully validating 3T data for clinical trial drugs is universally unfeasible due to high-levels of variation, including:

- Packing slips are not always included with the drug.
- Key TI elements are missing ~50% of the time, and no TS statements are available.
- In cases of placebo or study drugs, actual drug names can be blinded and unlabeled on purpose.
- Net-new clinical trial drugs do not have NDC #'s assigned yet, nor are they fully FDA approved.

October, 7, 2015

TO: CHA MEDICATION SAFETY COMMITTEE

FROM: BJ Bartleson, RN,MS, NEA-BC

RE: Sterile Compounding Advisory Workgroup and 8/15/2015 BOP Regulations

In response to the latest proposed regulations, the CHA Medication Safety Committee's Sterile Compounding Workgroup has convened to discuss educational strategies to assist hospital members with the upcoming proposed changes to the Board of Pharmacy's Compounding Regulations, Articles 4.5, 7 and 7.5 of Division 17 of Title 16 California Code of Regulations, Section 1735 et seq., 1751 et seq. 1752, 1753 and 1754. Due to the significance of the physical plant changes proposed, the workgroup has agreed to organize and give a comprehensive webinar at the appropriate time, preferably when the regulations are finalized.

Members: Jeannette Hanni, Candace Fong, Eddie Avedikian, Lynn Paulsen, Tom Jacobsen, Doug O'Brien, Steve Hinz, Christine Low

Ad Hoc organizations were added to address proposed physical plant changes. OSHPD, was added (Glenn Gall,) and Cal OSHA (Grace Delizo) was added do to their upcoming regulatory package development for Antineoplastic policies and procedure.

The draft webinar content is as follows:

- 1) Introduction
- 2) USP 797 to USP 800
- 3) BOP Sterile compounding regs
- 4) Cal OSHA Antineoplastic proposed regs
- 5) Solutions- BOP Program Flex and POC
- 6) Solutions – Gap analysis using the four matrixes developed addressing, lab testing requirements, temperature monitoring requirements, Frequency of Documentation, and Physical Plant requirements

The workgroup has been meeting via conference call to determine the most appropriate time and methods to deploy an educational webinar. It was determined that the webinar should be moved until the BOP regulations are finalized. The group agreed that in the meantime, to make member hospital and pharmacists aware, a FAQ should be devised and disseminated.



CHA Hazardous Sterile Compounding Webinar

Draft Outline, 12/16/2015

1. Introduction- New England Compounding Center issue up to where we are today with federal and state legislation –
2. Federal USP legislation – USP 797 and USP 800 – and CMS
3. BOP Sterile Compounding Regs –
4. Cal OSHA Antineoplastic Regulations –
5. Solutions- BOP Program Flex and POC
6. Solutions – Sterile Compounding Matrix tools, (Lab Testing Requirements, Temperature Monitoring Requirements, Documentation Requirements, Physical Plant Requirements)
7. Crosswalk between Federal and State Regs

CHA Medication Safety Committee Sterile Compounding Advisory Group Members

Pharmacists

Jeannette Hanni - Sutter

Candace Fong - Dignity

Doug Obrien – Kaiser

Lynn Paulsen – UCSF

Eddie Advekian – Providence

Christine Lowe – Scripps

Sara Stevens – Kaweah

Thomas Jacobson – Adventist

Andre Rossi – Sonora Regional

Amy Guiterriz – LA County

OSHPD

Glenn Gall

Cal OSHA

Grace Delizo

BOP

Ginny Herold

Timeline:

12/16/2015- meet with Liz

BOP modified text due 12/05/2015 being reviewed by BOP. Unsure if another regulatory period will occur. It would be best to do this after regulations are final, however, the group feels they are fairly “solid” at this point and don’t predict radical changes. We could do FAQ’s in Jan/Feb and pursue webinar later in Feb or March

01/07/2016

CHA Medication Safety Committee Meeting, continued work on Matrixes and other tools for webinar.

DRAFT



Sterile Compounding FAQ's, (12/2015)

- 1) What are the proposed Board of Pharmacy Compounding Regulations, and why have they been changed?
- 2) When will the Board of Pharmacy regulations be finalized?
- 3) What are some of the specific changes in the proposed regulations?
- 4) How much time will our hospital have to implement the new regulations, once the regulations are implemented?
- 5) What is the process for asking the BOP for a variance with the new regulations until I can remodel and come into compliance?
- 6) Why can't I use a barrier isolator to make hazardous drugs in a standard (positive -pressure) clean room?
- 7) What are USP 797 and USP 800 and how do they relate to the new proposed regulations?

MEDICATION GUIDELINE ACTIVITY MATRIX

ANTICOAGULANT GUIDELINES (Nasim Karmali: High Risk/High Alert Subcommittee)		
DATE	ACTIVITY	STATUS
November 2011	First Draft	
February 2012	Version 1.0	
June 2013	CHA pulled guidelines from website for update and revised format.	
October 2013	Edited and reformatted	Under review by Rory J. and BJ.
July 2014	Jeanette will send anticoag guidelines from Mills-Peninsula	
October 2014	Considered done except for Credit Section/agree to remove references and everyone will review	

CONTROLLED SUBSTANCE DIVERSION (Rory Jaffe)		
DATE	ACTIVITY	STATUS
May 16, 2013	Posted to CHPSO website	Complete.

FENTANYL TRANSDERMAL PATCH GUIDELINES (Various authors: High Risk/High Alert Subcommittee)		
DATE	ACTIVITY	STATUS
December 2010	First Draft	
April 2011	Version 1.0	
June 2013	CHA pulled guidelines from website for update and revised format.	
July 2013	Pam Richter volunteered to review/edit/update guidelines	
Nov 13, 2013	Guidelines template re-sent to Pam Richter	
February 2014	Pam Richter no longer at member hospital	Pending workgroup review
July 2014	Include Fentanyl with Safe Use of Opioids Guidelines	

INSULIN GUIDELINES (High Risk/High Alert Subcommittee)		
DATE	ACTIVITY	STATUS
July 2012	First Draft	
April 2013	Pending committee review and reformat.	
Aug 15, 2013	Jonathan asked for volunteers to help with review and revision, to which Nasim Karmali responded.	Pending review and reformat by Nasim Karmali
October 2013	Initial wordsmith review BJ/Rory	Forwarded to HR/HA for review
November 2013	Additional edits by E. Avedikian /J. Nelson	Edited.
December 2013	Back to BJ/Rory for final review	Pending final review
August 2014	Updates and revisions completed per Jillian Hacker	
October 2014	Need to add language regarding 2 nd insulin check – page 4	

MED-ER (Jonathan Nelson, et al: High Risk/High Alert Subcommittee)		
DATE	ACTIVITY	RESULT/STATUS
11/20/13	Draft submission of Med-ER Tool	
1/3/14	Draft guidelines require addt'l review by committee prior to posting to CHA website.	Review at January 8 committee meeting.
1/8/14	Insufficient time for detailed review during committee meeting. Consensus was that additional review/edit still needed.	Defer review.
1/23/14	Hanni, Bartleson and Jaffe met re document title, med management elements, column titles (recommended/ideal).	Decision made to call the work group together for addt'l feedback.
1/29/14	Menet provided references for medication management elements.	
2/5/14	Workgroup meets to finalize edits to the grid.	
2/6/14	Nelson re-inserted descriptions names "small, medium and large" to the columns. Document name was also changed to "Emergency Department Medication Safety Tool" Jaffe's recommendations will be added to the tool guiding	

STERILE COMPOUNDING

DATE	ACTIVITY	RESULT /STATUS

Additional Comments made after draft guidelines were submitted by Jonathan Nelson.

Guideline	Date	Name	Comment/Recommendation	Result
Med-ER	1/21/14	BJ/Rory	Met for re-review of Med-ER Grid. Edits have been done. Will meet with Jeannette Hanni before submitting for final committee approval.	Discuss edits with Jeannette Hanni
All	1/8/14	BJ	Recommended to committee that guidelines be reviewed more closely and discussed at April's meeting before the committee cast a final vote to publish the guidelines.	
Insulin & Med-ER	12/16/13	BJ/Rory	Met and re-reviewed guidelines.	
Insulin	12/10/13	Jonathan N.	Bob's recommendations incorporated. Update emailed to Ingrid for Rory and BJ's review.	<i>12/10/13: Revisions forwarded to BJ and Rory. Also included in January's meeting packet. -ih</i>
Insulin	12/9/13	Bob Menet	<p>Page 5, 3rd paragraph (Prescribing): Various entities may be charged with "policy and procedure" or "standardized procedures" review per Title 22, and there is no stipulation that they be done so "annually." For instance, nursing policy and procedures are to be reviewed every three years , or more often if necessary – see 70213(a)(4). Consider changing this entry to read: "Review and evaluate preprinted insulin order sets and insulin infusion protocols by the Pharmacy and Therapeutics (P&T) Committee minimally as established per hospital policy and more often if necessary." (It may be appropriate to include all committees involved in review of such order sets; e.g., "governing body," "medical exec," etc. as appropriate.</p> <p><i>(from a follow-up email)</i>...Realized my response may not have been as clear as I originally thought. "Various entities may be charged with "policy and procedure" or "standardized procedures" review per Title 22...." By 'various entities' I was trying to get at various committees within the organization being charged with review of such documents as policies and procedures, pre-printed order sets, etc.</p>	
Insulin	12/9/13	Bob Menet	Page 8, after last bullet (Other Considerations): Consider a fourth bullet addressing, "Establishment of demonstrated staff competencies to ensure safe and effective use of insulin therapies throughout the organization."	

Insulin	12/9/13	Dan Ross	Page 6: I just had one change, really a question or request for clarity – near the bottom of page 6 – shows in purple and I bolded it. Actual copy and paste is below so you can easily find it.	
Med-ER	11/20/13	Jonathan N.	Draft deliverable submitted with the following notes: Attached are the following: <ul style="list-style-type: none"> • Draft Med-ER deliverable which contains a cover sheet and the grid. • Draft cover sheet in word for ease in editing • Draft grid in excel for ease in editing. Our to-do was to finalize this and send to you to forward to the MSC committee for their vote. Perhaps BJ and Rory want to take a look first before sending it out? Let me know if anyone has any questions or edits that we could address.	<i>Revisions included in January's meeting packet. -ih</i>
Fentanyl	11/13/13	Pam R.	Requested guidelines template so she could convert from the old template and revise guidelines accordingly.	<i>Template sent -ih</i>
Opioid & Anticoag	11/10/13	Jonathan N.	Revised guidelines submitted with the following notes: <ul style="list-style-type: none"> • We utilized track changes and accepted most of your edits. We left a few edits as unaccepted where useful for explaining our edits. • At our last MSC meeting, there was discussion around the importance of indicating physician involvement in the development of the guidelines. The current guidelines include a list of the organizations which participated in the drafting process. Unfortunately, it looks like there were no physician groups represented. Perhaps a solution would be to simply state that the committee included "physician, pharmacist and nurse representatives" and leave it there without specifying the actual groups involved. • I spent some time trying to standardize the formatting for each specific document, but it would probably be advantageous for each guideline to get one final editorial/formatting pass before being republished. 	<i>Revisions included in January's meeting packet. -ih</i>
Opioid & Anticoag	10/17/13	Rory J.	1. First round of edits submitted by Rory and BJ 2. Edits forwarded to Eddie A. and Jonathan N.	<i>Edits forwarded to JN and EA -ih</i>
All	10/14/13	Ingrid H.	Guidelines templates and instructions emailed to Med Safety Committee members	

Assembly Bill No. 1202

CHAPTER 678

An act to add Section 144.8 to the Labor Code, relating to occupational safety and health standards.

[Approved by Governor October 9, 2013. Filed with
Secretary of State October 9, 2013.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1202, Skinner. Occupational safety and health standards: hazardous drugs.

Under existing law, the Occupational Safety and Health Standards Board within the Department of Industrial Relations promulgates occupational safety and health standards for the state, including standards dealing with toxic materials and harmful physical agents. Violations of these standards and regulations is a crime.

This bill would require the board to adopt a standard for the handling of antineoplastic drugs, as defined, in health care facilities regardless of the setting. The bill would require the standard to be consistent with and not exceed specific recommendations adopted by the National Institute for Occupational Safety and Health for preventing occupational exposures to those drugs in health care settings. By creating a new crime, this bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares the following:

(a) Health care personnel who work with or near hazardous drugs in health care settings may be exposed to these agents in the air, on work surfaces, clothing, and medical equipment, or through patient contact.

(b) According to the National Institute for Occupational Safety and Health (NIOSH), early concerns about occupational exposure to antineoplastic drugs first appeared in the 1970s. Antineoplastic drugs may cause skin rashes, infertility, miscarriages, and birth defects, and have been linked to a wide variety of cancers.

(c) In 2004, the NIOSH published an alert on preventing occupational exposures to antineoplastic drugs in health care settings, and updated that

alert in 2010. In this alert, the NIOSH “presents a standard precautions or universal precautions approach to handling hazardous drugs safely: that is, NIOSH recommends that all hazardous drugs be handled as outlined in this Alert.”

(d) It is the intent of the Legislature to require the Occupational Safety and Health Standards Board to adopt standards consistent with the NIOSH alert regardless of the setting in order to protect health care personnel from hazardous exposure to these drugs.

SEC. 2. Section 144.8 is added to the Labor Code, to read:

144.8. (a) As used in this section the following definitions shall apply:

(1) “Antineoplastic drug” means a chemotherapeutic agent that controls or kills cancer cells.

(2) “NIOSH” means the National Institute for Occupational Safety and Health.

(b) The board shall adopt an occupational safety and health standard for the handling of antineoplastic drugs in health care facilities regardless of the setting. In developing the standard, the board shall consider input from hospitals, practicing physicians from impacted specialties, including oncology, organizations representing health care personnel, including registered nurses and pharmacists, and other stakeholders, and shall determine a reasonable time for facilities to implement new requirements imposed by the adopted standard. The standard, to the extent feasible, shall be consistent with and not exceed recommendations in the NIOSH 2004 alert entitled “Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings,” as updated in 2010. The standard may incorporate applicable updates and changes to NIOSH guidelines.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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Antineoplastic Drug Handling Workgroup ROSTER

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Add new Section 51XX to read:

§ 51XX. Safe Handling of Antineoplastic Drugs in Health Care

(a) Scope and Application.

This Section applies to all health care settings where employees have occupational exposure to antineoplastic drugs.

NOTE: This section does not preclude the application of Section 3203 or other Title 8 safety orders to occupational exposure to non-antineoplastic hazardous drugs not covered by this section, nor does it preclude the application of other sections of Title 8, including but not limited to Sections 3203 and 5194, to occupational exposure to antineoplastic drugs.

(b) Definitions.

“Antineoplastic drug” means a chemotherapeutic agent that controls or kills cancer cells.

“Closed-system drug-transfer device (CSTD)” means a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drugs or vapor concentrations outside the system.

“Compounding aseptic containment isolator (CACI)” means a specific type of compounding aseptic isolator that is designed for the compounding of sterile hazardous drugs (HDs). The CACI is designed to provide worker protection from exposure to undesirable levels of airborne drugs throughout the compounding and material transfer processes and to provide an aseptic environment with unidirectional airflow for compounding sterile preparations.

“Containment primary engineering control (C-PEC)” means a ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential contaminant source
- The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation
- The use of air pressure relationships that define the direction of airflow into the cabinet
- The use of HEPA filtration on all potentially contaminated exhaust streams

Examples of C-PECs include Class I, II, or III biological safety cabinets (BSCs) or CACIs.

“Handling” means receiving, storing, compounding, dispensing, administering, transporting or disposing of antineoplastic drug products and preparations.

“Hazardous drug” means any drug including antineoplastic drugs identified by the National Institute for Occupational Safety and Health at the federal Centers for Disease Control and Prevention or any drug that meets at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low doses in humans or animals, genotoxicity, or new drugs that mimic existing hazardous drugs in structure or toxicity.

“Health care setting” means any facility, service or operation in which employees handle or are otherwise reasonably anticipated to be exposed to antineoplastic drugs in the course of providing treatment or other medical services to patients. Health care settings include, but are not limited to, pharmacies, hospitals and other healthcare institutions, patient treatment clinics, physicians' practice facilities, or veterinarians' offices in which antineoplastic drugs are handled.

“NIOSH” means the National Institute for Occupational Safety and Health.

“Occupational exposure” means reasonably anticipated work exposure to an antineoplastic drug without regard to the use of engineering controls or personal protective equipment (PPE).

“Supplemental engineering control” means an adjunct control (e.g., CSTD) that may be used concurrently with primary and secondary engineering controls. Supplemental engineering controls offer additional levels of protection and may facilitate enhanced occupational protection, especially when handling antineoplastic drugs outside of primary and secondary engineering controls (e.g., during administering).

(c) Antineoplastic drugs safety and health plan.

As part of the Injury and Illness Prevention Program (IIPP) required by Section 3203, each health care setting covered by this section shall establish, implement and maintain an effective written antineoplastic drugs safety and health plan (Plan). The Plan may be incorporated into the IIPP or may be maintained as a separate document.

The Plan shall include:

- (1) A written inventory of antineoplastic drugs in the workplace that shall include, but not be limited to, antineoplastic drugs listed in the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014 and reprinted in Appendix A.
- (2) A hazard assessment that shall include:
 - (A) Identification of the units and operations where antineoplastic drugs are received, distributed to end of use locations, dispensed, compounded, and/or provided to patients, and disposal areas.
 - (B) Identification of job classifications with occupational exposure in those locations and units.
 - (C) A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of subsection (c)(2)(B) of this standard.
 - (D) Evaluation of engineering controls, work practice controls, and personal protective equipment that are in place in those areas to control exposure.
 - (E) Assessment by the employees with occupational exposure in those units, of the effectiveness of the controls being used.
- (3) Policies and procedures to address the handling of antineoplastic drugs that shall include:

- (A) Detailed procedures for preparing, administering, and disposing of antineoplastic drugs.
- (B) Using and maintaining all equipment used to reduce exposure, such as ventilated cabinets, closed system drug-transfer devices, needleless systems, and PPE.
- (C) Cleaning and decontaminating work areas.
- (D) Waste handling and disposal, including patient waste.
- (E) Spill control.
- (F) Medical surveillance.
- (G) Training.

(d) Methods of compliance.

Where occupational exposure exists, the following types of exposure controls shall be implemented to minimize the exposure to employees, with the selection of controls to be selected according to the type of exposure to be controlled.

(1) Engineering Controls. Table X provides the minimum control method for handling specific drug formulations. Employers shall adopt these control methods, or higher levels of protection during the use of these formulations as follows:

- (A) A Class II or III biological safety cabinet (BSC) as defined in 5154.2 or compounding aseptic containment isolator (CACI) shall be used when compounding or preparing (withdrawing from vial or ampoule) antineoplastic drugs.

Note: When BSCs or CACIs are used to prevent harmful exposure from antineoplastic drugs or other hazardous drugs they shall conform to the provisions of Section 5143 and 5154.2 (BSCs only).

(B) Containment Supplemental Engineering Controls

1. A closed system drug transfer device (CSTD) shall not be used as a substitute for a BSC or CACI when compounding.
2. CSTDs shall be used when compounding or administering a prepared solution containing antineoplastic drugs through an IV or when compounding a solution for irrigation containing antineoplastic drugs, when the dosage form allows.
3. Needleless systems and needles with engineered sharps injury protection shall be used for administration of medications containing antineoplastic drugs and shall conform to the provisions of Section 5193.

(2) Personal Protective Equipment:

Employers shall perform a hazard assessment and select PPE in accordance with section 3380. Table X provides the minimum level of protection that shall be provided and used when handling the specific drug formulation as indicated. Employers shall provide the listed PPE or higher levels of protections for each formulation and activity, unless otherwise specified as follows:

- (A) Gloves

1. Select and provide employees with appropriate chemotherapy gloves that are approved for the antineoplastic drug to be handled or when there is potential for contact with antineoplastic drug-contaminated items or surfaces. Such approval of gloves shall be in accordance with the American Society of Testing Materials ASTM D6978 (2013) standard for assessing permeation resistance or its equivalent.
 2. Wear double gloves when there is a significant risk of breakage, contamination or permeation, such as during compounding, extended handling periods, and cleaning up large antineoplastic drug spills.
 3. Provide latex-free gloves to latex-sensitive employees.
 4. Inspect gloves for physical defects (pin holes or weak spots) before use.
 5. Change gloves every 30 minutes or when torn, punctured, or contaminated.
- (B) Protective clothing. When required, disposable gowns shall be tested and shown to resist permeability by antineoplastic drugs. Gowns shall be selected based on the antineoplastic drug handled.
1. Employees shall wear protective gowns when performing any of the following activities:
 - a. Performing chemotherapy drug preparation activities such as opening drug packaging, handling vials or finished products, labeling antineoplastic drug containers, or disposing of waste;
 - b. Reconstituting and admixing chemotherapy drugs;
 - c. Performing all activities associated with chemotherapy drug administration—opening the outer bag, assembling the delivery system, delivering the drug to the patient, and disposing of all equipment used to administer drugs;
 - d. Handling linens, feces, or urine from patients who have received chemotherapy drugs within the last 48 hours—or in cases where the drug may be present for longer periods of time, such as Cisplatin and Epirubicin hydrochloride, within the last 7 days.
 2. Gowns shall be made of polyethylene-coated polypropylene or equivalent nonlinting and nonabsorbent protective material.
 3. Gowns shall have closed fronts, long sleeves, and elastic or knit closed cuffs.
 4. Gowns shall not have seams or closures that could allow antineoplastic drugs to pass through.
 5. Gowns shall be changed per the manufacturer's information for permeation of the gown. If no permeation information is available for the gowns used, change them every 2–3 hours or immediately after a spill or splash.
 6. Gowns worn in antineoplastic drug handling areas shall not be worn to other areas in order avoid spreading contamination and exposing other healthcare workers.
- (C) Eye and Face protection
1. Appropriate eye and face protection shall be worn when there is a risk of spills or splashes of antineoplastic drugs or antineoplastic drug waste materials when

working outside of a containment primary engineering control (C-PEC) (e.g., administration in the surgical suite, working at or above eye level, or cleaning a spill).

2. Goggles shall be used whenever there is a splash hazard to the eyes.
3. Face shields in combination with goggles shall be used whenever there is a splash hazard to the face and eyes.

(D) Respiratory Protection

1. Employers shall ensure that employees are medically evaluated, fit-tested and trained to wear respiratory protection in accordance with section 5144.

Note: Surgical masks do not provide respiratory protection from drug exposure and shall not be used when respiratory protection is required.

2. Employees shall use N95 or equivalent respiratory protection during spill cleanup and whenever there is a potential for inhalation exposure to chemotherapy drug particulates.
3. Employees shall wear an elastomeric half-mask with a multi-gas/vapor cartridge and P100-filter when unpacking antineoplastic drugs that are not contained in plastic. If the type of drug can be better defined, then a more targeted cartridge can be used.
4. Employees shall wear an appropriate chemical cartridge-type respirator for events such as large spills of chemotherapy drugs, e.g. when an intravenous (IV) bag breaks or line disconnects.
5. Employees shall wear an appropriate full-facepiece, chemical cartridge-type respirator when attending to antineoplastic drug spills larger than what can be contained with a spill kit, or when there is a known or suspected airborne exposure to powders or vapors.

Table X. Personal protective equipment and engineering controls for working with antineoplastic drugs in healthcare settings*

Formulation	Activity	Double gloves	Protective gown	Eye protection	Respiratory protection	Ventilated engineering controls
Intact tablet or capsule	Administration from unit-dose package	no (single glove should be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing or otherwise manipulating	yes	yes	no	yes, if not done in a control	yes [†]

	tablets or capsules				device	
	Administration	yes	yes	no ²	yes, if powder generated	N/A
Oral liquid drug	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes [†]
	Administration	yes	yes	no [‡]	no [‡]	N/A
Topical drug	Compounding	yes	yes	yes	yes, if not done in a control device	yes [†]
	Administration	yes	yes	yes, if liquid that could splash [‡]	yes, if inhalation potential	N/A
Ampoule	Opening	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
Subcutaneous, intramuscular injection	Preparation (withdrawing from vial or ampoule)	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI
	Administration from prepared syringe	yes	yes	yes, if liquid that could splash [‡]	yes, if inhalation potential [‡]	N/A
Intravenous solution	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; CSTD
	Administration of prepared solution [§]	yes	yes	yes, if liquid that could	yes, if inhalation potential [‡]	N/A; CSTD

				splash [‡]		
Solution for irrigation	Compounding	yes	yes	yes, if not done in a control device	yes, if not done in a control device	yes, BSC or CACI; CSTD
	Administration (bladder, HIPEC, limb perfusion, etc.)	yes	yes	yes	yes	N/A
Powder/ solution for inhalation	Inhalation	yes	yes	yes	yes	yes, when applicable

*The table provides PPE and engineering control requirements for some of the possible scenarios that may be encountered in healthcare settings, but cannot cover all possible situations. For more detailed information on safe handling practices, see the reference list [NIOSH 2004; ASHP 2006; USP 2008, and ONS 2011]. BSC = Class II biological safety cabinet; CACI = compounding aseptic containment isolator; CSTD = closed system drug transfer device; HIPEC = hyperthermic intraperitoneal chemotherapy.

†For nonsterile preparations, an engineering control such as a fume hood or Class I BSC is sufficient. It is recommended that these activities be carried out in a control device, but it is recognized that under some circumstances, it is not possible. If the activity is performed in an engineering control that is used for sterile intravenous preparations, a thorough cleaning is required following the activity.

‡Required if patient may resist (infant, unruly patient, veterinary patient) or if administered by feeding tube.

§Intravenous tubing already attached and primed.

(3) Work Practice Controls.

(A) Receiving and Storage.

1. Employers shall establish procedures for receiving antineoplastic drugs that include visual examination of the shipping container for signs of damage or breakage (e.g., visible stains from leakage, sounds of broken glass containers).
2. Antineoplastic drugs shall be stored separately from non-hazardous drugs and separate from food/drink.
3. A spill kit shall be accessible in the receiving area.

(B) Drug Preparation and Administration. The employer shall ensure the following administrative and work practice controls are followed:

1. Prohibit eating, drinking, chewing gum, applying cosmetics, or storing food or drinks within the antineoplastic drug preparation area.
2. Properly clean all equipment, counters, and other surfaces.

3. Store and transport antineoplastic drugs in closed containers that minimize the risk of breakage.
 4. IV tubing and syringes shall be primed inside the ventilated cabinet, or primed in-line with nondrug solutions—not in the patient’s room.
 5. When the antineoplastic drug preparation is complete, the final product shall be sealed in a plastic bag or other sealable container for transport before taking it out of the ventilated cabinet.
 6. Seal and wipe all waste containers inside the ventilated cabinet before removing them from the cabinet.
 7. Remove all outer gloves and sleeve covers and bag them for disposal while inside the ventilated cabinet.
 8. Wash hands with soap and water immediately after removing gloves.
 9. Antineoplastic drugs shall be administered safely using protective medical devices and techniques.
 - a. Examples of protective medical devices include needleless and closed systems.
 - b. Examples of protective techniques include spiking or priming of IV tubing in a C-PEC and crushing tablets in plastic sleeves.
 10. CSTDs shall be used for administration when the dosage form allows.
- (C) Routine Cleaning, Decontaminating, Housekeeping, and Waste Disposal. The employer shall ensure the following measures are followed:
1. Perform cleaning and decontamination work in areas that are sufficiently ventilated to prevent buildup of hazardous airborne drug concentrations.
 2. Prohibit the use of unventilated areas such as storage closets for drug storage or any tasks involving antineoplastic drugs.
 3. Clean work surfaces with an appropriate deactivation agent (if available) and cleaning agent before and after each activity and at the end of the work shift.
 4. Establish periodic cleaning routines for all work surfaces and equipment that may become contaminated, including administration carts and trays.
 5. At a minimum, employees shall wear safety glasses with side shields and protective gloves for cleaning and decontaminating work.
 6. Employees shall wear face shields if splashing is possible.
 7. Employees shall wear protective double gloves for decontaminating and cleaning work.
 - a. Employees shall use gloves as required by subsection (d)(2)(A).
 - b. Make sure the gloves are chemically resistant to the decontamination or cleaning agent used.
 8. Employees shall wear two pairs of protective gloves and a disposable gown if they handle linens, feces, or urine from patients who have received antineoplastic drugs within the last 48 hours or in cases where the drug may be present for

longer periods of time, such as Cisplatin and Epirubicin hydrochloride, within the last 7 days.

9. Dispose of the gown after each use or whenever it becomes contaminated.
10. Wear face shields if splashing is possible.
11. Remove the outer gloves and the gown by turning them inside out and placing them into the yellow chemotherapy waste container. Repeat the procedure for the inner gloves.
12. Employees shall wash hands with soap and water after removing the gloves.
13. Properly dispose of all antineoplastic drug waste according to Federal, State, and local regulations (separately from regular waste).
14. Double-bag all chemotherapy waste including partially filled vials, undispensed products, unused IVs, needles and syringes, gloves, gowns, mats, and contaminated materials from spill cleanups or animal bodily fluids/waste.
15. Place materials with trace wastes (those that contain less than 3% by weight of the original quantity of antineoplastic drugs)—such as needles, empty vials and syringes, gloves, gowns, and tubing—in chemotherapy waste containers. Assure that such containers protect from sharps injuries.
16. Do not use red sharps containers for drug disposal.

(D) Spill Control.

1. The employer shall establish and implement effective written policies and procedures for antineoplastic drug spills.
2. Employers shall ensure that written policies and procedures address PPE required for various spill sizes, the possible spreading of material, restricted access to antineoplastic drug spills, and signs to be posted.
3. Employers shall ensure that cleanup of a large spill is handled by workers who are trained in handling hazardous materials in accordance with section 5192.
4. Spill kits shall be made available in areas where exposures may occur.
5. Employers shall ensure the proper disposal of spill cleanup materials in a hazardous chemical waste container, in accordance with EPA/ RCRA regulations regarding hazardous waste—not in a chemotherapy waste or biohazard container.

(e) Medical Surveillance.

The employer shall establish an effective medical surveillance program for workers exposed to antineoplastic drugs which shall include the following:

- (1) Administering reproductive and general health questionnaires to be completed at the time of hire and periodically thereafter.
- (2) Taking the history of employees' drug handling as an estimate of prior and current exposure, including dates of duty assignment related to antineoplastic drugs and similar types of information.

- (3) A plan to provide initial baseline clinical evaluation, including appropriately targeted medical history, physical examination, and laboratory testing for workers identified as being potentially exposed to antineoplastic drugs that anticipates their potential toxicities.
 - (4) A follow-up plan as needed for workers who have shown health changes suggesting toxicity or who have experienced an acute exposure (substantial skin contact or inhalation exposure, cleaning a large spill [a broken IV bag, leaking IV line], etc.).
- (f) Training. The employer shall ensure that all employees with occupational exposure participate in a training program at the time of initial assignment and whenever a new antineoplastic drug is introduced into their work area. Additional training and instruction shall be provided to all employees given new job assignments for which training has not previously been received; whenever new antineoplastic drugs and related processes, procedures or equipment are introduced to the workplace and represent a new hazard; whenever the employer is made aware of a new or previously unrecognized hazard involving antineoplastic drug handling; and, for supervisors to familiarize themselves with the safety and health hazards to which employees under their immediate direction and control may be exposed.
- (1) Employees shall be trained on the employer's Plan and how to properly:
 - (A) Handle antineoplastic drugs safely, including all Hazard Communication training requirements in accordance with section 5194;
 - (B) Clean and decontaminate work areas;
 - (C) Handle waste and dispose of all contaminated materials, including patient waste;
 - (D) Clean up spills;
 - (E) Use and maintain equipment such as ventilated cabinets, closed-system drug-transfer devices, needle-less systems; and
 - (F) Select and use the appropriate PPE.
 - (2) Employees shall be trained on the health effects associated with the antineoplastic drugs they are exposed to, such as skin rashes and adverse reproductive outcomes (including infertility, spontaneous abortions, and congenital malformations), leukemia and other cancers.
 - (3) The employer shall conduct periodic training reviews with all potentially exposed workers in workplaces where antineoplastic drugs are used and seek their input regarding the quality and effectiveness of the Plan.
- (g) Recordkeeping. The employer shall develop and maintain the following records in accordance with Section 3203(b) as records of the implementation of the Plan:
- (1) Records of inspections, including the hazard assessment.
 - (2) Records of investigation of occupational injuries and illnesses related to antineoplastic drugs handling.

- (3) Training records shall be created and maintained for a minimum of one year and include the following information: training dates; contents or a summary of the training sessions; names of training providers and employees.
- (4) All records required by this subsection shall be made available on request to the Chief of the Division of Occupational Safety and Health and his or her representatives for examination and copying.
- (5) Records of injury investigations shall not include “medical information” as defined by Civil Code Section 56.05(j).
- (6) Records required by Division 1, Chapter 7, Subchapter 1, Occupational Injury or Illness Report and Records, of these orders shall be created and maintained in accordance with those orders.

Appendix A. Antineoplastic drugs listed Table 1. Antineoplastic drugs listed by NIOSH as of 2014 including their American Hospital Formulary Service (AHFS) classification and if it has manufacturers' safe handling guidance (MSHG).

Drug	AHFS classification	MSHG	Reason for listing
abiraterone*	10:00 antineoplastic agents		FDA Pregnancy Category X
ado-trastuzumab emtansine	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D
altretamine	10:00 antineoplastic agents	yes	FDA Pregnancy category D
amsacrine	NA antineoplastic agents	yes	IARC Group 2B
anastrozole	10:00 antineoplastic agents		FDA Pregnancy category X
arsenic trioxide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen**; FDA Pregnancy Category D
azacitidine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
bacillus calmette Guerin (BCG)***	80:12 vaccines	yes	See special handling requirements**; FDA Pregnancy Category C
bendamustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
bexarotene	10:00 antineoplastic agents		FDA Pregnancy Category X
bicalutimide	10:00 antineoplastic agents		FDA Pregnancy Category X
bleomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D
bortezomib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
brentuximab vedotin	10:00 antineoplastic agents	yes	Conjugated monoclonal antibody; FDA Pregnancy Category D
busulfan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D

Drug	AHFS classification	MSHG	Reason for listing
cabazitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
capecitabine	10:00 antineoplastic agents	yes	Metabolized to 5-fluorouracil; FDA Pregnancy Category D
carboplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
carmustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
chlorambucil	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D
cisplatin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
cladribine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
clofarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
crizotinib	10:00 antineoplastic agents		FDA Pregnancy Category D
cyclophosphamide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D
cytarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
dacarbazine	10:00 antineoplastic agents	yes	FDA Pregnancy Category C
dactinomycin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
dasatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
daunorubicin	10:00 antineoplastic agents	yes	IARC Group 2B, AKA daunomycin; FDA Pregnancy Category D
decitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
degarelix	10:00 antineoplastic agents		FDA Pregnancy Category X
docetaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
doxorubicin	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D

Drug	AHFS classification	MSHG	Reason for listing
epirubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
eribulin	10:00 antineoplastic agents		FDA Pregnancy Category D
erlotinib	10:00 antineoplastic agents		FDA Pregnancy Category D
estramustine	10:00 antineoplastic agents	yes	FDA Pregnancy Category X
etoposide	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D
everolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
exemestane	10:00 antineoplastic agents		FDA Pregnancy Category X
floxuridine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
fludarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
fluorouracil	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
flutamide	10:00 antineoplastic agents		Indicated only for men; FDA Pregnancy Category D
fulvestrant	10:00 antineoplastic agents		FDA Pregnancy Category D
gemcitabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
gemtuzumab ozogamicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
goserelin	10:00 antineoplastic agents		FDA Pregnancy Category X
hydroxyurea	10:00 antineoplastic agents	yes	Special warning on handling bottles and capsules FDA Pregnancy Category D
idarubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
ifosfamide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
imatinib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D

Drug	AHFS classification	MSHG	Reason for listing
irinotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
ixabepilone	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
letrozole	10:00 antineoplastic agents		FDA pregnancy Category X
leuprolide	10:00 antineoplastic agents	yes	FDA Pregnancy Category X
lomustine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
mechlorethamine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
megestrol	10:00 antineoplastic agents		FDA Pregnancy Category X
melphalan	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D
mercaptopurine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
methotrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category X
mitomycin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D
mitotane	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
mitoxantrone	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D
nelarabine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
nilotinib	10:00 antineoplastic agents		FDA Pregnancy Category D
omacetaxin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
oxaliplatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
paclitaxel	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
pazopanib	10:00 antineoplastic agents		FDA Pregnancy Category D
pemetrexed	10:00 antineoplastic agents	yes	FDA Pregnancy Category D

Drug	AHFS classification	MSHG	Reason for listing
pentostatin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
pralatrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
procarbazine	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
romidepsin	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
sorafenib	10:00 antineoplastic agents		FDA Pregnancy Category D
streptozocin	10:00 antineoplastic agents	yes	IARC Group 2B; FDA Pregnancy Category D
sunitinib	10:00 antineoplastic agents		FDA Pregnancy Category D
tamoxifen	10:00 antineoplastic agents		IARC Group 1 carcinogen; FDA Pregnancy Category D
temozolomide	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
temsirolimus	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
teniposide	10:00 antineoplastic agents	yes	IARC Group 2A carcinogen; FDA Pregnancy Category D
thioguanine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
thiotepa	10:00 antineoplastic agents	yes	IARC Group 1 carcinogen; FDA Pregnancy Category D
topotecan	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
toremifene	10:00 antineoplastic agents		FDA Pregnancy Category D
trimetrexate	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
triptorelin	10:00 antineoplastic agents		FDA Pregnancy Category X
valrubicin	10:00 antineoplastic agents	yes	FDA Pregnancy Category C
vandetanib	10:00 antineoplastic agents	yes	FDA Pregnancy Category D

Drug	AHFS classification	MSHG	Reason for listing
vemurafenib	10:00 antineoplastic agents		FDA Pregnancy Category D
vinblastine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
vincristine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
vinorelbine	10:00 antineoplastic agents	yes	FDA Pregnancy Category D
vorinostat	10:00 antineoplastic agents	yes	FDA Pregnancy Category D



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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

To: Board Members

Subject: Agenda Item XV – Proposed Regulations for the Take Back of Prescriptions Medication

Background

Since the July 2015, board meeting, the board has continued to refine the board's proposed requirements for drug take back programs.

Meanwhile, additional counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public. This often involves pharmacies.

On September 26, the Drug Enforcement Administration (DEA) conducted another national Drug Take Back day. The board released a subscriber alert and posted information about this collection day on the board's web site.

Recommendation

After discussion at the September 9, 2015, Enforcement Committee meeting the committee made the following recommendation: Direct staff to complete work on the proposed regulation, including the policy comments made by the committee, and bring the proposed regulation to the board for possible initiation of a rulemaking.

The proposed regulation language and excerpt from the September 9 Enforcement Committee meeting minutes are provided immediately following this memo.

Medication Article 9.1

Prescription Drug Take-Back Programs

Section 1776

Pharmacies, hospitals/clinics with onsite pharmacies, distributors and reverse distributors licensed by the board and licensed skilled nursing facilities may offer, under the requirements in this article, specified prescription drug-take back services to the public to provide options for the public to destroy unwanted, unused or outdated prescription drugs. Each of these entities must comply with regulations of the federal Drug Enforcement Administration and the Board of Pharmacy regulations contained in this article.

All board-licensed authorized collectors should be vigilant to prevent patients or their agents from disposing of prohibited items through drug take-back collection methods. Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, hazardous medications (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Only California-licensed pharmacies and drug distributors (licensed wholesalers and third-party logistics providers) who are licensed in good standing with the board and also registered with the Drug Enforcement Administration as collectors may participate in drug take back programs authorized under this article.

Section 1776.1 Pharmacies

- (a) Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.
- (b) Pharmacies may provide take-back services to patients as provided in sections 1776 - 1776.4. Retail pharmacies and hospital/clinics with onsite pharmacies may establish collection receptacles in their facilities. Pharmacies may operate collection receptacles as specified in in section 1776.4 in skilled nursing facilities licensed under Health and Safety Code section 1250(c).
- (c) There are multiple federal and state requirements governing the collection and destruction of dangerous drugs. Pharmacies are expected to know and adhere to these requirements when operating a prescription drug take-back program.
- (d) For purposes of this article, prescription drugs means dangerous drugs as defined by California Business and Professions Code section 4022, including controlled substances. Controlled substances may be commingled in collection receptacles or mail back packages or envelopes with other dangerous drugs. Once drugs are deposited into a collection receptacle or mail back envelope or package by a patient, they are not to be separated by pharmacy staff or others.
- (e) The following dangerous drugs and devices are expressly prohibited from collection in

a pharmacy's collection receptacles: medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers). Signage shall be placed on collection receptacles as referenced in section 1776.3.

- (f) Prescription drugs that are eligible for collection in drug take-back programs operated by pharmacies are only those prescription drugs that have been dispensed by a pharmacy or practitioner to a patient or patient's agent. Dangerous drugs that have not been dispensed to patients (such as outdated drug stock in a pharmacy, drug samples provided to a medical practitioner or medical waste) may not be collected in pharmacy drug take-back programs.
 - 1. Pharmacy staff shall not review, accept, count, sort, or handle prescription drugs returned from the public.
 - 2. A pharmacy shall not accept or possess prescription drugs returned to the pharmacy by skilled nursing homes, residential care homes, other facilities, health care practitioners or other entities.
 - 3. A pharmacy shall not dispose of quarantined, recalled or outdated prescription drugs from pharmacy stock in a drug take-back collection receptacle. Instead the pharmacy must return these items to a reverse distributor.
- (g) A pharmacy must be registered with the federal Drug Enforcement Administration as a collector for purposes of operating a prescription drug take-back program. Such pharmacies cannot employ anyone convicted of a felony related to controlled substances, or anyone who has had a DEA permit denied, surrendered or revoked.
- (h) Any pharmacy that operates a drug take-back collection program as authorized in this article shall notify the board on a form designated by the board within 30 days of establishing the collection program. Additionally:
 - 1. Any pharmacy that ceases to operate a drug take-back program shall notify the board within 30 days on a form designated by the board.
 - 2. Any pharmacy operating a mail back program or maintaining collection receptacles shall identify to the board that it provides such services annually at the time of renewal of the pharmacy license, and shall identify all locations where its collection receptacles are located.
 - 3. Any tampering with a storage receptacle or theft of deposited drugs shall be reported to the board with 14 days.
 - 4. Any tampering, damage or theft of a removed liner shall be reported to the board within 14 days.
- (i) Before establishing a collection receptacle, the pharmacy must obtain collector status from the federal Drug Enforcement Administration. If the pharmacy later ceases to operate the collection receptacle, the pharmacy must notify the Drug Enforcement Administration within 30 days.

1776.2 Mail Back Package and Envelope Services from Pharmacies

- (a) Pharmacies that provide prescription drug take-back services may do so by establishing mail back services, whereby the public may obtain from the pharmacy

preaddressed mailing envelopes or packages for returning prescription drugs to a destruction location.

- (b) All envelopes and packages must be preaddressed to a location registered with the Drug Enforcement Administration as a collector that has onsite a method appropriate to destroy the prescription drugs. The pharmacy is responsible for ensuring that all preaddressed envelopes and packages it makes available to the public are preaddressed to be delivered to facilities that comply with this section.
- (c) The preaddressed envelopes and packages must be water and spill proof, tamper evident, tear resistant and sealable. The exterior shall be nondescript and not include markings that indicate the envelope or package contains prescription drugs. Postage shall be prepaid on each envelope or package.
- (d) The preaddressed envelope and package shall contain a unique identification number for each envelope and package, and certain instructions for users to mail back drugs.
- (e) The pharmacy distributing mail back envelopes and packages shall create and maintain records required by section 1776.5.
- (f) Individuals who mail back prescription drugs as provided in this section do not need to identify themselves as the senders.
- (g) Once filled with unwanted prescription drugs, the mail back packages or envelopes shall be mailed and not accepted by the pharmacy for return, processing or holding.

1776.3 Collection Receptacles in Pharmacies

- (a) Pharmacies that provide prescription drug take-back services to the public may do so by establishing a collection receptacle in the pharmacy whereby the public may deposit their unwanted prescription drugs for destruction. The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.
- (b) The pharmacy operating the collection receptacle must securely install the receptacle so it cannot be removed. The receptacle shall be installed in an inside location, where the receptacle is visible to pharmacy employees, but not located in emergency areas. In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care.
- (c) The receptacle shall include a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner.
- (d) In hours when the pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle.
- (e) The pharmacy is responsible for the management and maintenance of the receptacle. Pharmacy staff shall not accept, count, sort or handle prescription drugs returned from the public, but instead direct the public to deposit the drugs into the collection receptacle themselves.
- (f) The receptacle shall be locked and have a removable inner liner to contain the deposited prescription drugs.

- (g) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words “chemotherapy waste.”
- (1) The liner shall be waterproof, tamper evident and tear resistant.
 - (2) The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner’s manufacturer.
- (h) The liner shall be removable as specified in this section. The receptacle shall allow the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed or counted.
- (i) A liner may be removed from a locked receptacle by two employees of the pharmacy who shall immediately seal the liner and record in a log their participation in the removal of each liner from a collection receptacle. Removed liners shall not be opened, x-rayed, analyzed or penetrated.
- (j) Immediately after a liner is removed from a collection receptacle, the liner shall be placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words “Chemo Waste” so the sides may be visible from any lateral direction.
- (l) Liners that have been filled and removed from a collection receptacle, and stored in a rigid container must be stored in a secured, locked location in the pharmacy no longer than three days.
- (m) The pharmacy shall maintain a log to record information about all liners that have been placed into or removed from a collection receptacle. The log shall contain:
1. The unique identification numbers of all unused liners in possession of the pharmacy
 2. The unique identification number and dates a liner is placed in the collection receptacle,
 3. The date the liner is removed from the collection receptacle and placed in a rigid container,
 4. The names and signatures of the two pharmacy employees who removed and witnessed the removal of a liner from the collection receptacle, and
 5. The date the liner was provided to a licensed DEA-registered reverse distributor for destruction, and the signature of the two pharmacy employees who witnessed the delivery to the reverse distributor.
- (n) The pharmacy shall ensure the sealed inner liners and their contents are shipped to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or

- USPS) or by licensed distributor pick-up at the licensed pharmacy's premises.
- (o) The collection receptacle shall contain signage developed by the board advising the public that it is permissible to deposit Schedule II-V drugs into the receptacle, but not Schedule I drugs. Labeling shall also identify that medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers) may not be deposited into the receptacle. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
 - (p) The board shall develop signage to appear on the collection receptacle to provide consumer information the collection process.

1776.4 Collection in Skilled Nursing Facilities

Skilled nursing facilities licensed under Health and Safety Code section 1250(c) may participate in drug take-back programs as authorized by this article.

- (a) Skilled nursing facility personnel may dispose of a current resident's unwanted or unused prescription drugs by using mail back packages or envelopes and packages based upon a request by the resident patient. Mail back envelopes and packages shall conform to the requirements specified in section 1776.1. Records shall be kept by the skilled nursing facility noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent.
- (b) Only retail pharmacies and hospitals/clinics with onsite pharmacies may establish collection receptacles in skilled nursing facilities for the collection and ultimate disposal of unwanted prescription drugs.
 1. Any pharmacy and hospital/clinic with an onsite pharmacy operating collection receptacles in skilled nursing facilities shall be registered and maintain registration with the DEA as collectors.
 2. Any pharmacy or hospital/clinic with an onsite pharmacy that operates a collection receptacle at a skilled nursing facility shall notify the board within 30 days of establishing a collection receptacle on a form designated by the board.
 3. Any pharmacy or hospital/clinic with an onsite pharmacy that ceases to operate a collection site at a skilled nursing facility shall notify the board within 30 days on a form designated by the board.
 4. Any pharmacy operating a collection site at a skilled nursing facility shall list all collection receptacles it operates annually at the time of renewal of the pharmacy license.
- (c) When a pharmacy or hospital/clinic with an onsite pharmacy installs a collection receptacle in a skilled nursing facility, only the pharmacy shall remove, seal, transfer, and store or supervise the removal, sealing, transfer and storage of sealed inner liners at long-term care facilities as specified in this section.
- (d) Every pharmacy and hospital/clinic pharmacy that operates a collection site at any

- skilled nursing facility shall notify the board within 14 days of any loss from the collection receptacle or secured storage location for the storage of removed liners.
- (e) Within three business days after the permanent discontinuation of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death, the skilled nursing facility may place the patient's unneeded prescription drugs into a collection receptacle. Records of such deposit shall be made in the patient's records, with the name and signature of the employee discarding the drugs.
 - (f) A collection receptacle must be located in a secured area regularly monitored by skilled nursing facility employees.
 - (g) The collection receptacle shall be securely fastened to a permanent structure so that it cannot be removed.
 - (h) The receptacle shall be securely locked and substantially constructed, with a permanent outer container and a removal inner liner.
 - (i) The outer container shall include a small opening that allows deposit of drugs into the inside of the outer container and directly into the inner liner.
 - (j) The outer container shall prominently display a sign indicating that prescription drugs and controlled drugs in Schedules II – V may be deposited. The name and phone number of the collector pharmacy responsible for the receptacle shall also be affixed to the collection receptacle.
 - (k) Once deposited, the prescription drugs shall not be counted, inventoried or otherwise individually handled.
 - (l) A liner as used in this article shall be made of material used and rated to contain chemotherapy waste. The liner shall be yellow and labeled with the words "chemotherapy waste."
 - 1. The liner shall waterproof, tamper evident and tear resistant.
 - 2. The liner shall be opaque to prevent viewing or removal of any contents once the liner has been removed from a collection receptacle. The liner shall be clearly marked to display the maximum contents (for example, in gallons). The liner shall bear a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the manufacturer.
 - (m) The installation, removal, transfer and storage of inner liners shall be performed only by:
 - 1. One employee of the authorized collector and one supervisory level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector, or
 - 2. By or under the supervision of two employees of the authorized collector pharmacy.
 - (n) Upon removal from the collection receptacle, the liner shall be immediately sealed, and placed for storage, handling, and transport in a rigid container that may be disposable, reusable, or recyclable. Containers shall be leak resistant, have tight-fitting covers, and be kept clean and in good repair. Containers may be of any color and shall be labeled with the words "Chemo Waste" so the sides may be visible from

any lateral direction.

- (o) Sealed inner liners that are placed in a container may be stored at the skilled nursing facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction.
- (p) Liners housed in a container may be delivered to a reverse distributor for destruction by two pharmacy employees delivering the sealed inner liners and their contents directly to a reverse distributor's registered location, or by common or contract carrier or by reverse distributor pickup at the skilled nursing facility.
- (q) Records of the destruction shall be maintained that provide the date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and if applicable, the names and signatures of the two employees who transferred each liner.

1776.4 Reverse Distributors

- (a) A licensed reverse distributor (either a reverse wholesaler or a reverse third-party logistics provider) may accept the sealed inner liners of collection receptacles. Once received, the reverse distributor shall establish records required by this section.
- (b) A licensed reverse distributor may not count, inventory or otherwise sort or x-ray the contents of inner liners. All liners shall be incinerated by an appropriately DEA-licensed distributor.
- (c) Two employees of the reverse distributor shall pick up or accept the receipt of inner liners from DEA registrants.
- (d) A reverse distributor shall not employ as an agent or employee who has access to or influence over controlled substances, any person who has been convicted of any felony offense related to controlled substances or who at any time had a DEA registration revoked or suspended, or has surrendered a DEA registration for cause.
- (e) Each reverse distributor with an incineration site shall maintain a record of the destruction on DEA form 41. The records shall be complete, accurate, and include the name and signature of the two employees who witness the destruction.
- (f) For each sealed liner or mail back package received from collectors or law enforcement pursuant to federal CFR section 1317.55, the reverse distributor shall maintain records of the number of sealed inner liners or mail back envelopes/package, including the:
 - 1. Date of acquisition
 - 2. Number and the size (e.g., five 10-gallon liners, etc.)
 - 3. Inventory number of each liner or envelope/package
 - 4. The date and place and method of destruction
 - 5. Number of packages and inner liners received
 - 6. Number of packages and inner liners destroyed
 - 7. The number and signature of the two employees of the registrant that witnessed the destruction.

1776.5 Record Keeping Requirements for Board Licensees Providing Drug Take-Back Services

Each entity authorized by this article to collect unwanted prescription drugs from patients shall maintain the following records.

- (a) When obtaining unused mail-back packages and envelopes for future distribution:
 1. The collector pharmacy shall maintain records that identify: the date the envelope or package was obtained by the pharmacy, the number of packages/envelopes made available to the public, and the unique identification number of each package.
 2. For unused packages and envelopes provided to a skilled nursing facility or third party to make available to patients and other authorized individuals: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification number.
- (b) For each mail-back package or envelope distributed by a pharmacy, the pharmacy shall record the serial number of each package or envelope distributed and the date distributed.
- (c) For sealed mail-back packages received by the reverse distributor: the date of receipt and the unique identification of the individual package or envelope,
- (d) For sealed mail back packages destroyed onsite by the reverse distributor collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witness the destruction.
- (e) For pharmacies using collection receptacles, for each liner:
 1. Date each unused liner is acquired, its unique identification number and size (e.g., five gallon, 10-gallon). The pharmacy shall assign the unique identification number if the liner does not already contain one.
 2. Date each liner is installed in a receptacle, the address of the location where each liner is installed, the unique identification and size (e.g., five gallon, 10-gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation.
 3. Date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each removal.
 4. Date each sealed inner liner is transferred to storage, the unique identification and size (e.g., 5-gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage.
 5. Date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each

sealed inner was transferred, the unique identification number and the size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor.

- (f) For each reverse distributor (wholesaler or third-party logistics provider) accepting liners, immediately upon receipt of a liner:
1. The date of receipt of each liner, the unique serial number of the liner, the pharmacy from which the liner was received, the method by which the liner was delivered to the reverse distributor (e.g., personal delivery by two pharmacy staff, shipping via common carrier).
 2. For each liner destroyed by the reverse distributor collector: the method and date of destruction, listed by the unique identification number of liner and other items required by (f)(1), and the names and signatures of the two employees of the registrant who witness the destruction.

**September 9, 2015 Enforcement Committee
Meeting Minutes Excerpt**

Steven Gray representing Kaiser requested that the DOJ attend the California Society Hospital Pharmacists (CSHP) seminar to conduct CURES enrollment. Mr. Gray was asked to submit details of the meeting for consideration. Ms. Herold offered to help with CURES enrollment at this meeting.

There were no additional comments from the committee or public.

b. Update by the University of California, San Diego on Its Pilot Program to Permit Patients to Access Medication from an Automated Storage Device not Immediately Adjacent to a Pharmacy

Background

At the Board of Pharmacy's April 2015 Board Meeting, the board approved an 18-month pilot study under the auspices of the UCSD School of Pharmacy involving use of an automated storage device for prescription medication for which staff and their families of a Sharp Hospital in San Diego, who opt in, may pick up their outpatient medications from this device located in a hospital, instead of having to go to the community pharmacy. Consultation will be provided via telephone before medication can be dispensed to a patient.

This study was planned to start in June or July, 2015. However, in scheduling items for this committee meeting, we learned that the project is running a bit behind.

Discussion and Comment

At this meeting, via telephone, Dr. Hirsch delivered a presentation on the implementation of this program, which she anticipates will start in December 2015.

There were no comments from the public or committee.

A copy of this presentation can be found at the end of this document.

c. Discussion Regarding the Board's Proposed Regulations for the Take Back of Prescription Medication

Background

Since the July board meeting, work has continued to refine the board's proposed requirements for drug take back programs.

Meanwhile, additional counties have established requirements to permit or require take back of unwanted pharmaceuticals from the public. This often involves pharmacies.

On September 26, the Drug Enforcement Administration (DEA) will conduct another national Drug Take Back day. The board has released a subscriber alert and posted information about this collection day on the board's web site.

Board staff agreed to incorporate comments from this meeting into a draft and bring it to the October Board Meeting.

Board staff respectfully suggested a motion from this meeting for a recommendation that staff complete work on the proposed regulation, including incorporating comments made at this meeting, and bring the draft to the board meeting with a recommendation for the board to initiate a rulemaking by releasing the requirements for the 45-days of public comment.

Discussion and Comment

Ms. Freedman, board counsel, suggested that the committee focus on policy of the regulation and allow the board to tweak the language.

Heidi Sandborn, representing the California Product Stewardship Council, thanked the committee and stated the number one concern with this regulation is funding. She requested that the mandate be modified to include both a sharps container and a drug bin. She states that will provide more flexibility to local governments.

The San Mateo Department of Public Health expressed concerns with the sharps requirement and stated that this requirement may hinder pharmacies participation.

Mr. Weisser inquired into the cost of sharps disposal.

Jenn Jackson from San Francisco County voiced concern about the cost of sharps disposal. While she agreed it is necessary, she asked for clarification as to how existing pharmacies that do not take back controlled drugs would register.

The proposed regulations require pharmacies to register with the DEA. Ms. Jackson offered to provide the committee with information about the Health and Safety Code that allows for the co-mingling of sharps and drugs.

Mr. Weisser asked that a future agenda item include the manufacturer responsibility of drug take back.

A representative of the City of Santa Rosa agreed with comments made by previous speakers and requested clarification on several items including why inhalers are excluded. He requested that the committee remain cognizant of the impact the regulations may have on existing programs. Ms. Herold responded that pharmacies are DEA registrants and must comply with the DEA requirements irrespective of what the board does. The representative of Santa Rosa requested that the committee consider maximum flexibility and questioned about how the use of a common or contract carrier can ensure the chain of custody. He also asked if the language can reference "bags" instead of "liners".

It was noted that the committee should consider is if there is value in the board creating a standardized sign for all drug take back.

Dr. Gutierrez discussed the need to educate pharmacies about the DEA requirements to register as a collector.

Brian Ward of CSHP thanked the committee for moving forward with these regulations. He informed the committee that the Environmental Protection Agency (EPA) just released information about their requirements for drug take back. He encouraged the committee to ensure that the board's regulations are consistent with EPA requirements.

Dr. Gutierrez sought clarification from counsel on whether the board's regulation indicated that drug take back is not required in our regulation but is required by a local ordinance, which one supersedes the other. Counsel indicated she would research the issue.

Dr. Gutierrez recessed for a break at 11:17 a.m.

The meeting reconvened at 11:27 a.m.

Dr. Gray representing Kaiser made several suggestions:

- He stated that the term "tampering" is ambiguous and suggested that the committee provide a definition of this term.
- He suggested that the regulation require that the liner material be made of antineoplastic material.
- He suggested that the board clarify the definition of controlled substances to include the state and federal schedules.
- He asked for the purpose of the signage requirement and whether this posting provides safe harbor if a consumer places a prohibited item in the bin.
- He requested that the board pursue legislation to create the safe harbor.
- He asked for clarification on the placement of the bin and stated that it is ambiguous.
- He suggested that the board clarify the documentation requirement when the mail back option is provided to the consumer.

Committee Policy Discussion

Question: Should we assume that all medications being brought in are controlled substance?

Answer: Yes.

Question: Do we want to differentiate between sharps vs. other mail bins?

Answer: The committee recommended removing the sharps requirement.

The committee stated that pharmacies shall not be required to participate in drug take back programs and that pharmacies on probation is prohibited from participating in this program.

The committee stated that pharmacies participating in drug take back programs should not be prohibited from receiving reimbursement.

It was noted that the committee should focus on where the bins can be located and find other ways to prevent a consumer from dropping off medications when a pharmacy is closed. It was also noted that bins should be lockable when the pharmacy is closed.

The committee questioned whether there should be common signage and agreed that the board should develop a sign for posting.

Public Comment on Committee Policy

Heidi Sandborn expressed concern that some capacity will be lost if the board follows the DEA regulations because some pharmacies do not want to handle controlled substances.

Brian Warren sought clarification as to whether counsel will be researching drug take back, sharps take back or vs. both. Counsel advised that the current draft calls for both.

The Marin County Pharmacist Association recommended that the committee keep the focus on getting drugs out of the home to prevent drug abuse and overdose.

The City of Santa Rosa concurred with comments by Heidi Sandborn and expressed concern about the cost.

Tim James from the California Grocers Association is trying to determine how all of the different pieces will work together, including the technical aspects of the regulations. They are concerned that this program could compromise food safety. His association will provide written comments in the next few days.

Committee Recommendation:

Motion: Recommend that staff complete work on the proposed regulation, including the policy comments, and bring the proposed regulation to the board for possible initiation of a rulemaking.

M/S: Weisser/Lippe

Support: 5 Oppose: 0 Abstain: 0

There were no additional comments or questions.

Dr. Gutierrez recessed for a 30-minute lunch break at 12:24 p.m.

The meeting reconvened at 1:02 p.m.



The New York Times | <http://nyti.ms/1VLfC9W>

U.S.

D.E.A. Effort to Curb Painkiller Abuse Falls Short at Pharmacies

By **ALAN SCHWARZ** OCT. 10, 2015

When the Drug Enforcement Administration announced last year that pharmacies nationwide could accept and destroy customers' unwanted prescription drugs, experts in substance abuse called it a significant step toward easing the painkiller and heroin epidemic.

One year later, however, the response has been insignificant, dismaying optimists and leaving communities searching for other strategies. Only about 1 percent of American pharmacies have set up disposal programs, with none of those belonging to the two largest chains, CVS and Walgreens, which have balked at the cost and security risks, according to government and industry data.

Countless unused prescription pills like oxycodone and Xanax linger in household medicine cabinets, in easy reach of addicted adults and experimenting adolescents. People who develop painkiller dependencies often move on to heroin, which is considerably cheaper and provides a stronger high. About 23,000 Americans died of prescription-drug overdoses in 2013, more than twice the number from 2001, according to the National Institute on Drug Abuse.

Flushing unwanted medications down the toilet is legal but discouraged because they can pollute water sources; throwing them in household garbage that eventually reaches landfills creates similar environmental concerns.

The D.E.A. decided to allow retail pharmacies to collect unwanted drugs — generally in secure, mailboxlike receptacles — because the locations are convenient

for the public and already feature safeguards for the medicines, some of which can be worth \$40 per pill on the street. Pharmacies within hospitals and clinics are also eligible.

But participation is voluntary, and leaves pharmacies with the costs of collecting, safeguarding and incinerating the pills. In addition, at least eight states, including New York, have laws that forbid pharmacies to take back controlled substances.

A Walgreens spokesman said the company had not authorized any of its 8,200 locations to take back prescription drugs from customers. If someone asks to have unwanted medicine destroyed, he said, the store offers a do-it-yourself kit, for \$3.99, in which the pills are mixed with water and other substances to render their contents inactive.

“We consider this the safest and most convenient way to dispose of unused medications,” the spokesman, James Graham, said in a statement.

Since 2010, the D.E.A. has held 10 so-called take-back days — with the latest on Sept. 26 — during which the police and other law enforcement groups encourage people to bring them unwanted medications for disposal. While these have collected 2,400 tons of pills, limited research suggests that the vast majority are noncontrolled medications like cholesterol drugs, antibiotics, and even aspirin and dietary supplements. One expert likened the effort to “trying to eliminate malaria in Africa by killing a dozen mosquitoes.”

A CVS spokesman, Michael DeAngelis, said the company did not allow its 7,800 pharmacies to accept controlled medications, although it held a pilot program at one of its stores. He would not disclose the location or results.

Mr. DeAngelis said CVS instead sought to address prescription drug abuse through other means. For example, it has expanded its program of selling naloxone, a medication that can avert opioid overdoses, to customers without a prescription. And it pays for receptacles, which cost about \$800 each, that law enforcement officials use on the D.E.A.’s take-back days.

In some states, prescriptions for noncontrolled substances — those with vastly lower risks for misuse and addiction — are collected and redistributed to those in

need. Social services officials in Tulsa, Okla., have about 20 retired doctors who retrieve surplus prescription drugs from dozens of area long-term-care facilities and take them to a pharmacy where they are checked, sorted and donated to low-income residents.

Begun in 2004, the program has filled 180,000 prescriptions worth more than \$35 million retail. But it does not handle controlled substances.

“They have such value on the street,” said Linda J. Johnston, the director of Tulsa County Social Services. “It’s not unusual to hear on the news about a pharmacy being robbed. It’s something we wanted to sidestep.”

While Ms. Johnston said she understood pharmacies’ concerns about security, both in guarding drop boxes and transferring their contents to disposal facilities, she expressed some skepticism for those who balk at the cost of destroying the substances. The drugs collected during Tulsa’s D.E.A. take-back day, and in about 20 other locations nationwide, are incinerated free by the local plant of Covanta, the waste and energy company.

Several West Coast counties, including Alameda (which includes Oakland, Calif.) and King (which includes Seattle), have passed ordinances to require the source of prescription medications — drug companies — to underwrite and manage take-back programs. The Pharmaceutical Research and Manufacturers of America, the industry’s main trade association, sued Alameda County over its law, but lost in the United States Court of Appeals for the Ninth Circuit. The Supreme Court declined to review the case in May, and the program could become the first to begin operation next year.

Scott Cassel, the chief executive of the Product Stewardship Institute, a nonprofit environmental group, said manufacturers in other industries had been required to handle the disposal of their own environmentally harmful products. For example, mattress makers in Connecticut are responsible for disposing of discarded mattresses because they are expensive to destroy or recycle.

“The mattress people were understandably not enthusiastic about picking up the cost,” Mr. Cassel said, “but the idea is to protect the environment and to ask industries to handle the waste. Right now it’s the taxpayers.”

As for pharmacies, Mr. Cassel said that generally only small, independent locations had used the D.E.A.’s new guidelines to begin collecting controlled medications, partly out of civic responsibility but also as a means of getting more customers in the store.

The small number of participating pharmacies does not bode well for the future of the program, said Howard Weissman, the executive director of the St. Louis affiliate of the National Council on Alcoholism and Drug Dependence.

“People mean well and want to do the right thing, but in the same way we mean to bring our plastic bags back to grocery stores, we wind up just throwing them in the trash,” Mr. Weissman said of unused drugs. “Until we figure out how to get people to understand how dangerous this stuff can be, parents are going to keep stocking their medicine cabinets with loaded revolvers.”

Correction: October 13, 2015

Because of an editing error, an article on Sunday about a disposal system for unwanted prescriptions misstated, in some editions, part of the name of a group that has a St. Louis affiliate led by Howard Weissman, who commented on the practice. It is the National Council on Alcoholism and Drug Dependence (not Drug Abuse).

A version of this article appears in print on October 11, 2015, on page A18 of the New York edition with the headline: A Plan to Curb Pill Abuse Falls Short at Pharmacies .

Rx Drug Take Back--Local CA Ordinances

City/County	Description	Drop off locations	Date Effective	Status
Alameda County	Drug manufacturers must work with a Stewardship organization to develop a Product Stewardship Program, subject approval by the Department. Drop off sites are a mix of police stations and independent pharmacies	31 locations	8/3/12	n/a
LA County	Intends to model after Alameda, San Mateo, SF, and Santa Clara but includes sharps	n/a	n/a	08/11/15: Board voted to begin a stakeholder process and have staff draft an epr ordinance, expected to be presented in February 2016. Draft will be available Nov 13.
Marin County	Modeled after SF except requires a minimum of 25 drop-off sites throughout the County. If the minimum 25 drop off sites cannot be met, areas may be served through prediodic collection events.	16	####	

San Francisco City and County	Drug manufacturers must work with a Stewardship organization to develop a Product Stewardship Program, subject approval by the Department. Specifies that plans must show preference to retail pharmacies and law enforcement agencies as drop off sites. Requires each supervisorial district to host at least 5 drop off sites and allows areas unable to meet that threshold to be served through periodic collection events. Drop off sites are a mix of police stations and independent pharmacies	23 locations	4/17/15	n/a
San Luis Obispo County	Requires retail pharmacies to provide either a collection receptacle or a mail back envelope to customers for unsued drugs. Retail pharmacies must provide signage within 5 ft of any entrance for the take back program. Mail back envelopes must be provided at no cost to the customer and be offered at the time of purchase of any prescription drug. Retail pharmacies must provide mail back envelopes to returning customers. Only required to provide one envelope a month per customer.	all retail pharmacies in San Luis Obispo County	9/1/15	n/a
San Mateo County	Modeled after SF	13 locations	5/28/15	

Santa Barbara County	Intends to pursue EPR program	8 locations	n/a	10/6/15: Santa Barbara Board of Supervisors voted to draft an EPR ordinance. It is expected to be reviewed by the Board in early 2016.
Santa Clara County	Modeled after SF except requires 1 drop off site for every 20,000 County residents and no less than 10 drop off sites per supervisorial district (5). Allows areas that cannot meet the 10 drop off location threshold to be served through preiodic collection events. Current drop off locations are a mix of police/sheriff stations and independent pharmacies	14 locations	####	n/a
Santa Cruz County	Mandates retail pharmacy participation with locations either hosting a receptacle OR operating a mail back program for covered drugs. Covered drugs include brand name, generic, and non-prescription. Retailers must provide free sharps containers and may refuse sharps from consumers if not provided in an approved container. Retail costs are to be covered by product stewardship organization. Product stewardship plans must be submitted by March 1, 2016 and are subject to a 60 day review and approval	22 locations		11/10/15: The Dept of Public Works presented Board with draft ordinance. Final hearing expected December 8.



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

November 30, 2015

California State Board of Pharmacy
Attn: Lori Martinez
Lori.Martinez@dca.ca.gov
1625 N. Market Blvd., Suite N219
Sacramento, CA 95834

BY ELECTRONIC CORRESPONDENCE

RE: Reconciliation and Inventory Report of Controlled Substances, Notice of Proposed Regulations to Adopt Section 1715.65 of Article 2 of Division 17 of Title 16, California Code of Regulations

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed regulations and adoption of Section 1715.65 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR). The Board of Pharmacy (Board) has added these specific requirements for reconciliation and inventory reporting of controlled substances as part of their effort to combat drug loss and diversion from within pharmacies and prescription drug abuse within California.

The Board proposes to add specific requirements for periodic reconciliation and inventory at least every three months of all Schedule II controlled substances and at least one additional controlled substance as identified by the Board based on drug loss reports. According to the Board, by conducting a physical count inventory, pharmacists, pharmacies, and clinics will have more accountability and monitoring of controlled substances. The Board cites the availability of opioids is partly the cause of epidemic misuse of prescription medication. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. According to the Board, this will reduce the supply of controlled substances available for misuse and abuse without denying pain relief for those who need it.

CHA agrees with the underlying premise that comprehensive safeguards and highly reliable systems need to be in place to prevent controlled substance misuse, particularly with the high rate of opioid deaths across the nation and within the state. And while we agree with the need for comprehensive controls of opioid acquisition and distribution, we acknowledge the stringent hospital regulations and standards of practice presently in place, along with rigorous practices used by hospital pharmacists to secure all medications specifically to prevent misuse and

enhance appropriate use with patients. Presently, all hospital pharmacists undergo the “biennial inventory” of controlled substances required by federal law and agree that periodic inspection is necessary. In addition, each hospital, health system and clinic has a specific process in place for storage and security of controlled substances. The CHA Medication Safety Committee has developed the “Reducing Controlled Substances Diversion in Hospitals” tool to provide recommendations to hospitals on actions they could take to assess their resources and technology to develop an individualized diversion and prevention plan that protects organizations from substance diversion. The tool outlines recommendations utilizing present state and federal laws and regulations, as well as, stating best practice recommendations as goals for ongoing process improvement and high reliability performance. A section on storage and security of controlled substances identifies the numerous different ways controlled substances are securely stored within institutions, and therefore, how individualized plans for inventory and reconciliation must be utilized, especially as it pertains to narcotic storage outside of the main pharmacy, particularly in Administration Dispensing Cabinets (ADC’s).

CHA and its members agree that physical inventory of the pharmacy vault every three months is reasonable, and most hospitals perform this activity monthly. The area of greatest concern with the proposed regulations revolve around the hospital’s inventory of ADC’s and the variable type and level of safety and security systems, necessitating a well-designed policy specific to that institution’s resource capability. A periodic physical inventory every three months is not necessarily the best method to identify or limit diversion, depending on other technology and methods available to the organization. Systems in place and used by many organizations include biometric identification, blind counts, use of specific controlled substance software, etc. Hospitals need to provide the highest level of security within existing resources. Many of these alternative processes are far superior than a physical inventory, and the addition of labor intensive activity, as proposed in these regulations when other successful systems are in place, are wasteful and unnecessary.

CHA’s specific comments are outlined in the attached grid. As mentioned in previous comments, our main concern is the fiscal impact incurred by hospitals across the state to comply with this regulation when there is no evidence to support its efficacy. One hospital system reports the need for additional \$300,000 annually to provide ADC physical inventory. Extrapolated across 400 hospitals, this number would conservatively increase to over \$3 million dollars for hospitals to deploy. While ADC physical inventory is one of several methods to identify and limit diversion, it is not the most effective method and should not be mandated.

In section 1715.65 (a), CHA agrees with the BOP that periodic reconciliation and inventory functions defined by hospital policy should prevail. We agree that periodic physical inventory of the pharmacy vault is appropriate, however, physical inventory of the ADC’s should not be mandated due to the fiscal impact and availability of other equivalent, if not more successful methods such as biometric identification, blind counts, controlled substance software, etc.

In section 1715.65(b), CHA proposes to add designee status as all hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over

providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy.

In Section 1715.65(c) CHA specifically discusses our biggest concern with the proposed regulations on physical inventory count of ADC's. CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy vault is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do "blind counts" to verify they match the total in their software systems, if computerized software tracking software systems are in place.

If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue resource burden would occur. A California health care system with over 30 hospitals and 700 ADC's would need four hours of labor per machine to count all Schedule II controlled substances at an annual cost of \$300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over \$3 million annually. The physical inventory of ADC's should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.

As discussed, this is an unnecessary financial burden, as other safeguards listed in the grid are examples of activities implemented in hospitals that utilize ADC's e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADC's by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation technology.

In section 1715.65(e) CHA offers the same perspective as per section 1715.65(c). CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for narcotic administrative practice.

In section 1715.65(e)(3), CHA offers clarification language.

In section 1715.65(g), CHA would suggest that California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the Board within 30 days. ADC's located in hospitals or nursing homes would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggests changing the time frame to 30 days presently allowed for an actual irreconcilable loss of controlled drugs.

In section 1715.65(h), CHA agrees that additional measures should be implemented in response to unidentified controlled substance drug loss. However, we disagree that those measures should be specifically determined as presently proposed. Strike, “including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing”, and replace with “take additional steps to improve the security of the controlled substances to prevent losses”. Hospitals need to have flexibility in what resources are used to address narcotic loss.

In summary, hospitals and health systems are fully committed to combating drug loss and diversion from within hospital pharmacies. Each hospital has specific standardized policies and practices in place to mitigate diversion. We agree that robust systems need to be in place, however, we need to recognize the extreme resource variability, in particularly with ADC’s, and allow hospitals to develop plans and policies based on evidence and present resource capability. We are in full agreement that periodic, every three month physical inventory of the inpatient pharmacy vault is appropriate, and most hospitals are already performing this more often. Our main concerns, as discussed in depth, center around the physical inventory requirement for the ADC’s. This requirement is an unnecessary financial burden without appropriate evidence or rationale, particularly when other more stringent measures are present.

Once these regulations are finalized, the CHA Medication Safety Committee will update the medication safety tool, “Reducing Controlled Substances Diversion in Hospitals”, distribute, and continue to educate and foster improved narcotic administration practices that protect patients and lessens theft, diversion or other controlled substance untoward activities.

Respectfully Submitted:



BJ Bartleson, RN, MS, NEA-BS
Vice President, Nursing and Clinical Services

BJB:rf

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(a)	<p>“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.”</p> <p>This is added to ensure all Board licensees that dispense controlled substances are required to perform the inventory defined under this proposal.</p>	<p>“Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic reconciliation and inventory functions, defined by policy, to prevent the loss of controlled substances.”</p>	<p>California hospitals and health system pharmacies have stringent individualized standardized practices in place to prevent, detect, and mitigate controlled substance diversion. Because of the broad variability in types of facilities, and, medication administration resources, hospitals each define their individualized system in specific policies, as well as, perform periodic controlled substance inventory.</p> <p>All hospitals perform the required CMS biennial inventory of controlled substances and a monthly physical inventory of the respective pharmacy vault.</p> <p>While most hospitals have automated dispensing cabinets (ADC's), the types and utilization are variable, depending on available resources. Thus the most important aspect of this regulation should be the requirement for periodic reconciliation based on individualized hospital policy that defines the specific controlled substance procurement and administration process inventory and reconciliation process.</p>
1715.65(b)	<p>“The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.”</p> <p>This is added to ensure the licensee responsible for the pharmacy operations is reviewing the reconciliations and inventories. Additionally, the facility needs to develop policies and procedures to ensure that each reconciliation and inventory is completed following the same</p>	<p>“The pharmacist-in-charge or designee, or consultant pharmacist for a clinic shall review periodic reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled substances. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.”</p>	<p>All hospitals have standardized procedures to assign designee status in situations where they do not have direct supervision over providers. Those standardized reconciliation and inventory activities are done periodically per hospital policy,</p>

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>methods to prevent inaccurate collection of data. Finally, the Board reviews policies and procedures while performing site inspections and will be able to confirm if the policies and procedures implemented by the pharmacy or clinic meet the regulatory requirements.</p>		
1715.65(c)	<p>“Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of <u>all quantities of federal Schedule II controlled substances and at least one additional controlled substance</u> which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <u>dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u>”</p> <p>This subdivision specifies the required time frame of at least every three months. By requiring at least a quarterly inventory of all Schedule II controlled substances, pharmacists and pharmacies will be better equipped to spot and stop employee drug diversion from the pharmacy earlier and prevent excessive drug losses from occurring. While the Board is requiring the inventory to be completed quarterly, the term “at least” allows for the pharmacist-in-charge to use their professional judgment should they wish to perform the inventory more frequently. The additional requirement of at least one additional controlled substance based on drug loss reports allows the Board to utilize drug</p>	<p>“Perform a Periodic Inventory: An Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of <u>all quantities of federal Schedule II controlled substances</u> <i>*(within the inpatient pharmacy only if a licensed hospital)</i> and at least <u>one additional controlled substance</u> which may be specified by the Board each year as based upon loss reports made to the Board in the prior year. The Inventory Report shall be <u>dated and signed (electronic signature acceptable) by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.</u>”</p>	<p>CHA agrees that periodic inspection of controlled substances in the inpatient pharmacy is necessary; in fact, hospitals routinely perform a monthly physical inventory of the inpatient pharmacy vault. Most also do “blind counts” to verify they match the total in their software systems, if computerized software tracking software systems are in place.</p> <p>If a physical inventory count was required of all dispensing cabinets throughout the hospital by the Inpatient Pharmacy, an undue burden of resources would be incurred. A California health care system with over 30 hospitals and 700 ADC’s would need four hours of labor per machine to count all schedule II controlled substances at an annual cost of \$300,000. Extrapolate that to 400 plus California hospitals and this regulation will conservatively cost over \$3 million annually. The physical inventory of ADC’s should be optional if organizations have explicit alternatives in place to inventory and reconcile controlled substance diversion.</p> <p>As discussed, this is an unnecessary financial burden, as other safeguards listed below are examples of activities implemented in hospitals that utilize ADC’s e.g. blind counts, robust discrepancy resolution process, review of ADC overrides, and periodic inventory of the ADCs by nurses, etc. Hospitals deploy stringent ADC reconciliation procedures depending on the type and quantity of ADC resources, as well as available reconciliation</p>

16 CCR Section 1715.65 Reconciliation and Inventory Report of Controlled Substances 11/30/2015

Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>loss reports and alert pharmacies and clinics of high theft controlled substances that may not be Schedule II. As regular inventory is being completed on Schedule II controlled substances, those wishing to divert controlled substances may change their focus to non-Schedule II in order to avoid detection, an example of this is Promethazine with Codeine cough syrup. Promethazine with Codeine has a high potential for abuse, but it is not Schedule II. By requiring an inventory of at least one non-schedule II, the Board will be able to reduce the theft and misuse of an additional controlled substance. Finally, as the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that those who performed the inventory sign and date the Inventory Report, and that it be countersigned by the pharmacist-in-charge or consultant pharmacist to ensure they are aware and accountable for the inventory. By requiring the signing and countersigning of the Inventory Report, Board inspectors will know who completed the inventory during an inspection.</p>		<p>technology.</p> <p>Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities:</p> <ul style="list-style-type: none"> • Use of biometric identification to access ADCs • Use of “blind counts” when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of “blind counts” when restocking the ADCs • Required resolution of any controlled substance discrepancies on a <u>daily</u> basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing “blind counts.” • <u>Daily</u> monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
			<p>substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs.</p> <ul style="list-style-type: none"> • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software • Use of “blind counts” when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software <p>As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.</p>
1715.65(c)(1)	<p>“The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be <u>readily retrievable for three years.</u>”</p> <p>This requirement is added so that the Inventory Report will be readily available for review by Board inspectors as defined in Business and Professions Code (B&P) section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.</p>	No Comment	
1715.65(c)(2)	<p>“The biennial inventory of controlled substances required by federal law may</p>	No Comment	

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:"</p> <p>This subdivision allows for the use of the federally required biennial inventory to be used as one of the proposals quarterly inventories. This specification will eliminate the need for repetitive inventories to meet state and federal Requirements.</p>		
1715.65(c)(2)(A)	<p>"A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container."</p> <p>This subdivision specifies that, in order to use the biennial inventory, it must have been a physical count inventory and not an estimate. The federally required biennial inventory does not specify a physical count as required in subdivision (c) of this proposal, so this specification is necessary to ensure a physical count Inventory is completed.</p>	No Comment	
1715.65(c)(2)(B)	<p>"The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section."</p> <p>This subdivision specifies that in order to utilize the federally required biennial inventory, it must be no older than 90 days from the last physical inventory completed. This subdivision ensures that an inventory is completed at least once every three months.</p>	No Comment	

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
1715.65(d)	<p data-bbox="210 207 781 415">"A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c)."</p> <p data-bbox="210 461 781 1292">This subdivision requires a new pharmacist-in-charge to complete an inventory. While this is currently recommended, it is not required. Requiring a new pharmacist-in-charge to complete an inventory within 30 days of becoming pharmacist-in-charge will familiarize the pharmacist with the pharmacies policies and procedures and will hold them accountable for the drug inventory and drug losses that may occur after they become pharmacist-in-charge. The Board selected the 30 day time frame to allow the new pharmacist-in-charge time to acclimate to their new position and to allow time to address day to day operations. While not being mandated, the Board is also recommending that the outgoing pharmacist-in-charge should complete an inventory upon their departure. Completing an inventory upon departing will reduce or eliminate suspicion and possible disciplinary action against the departing Pharmacist-in-Charge should a drug loss be discovered by the new Pharmacist-in-Charge.</p>	No Comment	
1715.65(e)	<p data-bbox="210 1299 781 1471">"Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand,</p>	<p data-bbox="793 1299 1318 1471">"Reconciliation with Inventory Report: The pharmacy or clinic shall review, based on policy, all acquisitions and dispositions of controlled substances as part of the inventory process (within</p>	<p data-bbox="1331 1299 2047 1471">As per section 1715.65(c), CHA proposes this regulation apply only to inpatient pharmacies of a licensed hospital, and allow individualized reconciliation and inventory policies be applied to hospitals that utilize ADC's or other mechanisms for</p>

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	<p>based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.”</p> <p>This subdivision requires that the acquisition and disposition reports be reconciled with the inventory report. This reconciliation is necessary to ensure that controlled substances are not being ordered and diverted upon arrival without the knowledge of the pharmacist-in-charge. This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.</p>	<p>other inpatient pharmacy only if a licensed hospital or clinic) as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.”</p>	<p>narcotic administrative practice.</p> <p>If a physical inventory count was required of all dispensing cabinets throughout the hospital by the inpatient pharmacy, an undue burden of resources would be incurred. This is unnecessary as other individualized stringent safeguards are implemented, such as, blind counts; robust discrepancy resolution process, review of ADC overrides, periodic inventory of the ADCs by nurses, etc. (See more specific examples in section 1715.65(c).</p>
1715.65(e)(1)	<p>“Losses shall be identified in writing and reported to the Board and, when appropriate, to the Drug Enforcement Administration.”</p> <p>This subdivision specifies what the licensee is required to do if a loss of controlled substances is discovered. If a drug loss is discovered, it is necessary for the Board to be informed from a regulatory stance to determine if there is an issue with security at the pharmacy or clinic.</p>	No Comment	
1715.65(e)(2)	<p>“Likely causes of overages shall be identified in writing and retained.</p> <p>This subdivision specifies what the licensee is required to do if an overage of controlled substances is discovered. The Board does not need to be informed of the overage; however, it is necessary to</p>	No Comment	

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	<p>educate and ensure that the pharmacy or clinic maintains better records of their controlled substances.</p>		
<p>1715.65(e)(3)</p>	<p>“Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.”</p> <p>This subdivision specifies that a controlled substance is deemed to be a loss if it is unaccounted for after being in the inventory during the previous six-months. This subdivision will ensure that all controlled substances that are unaccounted for are deemed a loss and are reported as such. Reviewing the data for the prior six-month period will also catch counting and mathematical errors that may occur during the inventory process.</p>	<p>“Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, and, if the pharmacist-in-charge or consultant pharmacist determines there has been a loss of these controlled substances, then the losses shall be reported in the manner specified by paragraph 1.”</p>	<p>Suggestions for language clarification</p>
<p>1715.65(f)</p>	<p>“Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.”</p> <p>This subdivision is added to balance the inventory. Once the overages and/or losses have been reported, adjustments are made to the inventory so there is a stock on hand starting point for the next inventory period. This will ensure that each inventory period is looking at three months of data at a time in an effort to quickly</p>	<p>No Comment</p>	

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	determine when drug losses occur.		
1715.65(f)(1)	<p data-bbox="220 280 770 451">"Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date."</p> <p data-bbox="220 483 745 662">This subdivision adds documentation requirements to the stock on hand adjustments. When reviewing the inventory reports, it is necessary to know who made the adjustment and when to hold staff accountable for the inventory.</p>	No Comment	
1715.65(f)(2)	<p data-bbox="220 708 756 789">"The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report."</p> <p data-bbox="220 821 756 1024">As the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that they countersign the adjusted inventory report to ensure they are aware and accountable for the adjustments.</p>	No Comment	
1715.65(f)(3)	<p data-bbox="220 1076 766 1190">"The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years."</p> <p data-bbox="220 1222 772 1393">This subdivision adds the requirement that the inventory will be readily available for review by Board inspectors as defined in B&P section 4105(a). The three year time frame is defined in B&P Section 4105(c) and is maintained in this proposal.</p>	No Comment	
1715.65(g)		Language clarification and change of	

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
		<p>14 to 30 days per title 16, Division 17 section 1715.6, Reporting Drug Loss</p> <p>California regulations currently require pharmacies to report loss associated with pharmacy personnel within 14 days. All other losses are required to be reported to the board within 30 days. ADC's located in hospital or nursing home would be more susceptible to losses associated with nursing or medical personnel, more so than pharmacy personnel. This is because nursing and medical personnel access the machines on a more frequent basis than pharmacists who restock or replenish the supply. The actions of the non-pharmacy personnel are not under the direct supervision of the pharmacist or the pharmacist in charge. It may take greater than 14 days upon discovery of an inappropriate access or removal to perform an appropriate inquiry or investigation. It may be discovered that the access or removal was not actually "inappropriate" and over reporting could occur in an effort to meet the 14 day time period. CHA suggest changing the time frame to 30 days as allowed for an actual irreconcilable loss of controlled drugs as presently in regulations.</p>	
1715.65(h)		Strike," including installation of cameras, relocation of the controlled drugs to a more secure location within	

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		the pharmacy, or daily inventory counts of the drugs where shortages are continuing”, and replace with “take additional steps to improve the security of the controlled substances to prevent losses”. Hospitals need to have flexibility in what resources are used to address narcotic loss.	

Medication Safety Toolkit Manual

Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
Frontice		Emily							
	Title Page	Emily							
	Pubs Page	Emily							
	Intro	BJ/Mary					Build in contents of Jana's text and the Committee Memo		
	Acknowledgments	BJ/Emily							
	Quick Reference Guide	Emily							
1	Medication Guideline Activity Matrix	MS SubCmt		10/29			Revised May 2015		
2	Anticoagulants Guidelines	MS Cmte		10/29			"Anticoagulation Tool for Commonly Used Anticoagulants in the Inpatient Setting - Part 1" (BN)		
							"Anticoagulation Tool for Commonly Used Anticoagulants in the Inpatient Setting - Part 2"	Waiting on updates to Part 2 - may not receive by time of printing	
3	Reducing Controlled Substances Diversion in Hospitals	MS Cmte		10/29			Document dated May 2013		
4	Insulin Recommended Safe Practice Guidelines	MS Cmte		10/29			8/15 (BN)		
5	ED Medication Mgmt Safety Tool	MS Cmte		10/29			Current document dated 2014	Awaiting final updates	
6	Recommendations for Improving Safety of Opioid Use	MS Cmte		10/29			8/15 BN version		
7	Lab Testing Requirements for Medium and Low Risk Sterile Compounding	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
8	Temperature Monitoring Requirements	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
9	Sterile Compounding Frequency of Documentation	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
10	Physical Plant Requirements	Med Safety Cmte and CA Society of Health-System Pharmacists		10/29			PDF Only	Board of Pharmacy Regs still being finalized	
11	SB 1039 Implementation	BJ					Pharm Tech Regulations	To Come from BJ	
	<i>Color Pieces</i>								

Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
	Cover, Back Cover								

FOR MEMBERS

CHA Issues Summary of Discharge Planning Proposed Rule

Register for member call on Dec. 11, 11 a.m. (PT)

NOVEMBER 19, 2015 | PATRICIA BLAISDELL | DEBBY ROGERS, RN, MS, FAEN | ALYSSA KEEFE

CHA has released the attached summary detailing the Centers for Medicare & Medicaid Services (CMS) proposed rule for revising the discharge planning requirements for hospitals, critical access hospitals and home health agencies (HHAs). The summary details provisions of the proposed rule, which includes a requirement that hospitals and HHAs provide specific discharge instructions incorporating the patient's treatment preferences and goals of care to all inpatients and designated outpatients, including observation patients and outpatients undergoing same-day surgery or other procedures that require anesthesia or moderate sedation.

The summary also describes a new requirement, mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act, that all hospitals and HHAs assist patients and caregivers/support persons in selecting a post-acute care provider by using and sharing data on quality and resource use measures for inpatient rehabilitation facilities, long-term care hospitals, skilled-nursing facilities and HHAs.

CHA will host a member call Dec. 11 from 11 a.m. – 12:30 p.m. (PT) to provide an overview of the proposed rule and seek member input for CHA's comments. To register for the call, email Beth Demeter at bdemeter@calhospital.org. Comments on the proposed rule are due Jan. 4.



Medicare and Medicaid Programs: Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals and Home Health Agencies

Summary of Proposed Rule November 2015

The Centers for Medicare & Medicaid Services (CMS) has published in the November 3 *Federal Register* a proposed rule on Medicare and Medicaid requirements for discharge planning for hospitals, including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), critical access hospitals (CAHs) and home health agencies (HHAs). The proposed rule can be found at www.federalregister.gov/articles/2015/11/03/2015-27840/medicare-and-medicaid-programs-revisions-to-requirements-for-discharge-planning-for-hospitals.

CMS issued this proposed rule in order to modernize discharge planning requirements and bring them into closer alignment with current practice, to help improve quality of care and outcomes and to reduce avoidable complications, adverse events and readmissions. **Comments on the proposed rule are due January 4, 2016. CHA will host a members-only call on December 11 from 11:00 a.m. to 12:30 p.m. (PT) to review and discuss the proposed rule, in anticipation of submitting comments.** Members may register by contacting Beth Demeter at bdemeter@calhospital.org or (916) 552-7546. CHA will provide a draft comment letter prior to the comment deadline for use by members. Additional details on submitting comments are noted at the end of this summary.

BACKGROUND

CMS describes the rationale for discharge planning and its role in reducing avoidable hospital readmissions and patient complications. In addition to noting that transitions to post-acute care (PAC) settings and to the home present increased risks to patients, CMS states that hospitals and CAHs need to improve their focus on patients with psychiatric and behavioral health problems, including substance use disorders. CMS also reviews the provisions mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014, including the requirement that hospitals and certain PAC providers account for quality, resource use and other measures in assisting patients and their families during the discharge planning process. Compliance with these requirements will be assessed through on-site surveys by CMS, state survey agencies or accrediting organizations with a CMS-approved accreditation program.

The proposed rule amends 42 CFR 482, 484, and 485, which address requirements for discharge planning in hospitals (including LTCHs and IRFs), home health agencies and critical access hospitals, respectively. A separate proposed rule, “Reform of Requirements for Long Term Care Facilities,” which was published on July 16, 2015, addresses discharge planning requirements for skilled nursing facilities as well as other proposed changes. CHA has submitted comments on that proposed rule on behalf of members; a copy of the letter is available at www.calhospital.org/cha-news-article/cha-issues-comments-snf-conditions-participation-proposed-rule.

HOSPITAL AND CRITICAL ACCESS HOSPITAL DISCHARGE PLANNING

CMS describes hospital discharge planning as “a process that involves determining the appropriate post-hospital discharge destination for the patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination; and beginning the process of meeting the patient’s identified post-discharge needs.” CMS believes that providing more specific requirements for

actions that must be taken by hospitals prior to the patient's discharge or transfer to a PAC setting would lead to improved transitions of care and patient outcomes.

Specific to critical access hospitals, CMS notes that there is no current regulation on discharge planning Conditions of Participation, though CAHs are currently required to arrange for, or refer patients, to needed services that cannot be furnished at the CAH. CMS proposes new standards for CAHs that are similar to those for hospitals.

CMS proposes the following changes and revisions to hospital and CAH discharge planning requirements:

Design

A new proposed standard, "Design," would require the discharge planning process policies and procedures to be: (1) developed with input from the hospital's medical staff, nursing leadership as well as other relevant departments; (2) reviewed and approved by the governing body; and (3) specified in writing.

Applicability

CMS observes that the current discharge planning process requires hospitals to identify patients for whom a discharge plan is necessary, but does not necessarily lead to a discharge plan for all patients. CMS believes that this process results in some patients leaving the hospital without adequate preparation. Under the provisions of the proposed rule, hospitals would be required to provide specific discharge instructions for the following:

- All inpatients,
- Outpatients receiving observation services,
- Outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation is used,
- ED patients identified by the ED practitioner as needing a discharge plan, and
- Any other category of outpatients as recommended by the hospital's medical staff and specified in hospital policies and procedures.

Personnel

CMS would combine and revise two existing requirements to specify that a registered nurse, social worker or other personnel qualified in accordance with the hospital's discharge planning policy, coordinate the discharge needs evaluation and the development of the discharge plan.

Initiation of plan

Under the proposed rule, hospitals would be required to begin identification of the anticipated discharge needs for each applicable patient within 24 hours after admission or registration. The process would be completed prior to discharge home or transfer to another facility and without unduly delaying the patient's discharge or transfer. The same standards would apply if the patient's stay was less than 24 hours. CMS notes that this policy would not apply to emergency-level transfers for patients who require a higher level of care.

Ongoing review

The hospital's discharge planning process would be required to ensure ongoing patient evaluation throughout the patient's hospital stay or visit, so as to identify any changes in the patient's condition that would require modifications to the discharge plan, and would also be required to document any changes

in a patient's condition that would affect the patient's readiness for discharge or transfer in the discharge plan.

Communication with practitioner

The patient's practitioner would be required to be involved in the ongoing process of establishing the patient's goals of care and treatment preference, which inform the discharge plan. CMS proposes that hospitals be required to send a copy of the discharge summary within 48 hours of the patient's discharge, and pending test results within 24 hours of their availability.

Patient's goals of care and treatment preferences

CMS would implement a new requirement that the discharge process address the patient's goals of care and treatment preferences, and that those goals and preferences be taken into account throughout the discharge planning process. The patient and the caregiver/support person(s) would be required to be involved in the development of the discharge plan and informed of the final plan to prepare them for post-hospital care.

Factors to be considered

In developing the discharge plan the hospital would be required to consider several factors, including but not limited to:

- Admitting diagnosis,
- Relevant co-morbidities and medical/ surgical history,
- Anticipated needs post discharge,
- Readmission risk,
- Relevant psychosocial history,
- Communication needs, including language barriers, diminished eyesight and hearing, and self-reported literacy of the patient, patient's representative or caregiver/support person(s), as applicable,
- Patient's access to non-health care services and community-based care providers, and
- Patient's goals and treatment preferences.

CMS proposes that hospitals consider the availability of and patients' access to non-health care services, such as transportation or meal services, and be able to provide additional information on these services. CMS expects hospitals to be well informed of the availability of community-based services and organizations that provide care for patients who are returning home or who want to avoid institutionalization, including aging and disability resource centers, area agencies on aging and centers for independent living. Additionally, CMS encourages hospitals to develop collaborative partnerships with community-based services and organizations and to consider the availability of supportive housing as an alternative to homeless shelters.

Caregiver support

Under the proposed rule, hospitals would be required to consider the patient's or caregiver's capability and availability to provide the necessary post-hospital care. As part of the ongoing discharge planning process, hospitals would identify areas wherein the patient or caregiver would need assistance and address those areas in the discharge plan. The patient and the caregiver/support person(s) would be required to be involved in the development of the discharge plan and informed of the final plan to prepare them for post-hospital care.

For individuals being discharged to home, hospitals would be required to provide discharge instructions to the patient and/or caregiver /support person(s) as well as PAC providers or suppliers, as indicated at the time of discharge. CMS states that as a best practice, hospitals should confirm the patient's or caregiver's understanding of the discharge instructions, and consider the use of "teach-back" when providing discharge instructions.

Hospitals would be required to provide patients and caregivers being discharged to home with written information on warning signs and symptoms that may indicate the need to seek immediate medical attention, and what they should do, including whom they should contact, if those symptoms present.

Medication reconciliation

CMS proposes to require a medication reconciliation process that would include a reconciliation of the patient's discharge medication(s) as well as their pre-hospitalization/visit medication(s), and would require that corrective action be taken to resolve any discrepancies. The medication reconciliation process must be person-centered and incorporate solutions to linguistic, cultural, socio-economic and literacy barriers. For patients being discharged home, the process should also take into consideration how patients will obtain their medications post-discharge.

As part of the medication reconciliation process, CMS encourages practitioners to consider using their state's prescription drug monitoring program (state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients) during the evaluation of a patient's relevant co-morbidities and past medical and surgical history. **CMS is soliciting comments on whether providers should be required to consult with their state's prescription drug monitoring program and use its report to review a patient's risk of non-medical use of controlled substances and substance use disorders.**

The discharge instructions would also be required to include all medications (prescribed and over-the-counter) for use after discharge. The instructions should include name, indication and dosage of each medicine, as well as associated risks and side effects, as appropriate.

Follow-up process

For patients discharged to home, hospitals would be required to establish a post-discharge follow-up process. CMS does not propose a specific mechanism or timing for the follow-up process, but encourages hospitals to use innovative, low-cost post-discharge tools and technologies where health care providers and caregivers can ask simple questions that help identify individuals at risk for readmissions.

Selection of PAC provider

The proposed rule modifies and expands current regulations regarding the patient's selection of a post-acute care provider. Under the proposed rule, hospitals will be required to provide a list of available Medicare-participating IRFs, LTCHs, HHAs or SNFs to patients for whom such services are indicated. (HHAs would have to request to be listed by the hospital as available.) For patients enrolled in managed care organizations, the hospital would be required to make them aware of the need to verify the participation of providers in their plan network and to share information on provider participation in the managed care organization's network, if that information is known. The hospital would be required to document in the patient's medical record that the list was presented to the patient, and to inform the patient or their caregiver/support person(s) of the patient's freedom to choose among providers and to have their expressed wishes respected, whenever possible. As is currently required, the hospital would have to disclose any disclosure of any relevant financial interest in the providers.

CMS notes that CAHs would be expected to support patients as they choose a PAC setting that meets their goals and preferences, while informing them of the benefits of selecting the most appropriate setting to meet their needs, even if the facility is outside their desired location.

The hospital would be required to assist patients, their families or the patient's representative in selecting a PAC provider by using and sharing data on quality and resource use measures for HHA, SNF, IRF or LTCHs. The hospital would have to ensure that the PAC data on quality measures and data on resource use measures were relevant and applicable to the patient's goals of care and treatment preferences. CMS expects that the hospital will document in the medical record that these data were shared with the patient and used to assist the patient during the discharge planning process.

The relevant quality measures, as defined in the IMPACT Act, relate to the following domains: standardized patient assessments, including functional status, cognitive function, skin integrity and medication reconciliation. Resource use measures are defined as including total estimated Medicare spending per individual, discharge to community and measures to reflect all-condition risk-adjusted preventable hospital readmission rates. CMS notes that further definition of these terms will be addressed in forthcoming regulations or other issuances. However, CMS advises providers to use other sources for information on PAC quality and resource use until the measures stipulated in the IMPACT Act are finalized.

Inter-facility transfers

Hospitals would continue to be required to communicate necessary information about patients who are discharged or transferred to another facility. While CMS does not propose to mandate a specific transfer form, certain specified information would have to be provided to a receiving facility. At a minimum, this information must include:

- Demographic information,
- Contact information for the practitioner,
- Contact information for the person's caregiver/support person(s),
- Advance directive, if applicable,
- Course of illness/treatment,
- Procedures,
- Diagnoses, laboratory tests and other specified medically-related information; and
- Patients' goals and treatment preferences, including all other necessary information to ensure a safe and effective transition of care that supports the post-discharge goals of the patient.

CMS notes also its proposed continuation of the existing requirement that this information be provided at the time of the patient's discharge and transfer to the receiving facility. **CMS solicits comment on the proposed medical information requirements.** CMS encourages the use of electronic tools as well as direct communication between the sending and receiving facilities (i.e., clinician-to-clinician).

Assessment of discharge planning process

The hospital would be required to implement an ongoing, periodic review of a representative sample of discharge plans including those patients who were readmitted with 30 days of a previous admission. CMS notes that this evaluation may be incorporated into the Quality Assessment and Performance Improvement process; **CMS solicits comments on making this coordination a requirement.**

HOME HEALTH AGENCY DISCHARGE PLANNING

Current regulations require HHAs to prepare a discharge summary that includes the patient's medical and health status at discharge, include the discharge summary in the patient's clinical record and send the dis-

charge summary to the attending physician upon request. Under the proposed rule, HHAs would be required to develop and implement an effective discharge planning process that focuses on preparing patients to be active partners in post-discharge care, provides an effective transition of the patient from HHA to post-HHA care and reduces factors leading to preventable readmissions.

Discharge planning process

The proposed standards for home health discharge planning align closely with those for hospitals. HHAs would be required to:

- Ensure that the discharge goals, preferences and needs of each patient are identified and result in the development of a discharge plan for each patient.
- Include regular re-evaluation of patients to identify changes that require modification of the discharge plan, and be updated as indicated.
- Involve the physician responsible for the home health plan of care in the ongoing process of establishing the discharge plan.
- Involve the patient and caregiver(s) in the development of the discharge plan and inform them of the final plan.
- Consider caregiver/support person availability and the patient's or caregiver's capability to perform required care.
- For patients transferred to another HHA or discharged to a SNF, IRF or LTCH, the HHA would be required to assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF or LTCH data on quality measures and data on resource use measures.
- CMS would establish a new standard that would require the HHA to send necessary medical information to the receiving facility or health care practitioner, including, at a minimum, the same elements as those specified for hospitals. CMS encourages practitioners to consult with their state prescription drug monitoring program on the associated required medication reconciliation. **CMS asks for comment on whether, as part of the reconciliation process, practitioners should be required to consult with their state's prescription drug monitoring program even if the practitioner is not going to prescribe a controlled substance.**

ANTICIPATED EFFECTS

Effects on providers

CMS notes that its estimates of the effects of the proposed regulations, summarized below, are subject to significant uncertainty. **CMS welcomes comments on its assumptions and estimates.** CMS notes that providers may experience significant additional benefits, such as a reduction in patient readmission and other post-discharge complications. CMS also notes the some portion of entities' costs will be recovered by other third-party payments, as hospitals periodically revise their charges to private insurance carriers, and that can partially offset cost increases for the approximately half of all patients who are "private pay."

Provider	Frequency	Number	Impact (\$ millions)
Hospitals	One-time	4,900	17
	Annually		107
CAHs	One-time	1,328	7
	Annually		6
HHAs	One-time	11,930	34
	Annually		283
First year costs			454

Hospitals

CMS estimates the effects on hospitals to be about one-hundredth of one percent of total hospital expenditures and revenues.

Critical Access Hospitals

CMS estimates that the proposed rule would impose costs for CAHs of about \$4,600 per hospital, which CMS concludes is a small fraction of 1 percent of revenues.

Home Health Agencies

CMS notes that the greatest impact would be on HHAs. CMS estimates that this proposed rule would impose costs for HHAs averaging about \$24,000 per year, or 1.5 percent of total costs.

Effects on patients and Medicare care costs

CMS notes that assessing the impact of the proposed rule on patient and medical costs is difficult, given the multiple ongoing initiatives that may affect the same patients and that these changes represent an overlay on existing requirements. However, CMS also notes that decreasing post-discharge mortality morbidity for even a fraction of the 50 million patients discharged annually from hospitals, CAHs and HHAs would provide significant benefit, and that some research has found that transitional care reduces readmissions. **CMS welcomes comments that would provide evidence about these findings.**

To comment

CHA encourages that comments on the proposed rule be **submitted electronically** at www.regulations.gov. At the site, follow the instructions for “submitting a comment.” CMS must receive comments on the proposed rule by 2 p.m. (PT) on January 4, 2016. CMS requests that comments reference the file code CMS-3317-P.

For additional information

For questions or to provide input for the CHA comment letter, please contact Patricia Blaisdell, CHA vice president, continuum of care, at (916) 552-7553 or pblaisdell@calhospital.org, Alyssa Keefe, CHA vice president, federal regulatory affairs, at (202) 488-4688 or akeefe@calhospital.org, or Debby Rogers, CHA vice president, clinical performance and transformation, at (916) 552-7575 or drogers@calhospital.org.



**CALIFORNIA
HOSPITAL
ASSOCIATION**

*Providing Leadership in
Health Policy and Advocacy*

December 21, 2015

Gina McCarthy
Administrator
Environmental Protection Agency
Attn: Office of Resource Conservation and Recovery (5304P)
1200 Pennsylvania Avenue NW
Washington, DC 20460

Subject: Management Standards for Hazardous Waste Pharmaceuticals, EPA–HQ–RCRA–2007–0932

Dear Administrator McCarthy:

On behalf of our nearly 400 member hospital and health systems, the California Hospital Association (CHA) is pleased to submit comments on the federal Environmental Protection Agency (EPA) Management Standards for Hazardous Waste: Pharmaceuticals proposed rule issued September 25. The proposed rule establishes sector-specific regulations for the management of hazardous waste pharmaceuticals by health care facilities, including hospitals, clinics, retail pharmacies and reverse distributors. CHA appreciates EPA's commitment to addressing stakeholder concerns raised in previous rulemaking and revisiting this important topic. Moreover, CHA appreciates the additional 30 days provided to vet these proposals with member hospitals and health systems and respond to the agency with our comments.

CHA is generally supportive of the proposed sector-specific requirements that further clarify current regulation and address gaps in the intersection between EPA and Drug Enforcement Administration regulation. During the comment period, CHA convened a workgroup of health care facilities experts to review and analyze the proposed rule. In doing so, CHA spent considerable time considering existing state law and regulation issued by the California Department of Toxic Substance Control and the California Department of Public Health Medical Waste Management Program. CHA also conducted a survey of the workgroup to solicit input and feedback on operational challenges presented by the current polices, if any.

Currently, the California Department of Toxic Substance Control enforces federal Resource Conservation and Recovery Act (RCRA) requirements, as well as California hazardous waste requirements. Non-RCRA pharmaceutical waste, however, is enforced by the California Department of Public Health Medical Waste Management Program. **While CHA is supportive of the direction and policies set forth in the proposed rule, we are concerned about the interpretation and application of the policies in California — in particular how the two regulatory agencies will proceed in application, review and enforcement. CHA is concerned that without additional time for implementation, hospitals will be unable to comply.**

Understanding the complexities and overlap between federal and state law in California is particularly challenging for hospitals, health systems and other health care facilities. The complexity lies in having two state agencies with oversight responsibilities introducing the opportunity for inconsistent interpretation and application. This is further complicated with additional review by the California

Department of Public Health Center for Health Care Quality that has oversight for survey and certification.

While CHA has reached out to state oversight agencies to offer our assistance in reviewing and responding to this rule, we believe EPA should provide additional resources to state agencies to ensure shared understanding of these new regulations. We also believe EPA should provide technical assistance to state agencies, ensuring that both state and federal regulations can be complied with in an efficient manner. In addition, we believe EPA is well positioned to assist state agencies in developing resources to help educate hospitals and other health care facilities about how best to operationalize these new requirements within the framework of existing state law and regulation. **CHA urges EPA to develop technical assistance for states to smooth operational implementation. In addition, we believe EPA should work with the Centers for Medicare & Medicaid Services to ensure understanding of these rules in the context of the Medicare Conditions of Participation for hospitals. Education of hospital surveyors will be necessary at the federal and state level.**

Most importantly, CHA urges EPA to delay the effective date of the final rule to no earlier than one year from its release. CHA believes that state agencies need additional time prior to the effective date of the final rule to both understand the opportunities and challenges these new policies present, and develop resources to educate hospitals and health care facilities on compliance.

CHA is committed to working with our state agencies, but believes that, in light of the scope of these regulations and a myriad of state regulations, additional time is needed. Hospitals and other health care facilities will need time to understand the new requirements and then develop policies and procedures to ensure operational compliance. Hospitals will also need to determine the impact on existing waste disposal programs. For example, the final rule may affect contracts with waste haulers for medical waste (California) and hazardous waste. Contracts may need to be restructured, especially those based on minimal pick-up volumes for certain waste streams or those involving single and/or multiple company(ies) that pick up medical, chemical and pharmaceutical waste. Also, some waste vendors provide reusable waste containers for non-RCRA pharmaceutical waste disposal in California. Hospitals in California will need time to evaluate how to best manage their RCRA waste and what container management solutions existing waste vendors can provide for hospitals in California. In addition, such a program change will require time and resources to train thousands of health care workers to implement these new standards, including frontline health care workers and pharmacists if point-of-generation segregation and containerization practices are affected. In these times of health care systems that include multiple hospitals with numerous community clinics and practices, developing standardized training resources and curricula is an arduous, time consuming task. Time will be needed for hospitals to review their existing hazardous waste program and the new sector based rule to determine which hazardous waste management method best works for their operations and file updated notification of hazardous waste activities with EPA and Cal EPA.

California hospitals have a long history of working with state and federal environmental regulators and are good stewards in managing their various waste streams. **Hospitals are committed to compliance and to improving the protection of our environment; however, additional time is needed, by both state agencies and healthcare facilities, to ensure we do this efficiently and within the framework of existing state law.** CHA appreciates the opportunity to comment on these proposed rules. If you have any questions, please do not hesitate to contact Cheri Hummel, vice president emergency management and facilities, at chummel@calhospital.org or (916) 552-7681, or me at akeefe@calhospital.org or (202) 488-4688.

Sincerely,

/s/

Alyssa Keefe

Vice President Federal Regulatory Affairs

EPA Issues Proposed Rules Regarding Hazardous Waste at Health Care Facilities

NOVEMBER 2, 2015 | [ALYSSA KEEFE](#) | [CHERI HUMMEL](#)

The U.S. Environmental Protection Agency (EPA) has issued the attached proposed rules regarding hazardous waste generators and the disposal of pharmaceuticals. The hazardous waste generator improvement proposed rule is intended to enhance the safety of facilities, employees and the general public by improving hazardous waste labeling, as well as emergency planning and preparedness. The EPA states the proposed rule would simplify current federal regulations and provide greater flexibility in how facilities and employees manage their hazardous waste. In addition, the proposed hazardous waste pharmaceuticals rule would prohibit health care facilities from flushing hazardous waste pharmaceuticals down sinks and toilets. The EPA notes that the rule is intended to reduce the burden on health care workers and pharmacists working in health care facilities by creating regulations specific to these facilities, including hospitals, clinics, and retail stores with pharmacies and reverse distributors that generate hazardous waste.

CHA is currently reviewing the proposed rules in the context of current state regulations, which are often far more narrow than federal regulation, and will convene a workgroup to assess the impact on hospitals and other California health care facilities. At the request of CHA and other stakeholders, EPA recently extended its deadline to Dec. 24 for comments on the proposed rule.



FEDERAL REGISTER

Vol. 80

Friday,

No. 186

September 25, 2015

Part II

Environmental Protection Agency

40 CFR Parts 260, 261, 262, et al.

Hazardous Waste Generator Improve; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 262, 263, 264, 265, 268, 270, 273, and 279

[EPA-HQ-RCRA-2012-0121; FRL 9924-07-OSWER]

RIN 2050-AG70

Hazardous Waste Generator Improvements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is proposing to revise the hazardous waste generator regulations under the Resource Conservation and Recovery Act (RCRA) to improve compliance and thereby enhance protection of human health and the environment. Specifically, EPA proposes to revise certain components of the hazardous waste generator regulatory program; address gaps in the regulations; provide greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; reorganize the hazardous waste generator regulations to make them more user-friendly and thus improve their usability by the regulated community; and make technical corrections and conforming changes to address inadvertent errors, remove obsolete references to programs that no longer exist, and improve the readability of the regulations.

These proposed changes are both a result of EPA's experience in implementing and evaluating the hazardous waste generator program over the last 30 years, as well as a response to concerns and issues identified by the states and regulated community.

DATES: Comments must be received on or before November 24, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2012-0121, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and

should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Jim O'Leary, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304P), 1200 Pennsylvania Ave. NW., Washington, DC 20460, (703) 308-8827, (oleary.jim@epa.gov) or Kathy Lett, U.S. Environmental Protection Agency, Office of Resource Conservation and Recovery, (MC: 5304P), 1200 Pennsylvania Ave. NW., Washington, DC 20460, (703) 605-0761, (lett.kathy@epa.gov).

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

Entities potentially affected by this action include between 353,000 and 543,000 industrial entities that generate hazardous waste regulated under the RCRA Subtitle C regulations. Of this universe, between 293,000 and 470,000 are conditionally exempt small quantity generators (CESQGs) that will only be affected if they choose to take advantage of two voluntary programs being proposed. Entities potentially affected by this proposed rule include practically every industrial sector, including printing, petroleum refining, chemical manufacturing, plastics and resin manufacturing, pharmaceutical manufacturing, paint and coatings, iron and steelmaking, secondary smelting and refining, metal manufacturing, electroplating, circuit board manufacturing, and automobile manufacturing, among other industries.

As discussed in section XVIII, the Regulatory Impact Analysis (RIA) for this action, available in the docket for this action, estimates the future annualized cost to industry to comply with the proposed requirements is between \$6.2 and \$17.4 million (at a 7% discount rate). The annualized benefits for entities opting to take advantage of two voluntary programs in the proposed rule (*e.g.*, consolidation of CESQG waste by large quantity generators (LQGs) under the same ownership, and generators who change regulatory status episodically) is between \$6.2 and \$12.2 million (at a 7% discount rate) resulting

in a net annualized cost of between \$0.1 million and \$5.2 million.

The proposed Hazardous Waste Generator Improvements Rule is expected to yield a variety of benefits as generators change several of their waste management practices to comply with the proposed regulations. These benefits reflect the rule's focus on enhancing protection of human health and the environment while improving the efficiency of the RCRA hazardous waste generator standards. Ideally, the Agency would prefer to quantify and monetize the rule's total benefits. However, only some categories of benefits are quantifiable. For the majority of benefits, sufficient data are not available to support a detailed quantitative analysis. For example, the added flexibility from allowing a large quantity generator accumulating ignitable or reactive hazardous waste to obtain a waiver from the local fire department for 50-foot property line requirement at 40 CFR 265.176 (provided other safety requirements are met) is difficult to quantify. In addition, quantifying the benefits associated with emergency response due to changes in container labeling would require data on the annual number of emergencies at generator sites, the current risks associated with these incidents, the extent to which more detailed labeling would affect the procedures of emergency responders, and the reduction in risk associated with these changes. Detailed data on these items are not readily available. In this and in similar cases, the benefits are described qualitatively.

B. Incorporation by Reference (IBR)

This action is not proposing to add any new IBR material, however, we are proposing to reorganize one of the existing requirements containing IBR material to make the regulation easier for the reader to follow. We are proposing to copy § 265.201(g)(2) to § 262.16(b)(3)(vii)(B). To accommodate this change, we are proposing to update § 260.11(d)(1), which is the IBR reference section for these regulations, by adding a reference to § 262.16. The materials for which we are seeking incorporation by reference are for the NFPA 30 standard, Flammable and Combustible Liquids Code, and are available for inspection at the ANSI Incorporation by Reference (IBR) Portal, <http://ibr.ansi.org>. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. (For ordering information, call toll-free 1-800-344-3555.)

II. Statutory Authority

These regulations are proposed under the authority of sections 2002, 3001, 3002, 3003, 3004, 3007, and 3010 of the Solid Waste Disposal Act of 1965, as amended by the Resource Conservation and Recovery Act of 1976 (RCRA), as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924. This statute is commonly referred to as "RCRA."

III. What is the intent of this proposal?

EPA is proposing to revise the hazardous waste generator regulations under RCRA to improve compliance by the regulated community and support the efficient implementation of the hazardous waste generator regulations by EPA and the states and, thereby enhance protection of human health and the environment. Specifically, EPA proposes to (1) revise certain components of the hazardous waste generator regulatory program, primarily at 40 CFR 261.5 and 40 CFR part 262; (2) address identified gaps in the regulations; (3) provide greater flexibility for hazardous waste generators to manage their hazardous waste in a cost-effective and protective manner; (4) reorganize the hazardous waste generator regulations to make them more user-friendly and thus improve their usability by the regulated community; and (5) make technical corrections and conforming changes to address inadvertent errors, remove obsolete programs, and improve the readability of the regulations.

These proposed changes are a result of EPA's experience in implementing and evaluating the hazardous waste generator program over the last 30 years, as well as a response to concerns and issues identified by the states and regulated community.

The hazardous waste generator regulatory program was originally promulgated in 1980. Over the course of the last 30 plus years, the Agency, through experience with implementing the program, and in various meetings, correspondence, and discussions with the states and the regulated community, has become aware of ambiguities, inconsistencies, gaps, and a lack of flexibility in the regulations, which, if revised, could result in a program that is more effective in protecting human health and the environment. Many of these problems were identified in a 2004 program evaluation of the hazardous waste generator program conducted by EPA.¹ In 2013, a separate

EPA program evaluation addressing hazardous waste determinations also identified a number of problems related to generators being able to make a proper hazardous waste determination.² Several of the proposed provisions are also responsive to the 2014 Notice of Data Availability that EPA issued on the retail sector asking for comment on hazardous waste management practices in that sector and on challenges they face in complying with RCRA (79 FR 8926, February 14, 2014).

Many of the changes in this proposal are revisions to existing rules designed to improve generator compliance without any increase in burden. For example, the Agency has inconsistently addressed the situation where a generator generates both acute and non-acute hazardous waste in a calendar month. This inconsistency has resulted in uncertainty for the generator regarding what generator category, and thus which regulatory provisions, would apply during that calendar month. This proposal addresses the problem. The Agency is also proposing to replace the phrase "conditionally exempt small quantity generator" (CESQG) with the phrase "very small quantity generator" (VSQG) so as to be consistent with the other two generator categories—large quantity generators (LQGs) and small quantity generators (SQGs).

Another area of the program that needs revision is the closure regulations for hazardous waste generators under § 262.34(a)(1). The regulations do not expressly specify whether closure provisions apply to generators accumulating hazardous waste in containment buildings only or also to hazardous waste accumulated in containers, tanks and on drip pads. This notice proposes to revise the closure provisions to address these and other concerns.

The Agency is also proposing changes to improve flexibility for generators of hazardous wastes. One example is the proposal to enhance flexibility by allowing conditionally exempt small quantity generators (CESQGs) to send hazardous waste to an LQG that is under the control of the same person, provided certain conditions are met. Numerous situations exist in industry, government, and academia where an organization with satellite locations that qualify as CESQGs could take advantage of this provision in order to consolidate and

manage the hazardous waste in an environmentally sound manner. In addition, this proposal addresses the concern that some generators, such as generators located in urban environments, may find it difficult to meet the independent requirement that containers holding ignitable or reactive waste must be placed 15 meters (50 feet) from the site's property line. To build in flexibility, while maintaining protection of human health and the environment, we are proposing to allow generators to apply for a waiver from this requirement from their local fire department or emergency response organization, and if approved, maintain documentation of that agreement.

The Agency is also proposing to reorganize the hazardous waste generator regulations to make them more user-friendly for various stakeholders. For example, the current CESQG regulations are found at § 261.5, while the regulations for SQGs and LQGs are found in 40 CFR part 262. For convenience and ease of use, the Agency is proposing to move all the generator regulations into 40 CFR part 262. As a result of this reorganization, EPA is proposing to make a number of conforming changes to other parts of the regulations that cite particular sections of the part 262 regulations.

Lastly, the Agency is proposing to make several technical corrections that address inadvertent errors in the regulations, obsolete programs, and outdated citations.

IV. What is the scope of this proposal?

EPA is proposing to revise the hazardous waste generator regulations, primarily at 40 CFR 261.5 and throughout 40 CFR part 262. The Agency is also proposing some changes to parts 260, 263, 264, 265, 268, 270, 273, and 279 mostly for the purposes of maintaining consistency with the proposed changes in part 262.

The preamble discussion of these proposed changes is organized by where the existing regulations currently appear in the Code of Federal Regulations (CFR). The preamble to this proposed rule first addresses changes to the substance of the existing generator provisions, as well as a number of related changes (sections VI through XII). These proposed revisions are discussed using existing regulatory citations to make the discussion easier to understand by those already familiar with the hazardous waste generator regulations. In the cases where the Agency is proposing to revise a regulation and is also proposing to move it as part of the reorganization, the new citation for the provision in the

¹ Summary of Hazardous Waste Generator Regulatory Program Evaluation, November 2004.

See also public comments in Docket ID No. EPA-HQ-RCRA-2003-0014.

² Hazardous Waste Determination Program Evaluation, IEC, April 2013. <http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf>.

proposed regulatory text is provided at the end of that section of preamble discussion.

Following those sections, a discussion of the proposed reorganization of the hazardous waste generator regulations is presented (section XIII), including where the existing regulatory sections would be located in the proposed reorganization. As part of this discussion, we have provided a crosswalk table that compares where a particular regulatory section is currently in the regulations and where it would appear under the proposed reorganization.

Finally, a number of technical corrections are discussed (section XIV).

A. Proposed Revisions to 40 CFR Part 260—Hazardous Waste Management System: General

EPA is proposing to revise the definition of “small quantity generator” and add definitions for the other two generator categories as well as a definition for “central accumulation area” in § 260.10. In addition, we propose to change the name of the “conditionally exempt small quantity generator” category to “very small quantity generator” or VSQG.³ These proposed changes are discussed in section VI of this preamble.

B. Proposed Revisions to 40 CFR Part 261—Identification and Listing of Hazardous Waste

EPA is proposing four changes to the regulations currently in 40 CFR part 261. First, EPA is proposing to add a new provision that would explain what generator category would apply to a generator that generates both acute and non-acute hazardous waste in the same calendar month. Second, the Agency is proposing to revise the regulations at §§ 261.5(h) and (i) and 261.3 that address the mixing of a non-hazardous waste with a hazardous waste. Third, to make waste management more efficient in some cases and improve environmental protection, the Agency is proposing to amend § 261.5(f)(3) and (g)(3) to allow CESQGs to send their hazardous waste to LQGs that are operated under control of the same person. Under this proposal, a CESQG that wants to take advantage of this provision would need to comply with the proposed requirements. Finally, the Agency is proposing to amend § 261.6(c)

³ Despite this proposed change, in the preamble, EPA will continue refer to this category as CESQGs to make it easier to follow the other changes to the generator being proposed. We will use the term “VSQG” when directly quoting proposed regulatory text. This change is discussed fully in section VI of this preamble.

to require biennial reporting for owners or operators of facilities that recycle but do not store hazardous waste before the recycling.

These proposed changes are discussed in section VII of this preamble.

C. Proposed Revisions to 40 CFR Part 262—Standards Applicable to Generators of Hazardous Waste

EPA is proposing a number of changes to the regulations for generators of hazardous waste at 40 CFR part 262 to improve the understanding of the RCRA generator regulations in order to encourage increased compliance by the regulated community. These proposed changes include the following:

- Revising the scope and applicability section to distinguish between independent requirements and conditions for exemption for generators of hazardous waste.
- Revising the regulations for making hazardous waste determinations;
- Requiring re-notification by SQGs and LQGs;
- Revising the regulations for labeling and marking of containers, tanks, drip pads, and containment buildings when accumulating hazardous wastes;
- Revising the closure provisions for LQGs;
- Updating the preparedness, prevention, planning and emergency procedures provisions for SQGs and LQGs;
- Revising the provisions for satellite accumulation areas (SAA) for SQGs and LQGs;
- Revising the SQG regulations for accumulating hazardous waste on drip pads;
- Deleting obsolete regulations that refer to the Performance Track program;
- Revising the biennial reporting provisions for LQGs;
- Adding a provision that hazardous waste generators are prohibited from disposing liquid hazardous waste in landfills.

These proposed changes to the generator regulations in part 262 are discussed in section VIII of this preamble.

D. Proposed Addition to 40 CFR Part 262 for Generators That Temporarily Change Generator Category as a Result of an Episodic Event

To provide greater program flexibility, EPA is proposing to allow a CESQG or an SQG to maintain its existing generator category in the event of either a planned or unplanned episodic event in which the CESQG or SQG generates a quantity of hazardous waste in a calendar month that would otherwise bump the CESQG or SQG into a more

stringent generator regulatory category (e.g., CESQG to either an SQG or an LQG, or alternatively an SQG to an LQG), provided certain conditions are met. Because these events would be temporary and episodic in nature, the generator would only be allowed to take advantage of this provision once every calendar year. Generators may also petition EPA or the authorized state to request permission to initiate a second episodic event during a calendar year.

This proposed addition to the regulations is discussed in section IX of this preamble.

E. Proposed Revisions to 40 CFR Part 263—Standards Applicable to Transporters of Hazardous Waste

To improve environmental protection, EPA is proposing to revise the marking and labeling standards for transporters to be consistent with the proposed marking and labeling standards for containers for SQGs, LQGs, and satellite accumulation areas elsewhere in this proposal.

These proposed changes are discussed in section X of this preamble.

F. Proposed Revisions to 40 CFR Parts 264 and 265—Standards for Owners and Operators of Hazardous Waste TSDFs and Interim Status Standards for Owners and Operators of Hazardous Waste TSDFs

The Agency is proposing modifications to the biennial reporting provisions in 40 CFR parts 264 and 265 to specifically include facilities receiving hazardous wastes without a permit, such as reclaimers that do not store incoming materials and reclaimers operating under a variance. EPA is also proposing to modify the special conditions for ignitable and reactive wastes at § 265.176 to allow LQGs to apply for a waiver from their local fire departments if they are unable to meet the condition that hazardous waste be stored at least 15 meters (50 feet) from the site's boundary.

These proposed changes are discussed in section XI of this preamble.

G. Proposed Revisions to 40 CFR Part 268—Land Disposal Restrictions

EPA is proposing to revise the marking and labeling requirements at § 268.50 to be consistent with the proposed marking and labeling standards for containers at SQGs, LQGs, and satellite accumulation areas elsewhere in this proposal. These proposed changes are discussed in section XII of this preamble.

H. Proposed Reorganization of Hazardous Waste Generator Regulations

In addition to the proposed program changes outlined in this notice, EPA is proposing to reorganize the regulations for hazardous waste generators to consolidate most of the generator regulations into 40 CFR part 262 and reduce cross-referencing where possible. EPA believes this reorganization will assist CESQGs, SQGs, and LQGs in understanding their regulatory responsibilities.

The reorganization is discussed after completion of the other proposed changes in this proposal so that readers can more easily compare the existing regulatory framework with this proposal.

The reorganization is discussed in section XIII of this preamble.

I. Technical Corrections and Conforming Changes to 40 CFR Parts 260 Through 265, 270, 273, and 279

The Agency is proposing a number of technical corrections and conforming changes to correct existing errors in the hazardous waste generator regulations, as well as in other areas of the hazardous waste regulations, such as typographical mistakes, incorrect or outdated citations, and omissions of text. In addition, EPA is proposing technical changes to address the impacts of reorganizing the hazardous waste regulations.

These changes are discussed in section XIV of this preamble.

J. Request for Comment on Use of Electronic Tools To Streamline Hazardous Waste Reporting and Recordkeeping Requirements

As part of this proposed rule, the Agency is also exploring the feasibility of using electronic tools to streamline the hazardous waste recordkeeping and reporting requirements. EPA requests comment on the usefulness of such tools to help the regulated community comply with the recordkeeping and reporting requirements in the RCRA hazardous waste regulations.

This request for comment is discussed in section XV of this preamble.

V. Background

A. History of the Hazardous Waste Generator Program

As originally promulgated in 1980, the basic regulatory framework for hazardous waste generators consisted of two categories: Small quantity generators (SQGs) and large quantity generators (LQGs). Since then, there have been three major changes. First, as a result of the Hazardous and Solid

Waste Amendments (HSWA) of 1984, a rule was promulgated that created a third generator category by splitting the SQG category in two and creating conditionally exempt small quantity generators (CESQGs). (51 FR 10146, March 24, 1986).⁴

Second, also as a result of HSWA, the Land Disposal Restriction (LDRs) regulations required hazardous waste generators to ensure that their hazardous waste either met a specified treatment standard or performance standard, or, if not, was treated to specified concentrations or performance standards prior to land disposal.⁵

Third, the Agency modified the Uniform Hazardous Waste Manifest regulations and associated manifest document used to track hazardous waste from a generator's site to its ultimate disposition (70 FR 10776, March 4, 2005; 70 FR 35034, June 16, 2005). The revisions to the Uniform Hazardous Waste Manifest standardized the content and appearance of the manifest form, made the forms available from a greater number of sources, and adopted new procedures for tracking certain types of hazardous waste shipments with the manifest. Otherwise, the changes that have occurred to the hazardous waste generator regulatory program have been, for the most part, relatively minor.

B. The Current Hazardous Waste Generator Regulations

1. Determining Generator Category

The hazardous waste generator regulatory program is structured around the quantity of hazardous waste a person (or generator) generates in a calendar month (by site). The quantity of hazardous waste generated determines a generator's category for the month, which in turn determines what requirements are applicable to the generator (including determining how the generator can qualify for an exemption from other regulations, such as having to get a storage permit).

The three generator categories—LQG, SQG, and CESQG—are based on the quantities of acute and non-acute hazardous waste generated by the generator.

For non-acute hazardous waste, the thresholds are as follows:

—LQGs generate 1,000 kilograms or greater of hazardous waste in a calendar month.

—SQGs generate greater than 100 kilograms but less than 1,000 kilograms

of hazardous waste in a calendar month; and

—CESQGs generate no more than 100 kilograms of hazardous wastes in a calendar month.

For acute hazardous waste, the regulations at 40 CFR 261.5(e) state that if a generator generates acute hazardous waste in a calendar month in quantities greater than a total of one kilogram of acute hazardous waste listed in § 261.31 or 261.33(e) or a total of 100 kilograms of any residue or contaminated soil, waste, or other debris resulting from the cleanup of a spill of any acute hazardous waste listed in § 261.31 or 261.33(e), then all quantities of that acute hazardous waste are subject to the full set of LQG requirements.⁶

In order to determine what requirements are applicable, a generator must first identify all the hazardous waste it generates subject to regulation using the four-step process below:

1. Determine whether the material is a solid waste subject to RCRA regulations at § 261.2;

2. If the material is a solid waste, then determine whether the solid waste is specifically excluded from regulation by examining the exclusions at § 261.4(a) and (b);

3. If not excluded, then determine whether the solid waste is a hazardous waste at § 262.11; and

4. If the material is a hazardous waste, then determine whether it is exempt from being counted towards its generator category by reviewing the exemptions at § 261.5(c) and (d).

Once that is completed, the generator must count the amount of regulated hazardous waste generated during the calendar month to determine its generator category.

Once a generator determines its generator category for the month, it then must manage the hazardous waste it generates and accumulates in a manner that complies with specified requirements, including requirements that qualify the generator for an exemption from having to obtain a permit.⁷ Therefore, determining a generator's category is essential to

⁶ One of the technical corrections EPA is proposing with this rulemaking is to replace the word "waste" in this definition with the word "water." This would return the definition to what it read before it was changed, we believe accidentally, in 1985. See section XIV of this preamble for a discussion of the proposed technical corrections.

⁷ Note that the exemptions provided by the regulations are not just for a permit exemption. The exemption is also from RCRA section 3004(a)(1)–(6) regulations; *i.e.*, the regulations in 262 and 264, 267, etc.

⁴ Known as the Small Quantity Generator rule.

⁵ Land Disposal Restrictions, <http://www.epa.gov/osw/hazard/tsd/ldr/index.htm>.

determining the part 262 requirements a generator must comply with.

2. Types of Generator Standards: Requirements and Conditions

When RCRA was enacted in 1976, the law did not explicitly address whether a permit would be required for generators accumulating hazardous wastes. However, it was clear in the legislative history of RCRA that Congress did not want to interfere with commerce and impose permitting requirements on every generator who accumulated hazardous wastes. Therefore, Congress deferred to EPA in how it would reconcile this issue. When EPA developed the regulations applicable to generators, it established two types of requirements for them: (1) Independent requirements that would apply to generators regardless of whether or not they choose to obtain an exemption from the permit requirement and from other applicable requirements (“independent requirements”); and (2) requirements to meet in order to achieve the specific purpose of obtaining such an exemption from permitting and from other applicable requirements (“conditions for exemption”).

An “independent requirement” in the context of the RCRA hazardous waste generator regulations is an unqualified standard. For example, the requirements of 40 CFR part 262 subpart D (Recordkeeping and Reporting), and the requirements in §§ 262.30 through 262.33, are among the independent requirements applicable to generators. If a generator violates an independent requirement, it may be subject to an enforcement action under section 3008 of RCRA. Unlike conditions for an exemption, independent requirements have no direct relationship to the option of obtaining or maintaining an exemption from certain RCRA regulations.⁸

A “condition for exemption,” on the other hand, is a prerequisite that is necessary to occur or be met in order for something else to take legal effect. Thus, in the context of the RCRA hazardous waste generator regulations, a RCRA “condition for exemption” is a requirement that a generator must comply with in order to obtain or maintain an exemption from RCRA permitting requirements in part 270 and the requirements in part 264 or part 265. For example, a conditionally exempt small quantity generators (CESQGs)

must meet a condition for exemption in order for its hazardous waste to be exempt from the requirements in parts 124, 262 through 266, 268, or 270, or from any requirement for notification under section 3010 of RCRA for its hazardous waste. A CESQG that fails to meet all of the conditions for an exemption for CESQGs in § 261.5 would now be subject to all these requirements.

The conditions for exemption available to large and small quantity generators are found in the current regulations at § 262.34.⁹ Should a small quantity generator or large quantity generator fail to meet all the conditions for an exemption, it would not only be subject to having to obtain a permit under part 270 but also to the requirements in part 264 or part 265.

As stated above, complying with the conditions for exemption is not required because it is not mandatory for a generator to obtain and maintain an exemption from RCRA permitting requirements. Instead, when a generator does not comply with a certain condition or conditions for exemption, the consequence is that the generator either fails to obtain—or loses—the exemption from the RCRA permitting requirements (unless it has complied with all of the conditions for a different applicable exemption from those requirements). This means that, because there is no exemption, permitting requirements become applicable to the generator for the same time period that the generator is out of compliance with the conditions for exemption.

3. Types of Conditional Exemptions

The current RCRA regulations afford generators two types of conditional exemptions: (1) An exemption from most of the 40 CFR part 262 requirements, available to farmers and to CESQGs, and (2) an exemption from 40 CFR parts 124, 264 through 268, 270, and 279 requirements, and from the notification requirements of section 3010 of RCRA, available to SQGs and LQGs that accumulate hazardous waste.

The first conditional exemption is available only to farmers and CESQGs. With respect to farmers, this conditional exemption is found in part 262 subpart G and is limited to waste pesticides that are RCRA hazardous wastes that the farmer generates, provided the farmer triple rinses each emptied pesticide container in accordance with § 261.7(b)(3) and disposes of the pesticide residues on his own farm in a

manner consistent with the disposal instructions on the pesticide label. This exemption from part 262 relieves farmers and CESQGs from the requirements related specifically to the generation, management, and transportation of hazardous wastes provided such waste meets certain conditions, including that the waste is treated or disposed of on site or is delivered to an off-site treatment, storage, or disposal facility which is located in the United States and is one of seven specified types of facilities. Provided the farmer and/or CESQG meets these conditions, they are not subject to the 40 CFR part 262, as well as other hazardous waste management requirements.

The second type of conditional exemption relieves generators that accumulate hazardous waste from the permitting and other requirements applicable to treatment, storage, and disposal facilities and makes temporary accumulation of hazardous waste possible for generators and is found in § 262.34. In EPA’s experience, virtually every generator accumulates or stores its hazardous waste on site for some period before sending it to either an on-site or off-site permitted or interim status treatment storage or disposal facility (TSDF) or other RCRA-authorized disposal site. However, provided the generator meets the conditions in this exemption, they would not be subject to the permitting requirements and operations requirements applicable to a hazardous waste management facility for storage, or a “storage facility.”¹⁰

The generator regulations in part 262, therefore, are made up of both independent requirements and conditions for exemptions. All generators are subject to at least one requirement in part 262 (*i.e.*, making a hazardous waste determination); however, the total number of part 262 requirements applicable to a generator depends on the total quantity of hazardous waste it generates each calendar month and therefore what generator category it is for that month. All generators can choose the extent of their regulation under RCRA by either meeting, or failing to meet, all of the conditions for an exemption from regulation as a storage facility.

Of all the generators, LGQs are subject to the most independent requirements. The current regulations at § 262.34(a) are quite clear for LQGs where they state that a generator may accumulate hazardous waste on-site for 90 days or less without a permit or without having

⁸ EPA is proposing to make the distinction between “independent requirement” and “condition for exemption” more clear by placing definitions of these terms in the regulations at § 262.1. See section VIII.A.1 for additional discussion.

⁹ Under this proposed rule these conditions for exemption would be moved to proposed sections §§ 262.14 through 262.17.

¹⁰ See 40 CFR 270.2 (“hazardous waste management facility”).

interim status, provided that it meets the listed conditions for the exemption. These conditions relate to the technical requirements for containers, tanks, drip pads, and containment buildings, in addition to marking and labeling of containers, closure, personnel training, emergency response procedures, and contingency planning. In effect, should an LQG not meet any one of these conditions, it would be operating illegally without a permit. The same regulatory framework applies to CESQGs and SQGs, but with different conditions.

SQGs have fewer independent requirements and conditions for exemption than LQGs. In particular, SQGs have longer accumulation time limits than LQGs (up to 180 days, or 270 days, if the hazardous waste is shipped greater than 200 miles) and have fewer regulations related to personnel training, contingency planning, and emergency response procedures. SQGs

also do not have to submit biennial reports. However, like LQGs, SQGs must obtain an EPA ID number, meet the technical standards for containers and tanks, comply with manifesting regulations, and send their hazardous waste to a RCRA permitted hazardous waste TSDF. In addition, SQGs may not accumulate more than 6,000 kilograms of hazardous waste at any one time.

CESQGs have very few conditions. Specifically, in order for CESQGs to be excluded from 40 CFR parts 124, 262 through 266, 268, and 270 and the notification requirements of section 3010 of RCRA, they must (1) make correct hazardous waste determinations;¹¹ (2) accumulate no more than 1,000 kilograms of hazardous waste at any one time or accumulate no more than the quantities of acute hazardous wastes set forth in § 261.5(e)(1) or (2) at any one time; and (3) send hazardous waste to one of seven specified types of facilities

described in §§ 261.5(e)(3) and 261.5(g)(3).¹² All other regulations applicable to LQGs and SQGs are not applicable to CESQGs that comply with these conditions.

Table 1—Summary of Generator Regulations provides a summary of requirements that represent conditions for an exemption for CESQGs, SQGs and LQGs. As noted in the table, the category “Conditions for Exemption” applies to such requirements as the quantity generated and accumulated, accumulation time, the technical standards for containers, tanks, drip pads and containment buildings, marking and labeling, personnel training, contingency planning and emergency procedures. It is important to note that a waste determination is an independent requirement for SQGs and LQGs, whereas it is a condition for exemption for CESQGs as defined at § 261.5(f)(1) and (g)(1).¹³

TABLE 1—SUMMARY OF GENERATOR REGULATIONS

	CESQGs	SQGs	LQGs
Generator Category	≤100 kg/month ≤1 kg/month of acute hazardous waste. ≤100 kg/month of acute spill residue or soil. §§ 261.5(a) and (e)	>100 and <1,000 kg/month ≤1 kg/month of acute hazardous waste. ≤100 kg/month of acute spill residue or soil. §§ 262.34(d) and 261.5(e)	≥1,000 kg/month >1 kg/month of acute hazardous waste >100 kg/month of acute spill residue or soil §§ 262.34(a) and 261.5(e).
Conditions for Exemption			
Hazardous Waste Determination.	§ 262.11	N/A	N/A.
On-Site Accumulation Quantity.	≤1,000 kg ≤1 kg acute ≤100 kg of acute spill residue or soil § 261.5(f)(2) and (g)(2)	≤6,000 kg § 262.34(d)(1)	No limit.
Satellite accumulation	Not applicable	§ 262.34 (c)(1) and (2)	§ 262.34 (c)(1) and (2).
Accumulation Time Limits	None	≤180 days or ≤270 days (if greater than 200 miles). § 262.34(d)(2) and (3)	≤90 days. § 262.34(a).
Accumulation Conditions	§ 261.5 (f)(1) and (2); § 261.5 (g)(1) and (2).	Reduced standards for the management of hazardous waste in containers and tanks. § 262.34(d)(2) and (3)	Full compliance for management of hazardous waste in containers, tanks, drip pads, or containment buildings. § 262.34(a).
Sent To:	One of seven state approved or RCRA permitted/interim status facilities. § 261.5(f)(3) and (g)(3)	RCRA permitted/interim status facility.	RCRA permitted/interim status facility.
Personnel Training	Not required	Reduced training standards § 262.34(d)(5)(iii)	Full compliance with §§ 265.16 and 262.34(a)(4).
Marking and labeling	Not required	§ 262.34 (a)(2) and (3)	§ 262.34 (a)(2) and (3).
Contingency Plan	Not required	Reduced standards § 262.34(d)(5)(i)	Full compliance with part 265 subparts C and D. § 262.34(a)(4).

¹¹ Making a correct hazardous waste determination is a condition for the exemption for CESQGs but an independent requirement for SQGs and LQGs.

¹² A CESQG may send hazardous waste to the following types of facilities: (1) A hazardous waste facility permitted by EPA; (2) an interim status hazardous waste facility; (3) a hazardous waste facility permitted by an authorized state; (4) a

facility permitted, licensed or registered by a state to manage municipal solid waste; (5) a facility permitted, licensed or registered by a state to manage non-municipal non-hazardous solid waste; (6) a facility which beneficially uses or reuses or legitimacy recycles or reclaims its wastes or treats its waste prior to beneficial use or reuse or legitimacy recycling or reclamation; or (7) universal waste handler or destination facility subject to the

requirements in 40 CFR part 273. The Agency is proposing an eighth location where CESQGs would be allowed to send their hazardous wastes (e.g., an LQG within the same company provided specified conditions are met).

¹³ Note that state hazardous waste programs may be more stringent than the federal program and also broader in scope.

TABLE 1—SUMMARY OF GENERATOR REGULATIONS—Continued

	CESQGs	SQGs	LQGs
Emergency Procedures	Not required	Part 265 subpart C § 262.34(d)(5)(iv)	Full compliance with part 265 sub- parts C and D. § 262.34(a)(4). § 262.34(a)(1)(iv)/§§ 265.111 and 265.114.
Closure	Not required	Not required	
Land Disposal Restrictions ...	Not required	40 CFR 262.34(a)(4)/40 CFR part 268.	40 CFR 262.34(a)(4)/40 CFR part 268.

C. Hazardous Waste Generator Demographics

In 2011, 16,447 generators reported generating approximately 34.4 million tons of hazardous waste.¹⁴ Of the 16,447 generators, 14,262 were LQGs and 2,185 were non-LQGs, meaning these entities submitted a biennial report but did not report generating sufficient amounts of hazardous waste to be categorized as an LQG.

The fifty largest hazardous waste generators reported generating 28.7 million tons, or 83 percent of the total. Additionally, 3,148 generators, or approximately 19 percent of the total reporting universe, reported generating only one hazardous waste stream, while 8,435 generators, or 51 percent of the total reporting universe, reported generating between one and five hazardous waste streams.¹⁵ At the other extreme were 843 generators, or 5 percent of the total reporting universe, that reported generating 41 or more hazardous waste streams. These generators included sites from the waste treatment industry as well as academic and industrial laboratories.

Of the 34.4 million tons of hazardous waste generated in 2011, 30.5 million tons, or 89 percent, were generated in just five industrial sectors: Basic Chemical Manufacturing (which alone accounted for 55 percent of the hazardous waste generated); Petroleum and Coal Products Manufacturing; Waste Treatment and Disposal; Pesticide, Fertilizer, and Other Chemical Manufacturing; and Iron and Steel Mills and Ferroalloy Manufacturing.

Unlike LQGs, who must submit a biennial report every two years describing the types and quantities of hazardous waste generated and its subsequent disposition, SQGs are not required to provide such information to the Agency. Consequently, the Agency lacks the level of detail for SQGs that is

available for LQGs. However, based on a review of biennial report data provided by treatment, storage, and disposal facilities (which must report waste received from all hazardous waste generators) and site identification data (from SQGs obtaining an EPA ID number), EPA estimates the number of SQGs to range from 45,762 to 59,702.¹⁶

Because CESQGs are not required to obtain a RCRA ID, the information available to the Agency is limited to those states that require their CESQGs to obtain a RCRA ID. Therefore, in estimating the size of the CESQG universe, the Agency developed a methodology that extrapolated the size of the CESQG universes based on the data available in those states that require CESQGs to obtain a RCRA ID. We first established a ratio of SQGs to CESQGs in those states where information was available on the CESQG universe and then used that ratio to estimate the size of a state's CESQG universe where CESQG information was unavailable. Using this methodology, EPA currently estimates the size of the CESQG universe to range from 302,807 to 425,752.¹⁷ However, we believe this range most likely underestimates the true number of CESQGs because we believe there are many more facilities unaware of their obligations under the RCRA hazardous waste regulations and the need to conduct correct hazardous waste determinations.

¹⁴ Estimate of Total Number of SQGs and CESQGs, July 2013. We estimated this range by doing the following: (1) Identifying hazardous waste generators who shipped hazardous waste off site in 2007, 2009, and 2011 using the Biennial Report's WR form and (2) cross walking that universe with data received from Site ID forms to identify the "active" SQG universe. The high-end estimate represents SQGs who shipped hazardous waste off site in any one of the three Biennial Report cycles, since many hazardous waste generators fluctuate in the regulatory status from year to year. The estimate also includes new SQGs who notified after the 2011 biennial report. The low-end represents SQGs who shipped hazardous waste off site in 2011 only as well as new SQG notifiers. A copy of the results can be found in the docket to this proposal.

¹⁷ Methodology to Estimate the National Number of CESQGs, July 2013.

D. 2004 Hazardous Waste Generator Program Evaluation

On April 22, 2004, EPA published the "Hazardous Waste Generator Program Evaluation" Advanced Notice of Proposed Rulemaking (69 FR 21800). The purpose of the April 2004 notice was to seek information from stakeholders in order to evaluate the effectiveness of the RCRA hazardous waste generator program, as well as to identify areas for potential improvement.

Specifically, the April 2004 notice requested that stakeholders answer a series of questions in a number of areas of the hazardous waste generator regulatory program, including program effectiveness, improvements, redundancy, innovation, performance, burden reduction, pollution prevention and recycling, and priorities. Questions included whether the existing RCRA hazardous waste generator regulatory program is meeting its goal of protecting human health and the environment and whether the regulations are easy to understand, including questions asking which specific regulations are unclear or have been interpreted inconsistently.

EPA also included in the April 2004 notice a list of program areas that had previously been identified by stakeholders as needing improvement. These program areas included waste accumulation times, waste generation quantity thresholds and counting rules for LQGs, SQGs, and CESQGs, episodic generator provisions, waste sampling and testing, waste management standards, satellite accumulation, generator accumulation and treatment in containers or tanks, closure standards for generators, co-generator standards, RCRA identification numbers, waste minimization, and land disposal restriction requirements applicable to generators. During the comment period, EPA also held four public meetings in May 2004 in Boston, MA, Chicago, IL, Washington, DC, and Seattle, WA.

In response to the April 2004 notice and the May 2004 public meetings, EPA received over 500 comments from 55 organizations and individuals, including 9 states, 5 federal agencies, 2

¹⁴ EPA's National Biennial RCRA Hazardous Waste Report (Based on 2011 Data) <http://www.epa.gov/osw/inforesources/data/br11/index.htm>.

¹⁵ Summary of the number of GM forms submitted by LQGs in 2011 Biennial Report.

universities, 12 trade associations, and 22 companies.¹⁸ Overall, EPA's effort to seek information regarding the effectiveness of the hazardous waste generator regulatory program received a favorable response.

Many commenters agreed that implementation of the generator regulations has made significant improvements in managing hazardous waste and has resulted in fewer releases of hazardous waste to the environment. However, many commenters identified several improvements they believed needed to be made to regulations. Specifically, they suggested the following:

- Simplify the regulations to make them more user-friendly and easy to understand, such as eliminating cross-referencing and codifying guidance into regulations, where applicable.
- Improve the efficiency of the program by clearing up ambiguities and removing potential redundancies, such as defining what constitutes a closed container and clarifying parts of the satellite accumulation regulations.
- Provide greater flexibility in the regulations, such as regulations that allow for episodic generation and that allow wastes to be shipped from remote locations to a centralized location to enable better waste management.
- Require re-notification to ensure better data quality to support compliance monitoring of SQG facilities (state commenters).
- Improve regulations on hazardous waste determinations, including when it is appropriate to use generator knowledge instead of analytical testing (Industry commenters).

In response to the comments on the April 2004 notice, EPA took several actions to help improve the hazardous waste generator program in order to foster better compliance. Actions included (1) improving EPA's Web site for the hazardous waste generator regulatory program,¹⁹ (2) developing an online guide to the hazardous waste generator regulations,²⁰ (3) releasing guidance for management of hazardous waste in closed containers,²¹ (4) issuing

¹⁸ Public comments can be found in Docket ID No. RCRA-2003-0014.

¹⁹ <http://www.epa.gov/osw/hazard/generation/index.htm>.

²⁰ "Hazardous Waste Generator Regulations: A User-Friendly Reference Document" (<http://www.epa.gov/osw/hazard/downloads/tool2012.pdf>).

²¹ Memorandum from Betsy Devlin, Acting Director of EPA's Waste Recovery and Waste Management Division, to RCRA Division Directors, "Closed Container Guidance: Questions and Answers (Qs & As), November 3, 2011, incorporating Memorandum from Robert Dellinger, Director of EPA's Materials Recovery and Waste

a technical corrections direct final rule,²² and (5) conducting an evaluation of the hazardous waste determination program.²³ While these actions have helped to improve the hazardous waste generator program, the Agency recognizes that many of the changes identified by commenters can only be made through rulemaking. Thus, this proposed rule requests comment on a number of changes to the hazardous waste generator regulations.

VI. Proposed Revisions to 40 CFR Part 260—Hazardous Waste Management System: General

A. Generator Category Definitions (40 CFR 260.10)

EPA is proposing to codify definitions for the three categories of hazardous waste generators (CESQG, SQG and LQG). The term "small quantity generator" is codified in the regulations, but is outdated, whereas "conditionally exempt small quantity generator" and "large quantity generator" have been used within the RCRA hazardous waste community for several decades, but their exact definitions have not been codified. The regulations differentiate between the categories by stating the quantity of hazardous waste generated in a calendar month in each instance.

As the terms are most commonly used, CESQGs are generators that generate 100 kilograms or less of non-acute hazardous waste and 1 kilogram or less of acute hazardous waste in a calendar month; SQGs are generators that generate greater than 100 kilograms of non-acute hazardous waste but less than 1,000 kilograms of non-acute hazardous waste and 1 kilogram or less of acute hazardous waste in a calendar month; and LQGs are generators that generate 1,000 kilograms or greater of non-acute hazardous waste and/or greater than 1 kilogram of acute hazardous waste in a calendar month. However, generators often fail to consider residues from the cleanup of a spill of acute hazardous waste or do not count both the non-acute and acute hazardous waste they generate in a calendar month. The proposed definitions have been drafted to incorporate all the various categories of hazardous wastes—that is, acute hazardous waste, non-acute hazardous waste, and residues for the cleanup of a spill of acute hazardous wastes.

Management, Division, to RCRA Division Directors, "Guidance on 40 CFR 264.173(a) and 265.173(a): Closed Containers," December 3, 2009, RCRA Online 14826.

²² 75 FR 12989, March 18, 2010.

²³ Hazardous Waste Determination Program Evaluation, April 2013 (<http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf>).

Considering the significance a generator's category has in determining the appropriate set of regulations that the generator must comply with, the Agency believes it is necessary to define the specific hazardous waste generator categories in the regulations.

The proposed generator category definitions are based solely on the amount of hazardous waste generated. While EPA acknowledges that accumulation limits may trigger different generator regulations, those accumulation limits do not affect a generator's generation category, which is based on how much hazardous waste is generated in a calendar month.

Therefore, EPA is proposing to add the following definitions to § 260.10:

Very small quantity generator is a generator who generates less than or equal to the following amounts in a calendar month: (1) 100 kilograms (220 lbs) of non-acute hazardous waste; and (2) 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e); and (3) 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in sections § 261.31 or § 261.33(e);²⁴

Small quantity generator is a generator who generates the following amounts in a calendar month: (1) Greater than 100 kilograms (220 lbs) but less than 1000 kilograms (2200 pounds) of non-acute hazardous waste; and (2) less than or equal to 1 kilogram (2.2 lbs) of acute hazardous wastes listed in § 261.31 or § 261.33(e); and (3) less than or equal to 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e);

Large quantity generator is a generator who generates any of the following amounts in a calendar month: (1) Greater than or equal to 1000 kilograms (2200 lbs) of non-acute hazardous waste; or (2) greater than 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e); or (3) greater than 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water,

²⁴ As part of this rulemaking, EPA is proposing to change the name of "conditionally exempt small quantity generator (CESQG)" to "very small quantity generator (VSQG)." This change is discussed in section VI.B. For the sake of a consistent discussion, however, EPA is using the term CESQG throughout the preamble unless directly stating the content of the proposed regulatory text.

of any acute hazardous waste listed in § 261.31 or § 261.33(e).

EPA is also proposing to add definitions to § 260.10 for the terms “acute hazardous waste” and “non-acute hazardous waste,” which are both used in the above definitions for generator categories. The term acute hazardous waste is used for hazardous wastes that are particularly dangerous to human health and is defined as those hazardous wastes that meet the listing criteria in § 261.11(a)(2) and are therefore listed in § 261.31 and assigned the hazard code of (H) or are listed in § 261.33(e), also known as the RCRA P-list. In this proposal, any distinctions

between acute and non-acute hazardous wastes are only being made in the context of determining generator category. Generally the term “hazardous waste” refers to both acute and non-acute hazardous waste.

As previously stated, the definitions of generator categories are based solely on the amount of hazardous waste generated in a calendar month and are generally consistent with how the regulated community understands the various categories based on EPA’s references in existing publications to how much hazardous waste is generated in a calendar month. Additionally, these definitions reflect that a generator may

only have one generator category in a calendar month even if the generator generates both acute hazardous waste and non-acute hazardous waste in the same calendar month, a topic discussed further in section VII.A.

In practice, five waste generation scenarios exist with different combinations of acute hazardous waste, non-acute hazardous waste, and residues from the cleanup of spills of acute hazardous waste generated in a calendar month. These scenarios are summarized in Table 2—Generator Categories Based on Quantity of Waste Generated.²⁵

TABLE 2—GENERATOR CATEGORIES BASED ON QUANTITY OF WASTE GENERATED

#	Quantity of acute hazardous waste generated in a calendar month	Quantity of non-acute hazardous waste generated in a calendar month	Quantity of residues from the cleanup of acute hazardous waste generated in a calendar month	Generator category
1	> 1 kg	Any amount	Any amount	LQG.
2	Any amount	≥ 1,000 kg	Any amount	LQG.
3	Any amount	Any amount	> 100 kg	LQG.
4	≤ 1 kg	> 100 kg and < 1,000 kg	≤ 100 kg	SQG.
5	≤ 1 kg	≤ 100 kg	≤ 100 kg	VSQG/(CESQG).

Note: When calculating generator categories, the quantities of acute hazardous waste and non-acute hazardous waste are considered separately.

In three of the scenarios in Table 2—Generator Categories Based on Quantity of Waste Generated, the generator would be an LQG, in one scenario the generator would be an SQG, and in one scenario the generator would be a CESQG. In the first three scenarios, the generator is an LQG if it generates any of the following in a calendar month, regardless of the amounts of hazardous waste generated in the other categories: more than 1 kilogram of acute hazardous waste, 1,000 kilograms or more of non-acute hazardous waste, or more than 100 kilograms of residues from the cleanup of a spill of acute hazardous waste. This is made clear in the proposed regulatory definition of “LQG” by use of the word “any” and by the use of the word “or” between (1), (2), and (3). In these scenarios, the generator would need to comply with the independent requirements and conditions for the exemption for LQGs (specified in proposed § 262.17), as well as any applicable regulations for SAAs at § 262.15.

In the fourth scenario, the generator would be an SQG if, in a calendar

month, it generates greater than 100 kilograms and less than 1,000 kilograms of non-acute hazardous waste and also 1 kilogram or less of acute hazardous waste and 100 kilograms or less of residues from the cleanup of a spill of acute hazardous waste.²⁶ The proposed regulatory text expresses this scenario by using the word “and” between (1), (2), and (3) in the definition of SQG. As a result, the generator would need to comply with the independent requirements and conditions for the exemption for SQGs (specified in proposed § 262.16), as well as any applicable regulations for SAAs at § 262.15.

Finally, in the fifth scenario, if a generator generates 1 kilogram or less of acute hazardous waste and 100 kilograms or less of non-acute hazardous waste and 100 kilograms or less of residue from the cleanup of a spill of acute hazardous waste, then the generator is a CESQG for that calendar month. The proposed regulatory text expresses this scenario by using the word “and” between (1), (2), and (3) in the definition. As a result, the generator would need to comply with the conditions for the exemption for CESQGs (specified in proposed § 262.14).²⁷

EPA requests comment on these proposed changes.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

B. Renaming CESQG to VSQG (40 CFR 260.10)

Currently only one of the three generator categories—CESQG—uses the words “conditionally exempt” in its title; however both SQGs and LQGs, which typically accumulate hazardous waste on site, are also conditionally exempt from obtaining a RCRA permit or complying with the interim status standards in 40 CFR parts 264 and 265, respectively, provided they meet certain conditions. In addition, while CESQGs are subject to few conditions for exemption, they are still considered hazardous waste generators, and must comply with the relevant regulations. If a CESQG does not comply, it would be out of compliance with the hazardous waste regulations and potentially subject to enforcement action. This inconsistency in terminology has caused some confusion throughout the regulated community. Therefore, EPA is proposing to change the name of the category from “conditionally exempt small quantity generator (CESQG)” to “very small quantity generator (VSQG).”

²⁵ EPA is proposing to include this table in the regulations as Table 1 in § 262.13.

²⁶ Amount of hazardous waste accumulated on site at any given time can also impact what regulations the SQG must comply with.

²⁷ EPA is proposing to move the CESQG regulations from §§ 261.5 to 262.14. See section XIII of this preamble for more information.

EPA notes that this change is consistent with some states, such as Minnesota, which are already using the VSQG term. All regulations applicable to a CESQG would apply to a VSQG.

EPA requests comment on this proposed change.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

C. Definition of Central Accumulation Area (40 CFR 260.10)

The Agency is also proposing to define the term “central accumulation area” in § 260.10 to mean any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 (for small quantity generators) or § 262.17 (for large quantity generators).²⁸ The definition also states that a central accumulation area at an eligible academic entity that chooses to be subject to part 262 subpart K must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste.

LQGs may accumulate hazardous waste on site without a permit or complying with the interim status standards for up to 90 days provided they comply with § 262.34(a) and SQGs may do the same for up to 180 days, provided they comply with § 262.34(d) though (f).²⁹ Over the years, stakeholders have used different terms to refer to these on-site generator accumulation areas, including “generator accumulation areas,” “less-than-90-day areas,” and “less-than-180-day areas.” In December 2008, EPA promulgated a definition of “central accumulation area” in subpart K of part 262 to refer to these types of areas (“Academic Labs Rule”; 73 FR 72912, December 1, 2008). As explained in the preamble to the proposed Academic Labs Rule, EPA codified the term “central accumulation area” for the sake of convenience to distinguish these types of accumulation areas from satellite accumulation areas and laboratories, which are both subject to different regulations than central accumulation areas are. At the time, EPA promulgated the term in § 262.200 and indicated that the definition only

²⁸ This proposed definition includes citations to new sections of part 262 that we are proposing to include as part of the reorganization of the generator regulations. The existing small quantity generator regulations are at §§ 262.34(d) through (f) and the existing large quantity generator regulations are at § 262.34(a). For a full discussion of the proposed reorganization, see section XIII of the preamble.

²⁹ As noted previously, SQGs can accumulate hazardous waste for up to 270 days if they ship the hazardous waste greater than 200 miles.

applied to part 262 subpart K. Since then, the term has become more widely used and EPA is now proposing to define the term “central accumulation area” in § 260.10 to allow its use when referring to generator accumulation areas that are not operating under part 262 subpart K.

EPA emphasizes that we are proposing to define the term “central accumulation area” only as a matter of convenience. It is helpful for both the regulated community and the implementers to have a common term to use when referring to locations where generators accumulate hazardous waste other than satellite accumulation areas. Furthermore, the term is helpful for EPA to use when writing regulations, preamble, and guidance. The addition of the term does not establish any new regulatory standards or burden on generators. Generators may continue to have more than one central accumulation area on site; the use of the word “central” does not limit a generator to one area.

We have rephrased the proposed definition from how it currently appears in part 262 subpart K to make this clearer. The definition, as it appears in part 262 subpart K, currently states that a central accumulation area means an on-site hazardous waste accumulation area. We are proposing to revise the definition to say that a central accumulation area means *any* on-site hazardous waste accumulation area. Further, the use of the word “central” does not indicate that the generator must establish the central accumulation area in a location that is centrally located within the site. The use of the word “central” is used because many generators use a central accumulation area to consolidate or *centralize* their hazardous waste from multiple satellite accumulation areas prior to shipment off-site.

Because the proposed definition to be added to § 260.10 will now reference part 262 subpart K (the definition states that a central accumulation area at an eligible academic entity that chooses to be subject to part 262 subpart K must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste), we are proposing to remove the definition of central accumulation area from part 262 subpart K.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The definition of “central accumulation area” references other regulatory citations that are part of the proposed reorganization. The reorganization is discussed in section XIII of this preamble.

VII. Proposed Revisions to 40 CFR Part 261—Identification and Listing of Hazardous Wastes

EPA is proposing four changes to the regulations currently in 40 CFR part 261. First, the Agency is proposing to add a new provision that would explain what generator category would apply to a hazardous waste generator that generates both acute and non-acute hazardous waste in the same calendar month. Second, EPA is proposing to modify the regulations at §§ 261.5(h) and (i) and 261.3 that address the mixing of a non-hazardous waste with a hazardous waste. Third, the Agency is proposing to amend § 261.5(f)(3) and (g)(3) to allow a CESQG to send its hazardous waste to an LQG under control of the same person. Finally, the Agency is proposing to amend § 261.6(c) to require biennial reporting for owners or operators of facilities that recycle hazardous waste without storing them before they are recycled.

A. Generators That Generate Both Acute and Non-Acute Hazardous Waste in the Same Calendar Month (40 CFR 261.5)

When a generator is determining what category it belongs in, it must consider three relevant categories of hazardous waste: hazardous waste (or non-acute hazardous waste, for purposes of this discussion), acute hazardous waste, and residues from the cleanup of a spill of acute hazardous waste. EPA is proposing regulations that make clear what a generator’s category is for a calendar month when it generates any combination of non-acute hazardous waste, acute hazardous waste, and residues from the cleanup of a spill of acute hazardous waste in the same calendar month and which set of regulations apply. Currently, the RCRA hazardous waste regulations do not address situations involving combinations of wastes and Agency statements about this issue have been inconsistent.

According to the November 19, 1980, FR notice discussing changes to § 261.5, “the regulation is revised to clarify that the lower exclusion levels for acutely hazardous waste apply only to generators who otherwise are deemed small quantity generators.³⁰ The Agency believes that a generator who produces more than 1,000 kilograms of hazardous waste a month and is therefore subject to full regulation should handle his

³⁰ Note: Prior to 1986, there were only two categories of generators: large quantity generators and small quantity generators. When the small quantity generator regulations were promulgated in 1986, a third category of generators, conditionally exempt small quantity generators, was established.

acutely hazardous wastes in the same manner as his other wastes” (45 FR 76622).

In other words, if a generator generates 1,000 kilograms or more of non-acute hazardous waste in a calendar month, it would be considered an LQG for that month and therefore should, for both practical and environmental reasons, manage the acute hazardous wastes under the same regulations as an LQG (even if the amount of acute hazardous waste generated in a calendar month is less than 1 kilogram).

However, a provision regarding how to determine one’s generator category when generating a combination of non-acute hazardous waste, acute hazardous waste, and residues from the cleanup of a spill of acute hazardous waste was not included in the regulatory language.

Conversely, in a September 2, 1987, letter concerning the accumulation time for acute hazardous waste and non-acute hazardous waste in the same month, the Agency stated, “Acute hazardous wastes are counted and managed separately from hazardous wastes (§ 261.5(e)). In the example given, the generator would have 90 days to send the acute hazardous waste off site, but would have 180 days for the non-acute hazardous waste.”³¹ These different Agency interpretations have ultimately led to confusion regarding which regulations apply to hazardous waste generators that generate different categories of hazardous waste in the same calendar month.

The Agency believes the more practical approach is for a generator to be in only one generator category in a calendar month, the approach outlined in the 1980 **Federal Register** discussion. When a generator generating only non-acute hazardous wastes counts its waste, it must consider the total amount of all its different kinds of non-acute hazardous waste, not the amount of each type of hazardous waste (such as, type of waste identified by individual EPA hazardous waste number) separately. Considering the combination of acute hazardous wastes, non-acute hazardous wastes, and residues from the cleanup of a spill of acute hazardous waste generated in a calendar month when determining what category a generator belongs to follows the same logic. In addition, many of the regulations for LQGs are site-wide, such as submitting the biennial report, developing a contingency plan, and conducting training, and therefore a

generator would still have to comply with these conditions and would not gain a significant economic advantage by having more than one generator category. We note that many EPA Regions and states have taken this same approach in implementing the RCRA hazardous waste program.

This is why EPA is proposing to expressly state in the definitions which generator category would apply to hazardous waste generators that generate a combination of non-acute hazardous waste, acute hazardous waste, and/or residues from the cleanup of spills of acute hazardous waste in a calendar month as discussed in section VI of this preamble. In conjunction with these changes, EPA is proposing a new section § 262.13 explaining how a generator determines which generator category applies to it. This topic is fully discussed in section VIII of this preamble. The Agency is soliciting comment on the proposal to revise the existing regulations to indicate that a generator can only have one generator category in a calendar month, according to the quantity of acute and non-acute hazardous waste it generates.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. All the proposed definitions of generator categories would be found in § 260.10. The reorganization is discussed in section XIII of this preamble.

B. Generators That Mix a Non-Hazardous Waste With a Hazardous Waste

EPA is proposing to modify how mixtures of non-hazardous waste and hazardous waste would affect the generator categories of CESQGs and SQGs. Additionally, EPA is proposing to add a reference in 40 CFR part 262 that assists LQGs with finding the regulations applicable to mixing hazardous waste with non-hazardous waste.

1. CESQGs That Mix a Non-Hazardous Waste With a Hazardous Waste (40 CFR 261.5(h) and (i))

With the partitioning of the original 1980 SQG regulations into two sets of regulations for CESQGs and SQGs in 1986, potential confusion surrounds the current reading and implementation of § 261.5(h) and (i). When the regulations at § 261.5(h) and (i) were promulgated on November 19, 1980 (45 FR 76623), the title of § 261.5 was “Special requirements for hazardous waste generated by small quantity generators.” At that time, there were only two hazardous waste generator categories: LQGs and SQGs. Prior to the

promulgation of the new SQG regulations on March 24, 1986 (52 FR 10146), an SQG was a generator who generates less than 1,000 kilograms of hazardous waste in a calendar month; the regulations did not make a distinction between SQGs and CESQGs at that time. Prior to 1986, paragraphs (h) and (i) of section 261.5 read as follows:

“(h) Hazardous waste subject to the reduced requirements of this section may be mixed with non-hazardous waste and remain subject to these reduced requirements even though the resultant mixture exceeds the quantity limitations identified in this section, unless the mixture meets any of the characteristics of hazardous waste identified in subpart C.

(i) If a small quantity generator mixes a solid waste with a hazardous waste that exceeds a quantity exclusion level of this section, the mixture is subject to full regulation.”

With the promulgation of the SQG regulations in 1986, SQGs were broken into two classes of generators: (1) CESQGs (generators who generate up to 100 kilograms of hazardous waste in a calendar month) and (2) SQGs (generators who generate greater than 100 kilograms and less than 1,000 kilograms of hazardous waste in a calendar month). The regulations for CESQGs were established at § 261.5, while those for SQGs were moved to § 262.34 (d)–(f). Similarly the title of § 261.5 was changed to read, “Special requirements for hazardous waste generated by *conditionally exempt* small quantity generators” [emphasis added]. The language of § 261.5(h) did not change when the SQG regulations were promulgated, while paragraph (i) was modified slightly to read: “If any person mixes a solid waste with a hazardous waste that exceeds a quantity exclusion level of this section, the mixture is subject to full regulation.” The phrase “any person” was substituted for the phrase “small quantity generator.”

EPA believes that the readability of these regulations could be improved, particularly for paragraph (i), to expressly state whether the regulation applies to situations where the hazardous waste being mixed exceeds the CESQG quantity exclusion level or to situations where the mixture exceeds the CESQG quantity exclusion level. Additionally, “full regulation,” could be interpreted as regulation commensurate with an LQG, even if the resultant mixture exceeds CESQG quantity levels, but not SQG quantity levels.

For these reasons, EPA is proposing to modify the language regarding mixing of non-hazardous waste with hazardous waste by CESQGs (which is currently

³¹ Letter from Marcia E. Williams, Director of EPA’s Office of Solid Waste, to Fred Hutchison, University of Idaho, September 2, 1987, RCRA Online 11288.

located at § 261.5(h) and (i)) to make these points clear. Specifically, it states that a CESQG may mix listed or characteristic hazardous waste with non-hazardous waste and remain eligible for the conditional exemption provided that either of the following is true:³² (1) The mixture does not exhibit any of the characteristics of hazardous waste identified in subpart C of part 261 of this chapter; or (2) the mixture does not cause the generator to exceed the very small quantity generator calendar month quantity limits identified in the definition of very small quantity generator at § 260.10.³³

For example, if a CESQG mixed 50 kilograms of characteristic hazardous waste with 100 kilograms of non-hazardous waste and the resultant 150 kilograms mixture did not retain the characteristics of hazardous waste, then the generator could still comply with the CESQG conditions. However, if a CESQG mixed 50 kilograms of characteristic hazardous waste with 100 kilograms of non-hazardous waste and the resultant 150 kilograms mixture *did* retain the characteristics of hazardous waste, then the generator would no longer be a CESQG, but an SQG, and the generator would need to comply with all applicable regulations for an SQG for that calendar month. Similarly, if a CESQG mixed 50 kilograms of characteristic hazardous waste with 1,000 kilograms of non-hazardous waste and the resultant 1,050 kilograms mixture retained the characteristics of hazardous waste, then the generator would no longer be a CESQG, but an LQG, and the generator would need to comply with all applicable regulations for an LQG for that calendar month.³⁴

EPA notes that the regulations covering mixing of hazardous and non-hazardous waste would apply regardless of when the initial wastes are generated. In other words, when a generator mixes a hazardous waste with a non-hazardous waste, the generator may have changed the properties of the hazardous waste and thus must make a hazardous waste determination on the resultant mixture. For example, if a CESQG mixed 50 kilograms of characteristic hazardous waste that it generated at different

points over the last three months with 100 kilograms of non-hazardous waste and the resultant mixture *did* retain the characteristics of hazardous waste, then the generator would no longer be a CESQG at the point that the mixture was generated, but an SQG, and the generator would need to comply with all applicable regulations for an SQG for that calendar month during which the mixing occurred. The time period for the accumulation of wastes begins at the point the mixture is generated and the generator becomes a SQG.

In modifying the language, the Agency is not changing the intent of the existing hazardous waste regulations, but is improving the readability of the regulatory text. Thus, this change in language does not impose any additional burden on CESQGs.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The reorganization of the generator regulations would move these provisions to 262.14(b). The reorganization is discussed in section XIII of this preamble.

2. LQGs and SQGs That Mix a Non-Hazardous Waste With a Hazardous Waste (40 CFR 261.3)

LQGs and SQGs are subject to the mixture rule in § 261.3. In short, the mixture rule has three parts: (1) If non-hazardous waste is mixed with listed hazardous waste, then the mixture is considered the listed hazardous waste (§§ 261.3(a)(2)(iv) and 261.3(b)(2)); (2) if non-hazardous waste is mixed with listed hazardous waste that is listed solely for exhibiting an ignitability, corrosivity, or reactivity characteristic in part 261 subpart C (such as F003 hazardous waste), then the mixture is considered hazardous waste only if it exhibits a characteristic (§ 261.3(g)(2)(i)); and (3) if non-hazardous waste is mixed with characteristic hazardous waste, then the mixture is considered hazardous waste only if the mixture exhibits a characteristic of hazardous waste (§ 261.3(b)(3)) (45 FR 33066, May 19, 1980; 66 FR 27266, May 16, 2001).

However, because the mixture rule appears in § 261.3 and the SQG and LQG regulations appear in 40 CFR part 262, the regulated community may not totally appreciate how the mixture rules apply to SQGs and LQGs. Therefore, EPA is proposing to include references in §§ 262.16(c) and 262.17(f) that assist SQGs and LQGs with finding the regulations applicable to the mixing of hazardous waste with non-hazardous waste. Additionally, EPA wants to modify the regulations to improve understanding of what circumstances an

SQG may mix hazardous waste with non-hazardous waste and still remain subject to the SQG requirements.

Specifically, EPA is proposing to add a provision for SQGs that states that a small quantity generator may mix its hazardous waste with non-hazardous waste and remain eligible for the conditional exemption applicable to a small quantity generator under two circumstances: (1) The mixture is not a hazardous waste according to the mixture rules in §§ 261.3(a)(2)(iv), 261.3(b)(2), 261.3(b)(3), and 261.3(g)(2)(i); or (2) if the mixture is a hazardous waste, the mixture does not cause the generator to exceed the small quantity generator quantity limits for a calendar month, as identified in the definition of small quantity generator at § 260.10.³⁵

For example, if an SQG mixed 100 kilograms of listed hazardous waste (that was not listed solely for the ignitability, corrosivity and/or reactivity characteristic) with 1,000 kilograms of non-hazardous waste, then the resultant 1,100 kilogram mixture would be considered a listed hazardous waste and the generator would no longer be an SQG, but rather an LQG. The generator would then need to comply with all applicable regulations for an LQG for that month during which the SQG mixed the waste.³⁶

However, if an SQG mixed 100 kilograms of either characteristic hazardous waste or listed hazardous waste (that was listed solely for the ignitability, corrosivity and/or reactivity characteristic) with 1,000 kilograms of non-hazardous waste and the resultant 1,100 kilograms mixture did not retain the characteristics of hazardous waste, then the generator could still comply with the SQG regulations because the resulting mixture would no longer be considered a hazardous waste (although it would still be subject to applicable land disposal restriction requirements in 40 CFR part 268).

EPA is also proposing to add a provision for LQGs that states that mixtures of hazardous waste with non-hazardous waste are subject to the mixture rule in § 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i).

In modifying the language, the Agency is not changing the existing hazardous waste regulations, but is improving the readability of the

³² EPA is proposing to use the term "very small quantity generator (VSQG)" in place of "conditionally exempt small quantity generator." See section VI.B of this preamble for more information.

³³ This regulatory citation is the proposed new location for the definition of a VSQG. See section VI.B of this preamble for more information.

³⁴ Additionally, the generator would have to comply with the SQG or LQG regulations for as long as its total quantity of hazardous waste accumulated on-site was greater than or equal to the CESQG accumulation limit of 1000 kg.

³⁵ This regulatory citation is the proposed new location for the definition of SQG. See section VIII of this preamble for more information.

³⁶ Additionally, a generator would have to comply with the LQG regulations for as long as its total quantity of hazardous waste accumulated on-site was greater than or equal to the SQG accumulation limit of 6000 kg.

regulatory text. Thus, this change does not impose any additional burden on SQGs and LQGs.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. EPA is proposing to address the mixing regulations for SQGs at § 262.16(c) and the mixing regulations for LQGs at § 262.17(f). The reorganization is discussed in section XIII of this preamble.

3. Request for Comment

The Agency requests comment on whether the proposed language for CESQGs and SQGs improves the understanding of the regulations regarding how mixtures of non-hazardous waste and hazardous waste would affect the generator category for CESQGs and SQGs. Additionally, EPA requests comment on whether the proposed language for LQGs assists LQGs in more easily finding the applicable mixture regulations.

C. Allowing CESQGs To Send Hazardous Waste to LQGs Under the Control of the Same Person

EPA is proposing to allow CESQGs to send their hazardous waste to an LQG that is under the control of the same person, as defined at § 260.10, provided both the CESQG and LQG comply with specified conditions.³⁷

1. Purpose

Under the existing regulations at § 261.5(f)(3) for acute hazardous waste, and § 261.5(g)(3) for non-acute hazardous waste, a CESQG may either treat or dispose of its hazardous waste on site or ensure delivery to an off-site treatment, storage, or disposal facility, which can include RCRA-permitted hazardous waste facilities, interim status hazardous waste facilities, municipal solid waste facilities, non-municipal non-hazardous waste facilities, recycling facilities, and universal waste handlers. The existing CESQG regulations do not allow a generator to send its hazardous waste off site to another generator, unless the receiving generator has a storage permit or is otherwise one of the types of facilities cited above. Thus, persons looking to reduce their overall environmental liability across multiple sites are prohibited from managing their CESQG hazardous waste at one or more of their LQG sites without first obtaining a permit or complying with the interim

³⁷ EPA is also proposing to rename "CESQG" to "VSQG" (very small quantity generator) (see section VIII.A.1 of the preamble for more information). However, for this discussion, we continue to use CESQG as this term is most familiar to the regulated community.

status standards, both of which would increase regulatory burden and costs.

EPA believes that allowing CESQGs to send their hazardous waste to an LQG that is under the control of the same person would provide an additional option for CESQGs to manage their hazardous waste. It may also improve the management of that hazardous waste for four main reasons.

First, LQGs are subject to more stringent management conditions, such as accumulation time, labeling, training, emergency planning, and containment standards, as compared to CESQGs. In addition, LQGs may only transport hazardous waste to a RCRA-permitted or interim status hazardous waste TSDF, which in turn, is subject to more stringent management standards than the municipal or non-municipal solid waste facilities that CESQGs are allowed to use. Therefore, allowing hazardous waste generated by a CESQG to be sent to an LQG under the control of the same person could improve overall oversight and management of the hazardous waste and enable more effective environmental protection. Furthermore, a company, because of economies of scale, may reduce its overall waste management costs, as well as its potential financial liabilities for hazardous waste it generates at CESQG facilities, as it would be handled under the more comprehensive LQG and TSDF regulatory programs.

Second, whereas LQGs have up to 90 days to accumulate hazardous waste in compliance with all the LQG conditions for exemption without having to obtain a RCRA storage permit or comply with all the other standards otherwise applicable, CESQGs may accumulate up to 1,000 kilograms of non-acute hazardous waste or up to 1 kilogram of acute hazardous waste or up to 100 kilograms of residues from the cleanup of a spill of acute hazardous waste without any time constraint. Even though the amount of hazardous waste allowed on site by CESQGs at any one time is limited, the longer that hazardous waste is accumulated on site the greater the risk of adverse impacts to human health and the environment. Allowing CESQGs to send their hazardous waste to an LQG under the control of the same person may reduce the overall time that the CESQG accumulates hazardous waste on site, which would further reduce the potential risk to human health and the environment.

Third, this proposed change would allow consolidation by an LQG of hazardous waste generated by several CESQGs under its control, which

increases the potential opportunities for hazardous waste recycling by the LQG.

Fourth, this proposed change would give companies flexibility in allocating labor and resources required to manage the company's total quantity of hazardous waste generated, as the company would be allowed to consolidate its hazardous waste from CESQG facilities at its LQG sites.

EPA has received requests over the years from industry for the regulations to allow CESQGs to send their hazardous waste to LQGs for consolidation. EPA believes that such a change in the regulations would enable generators to employ greater control over the management of their hazardous waste, thereby resulting in improved efficiency and reduced liability for the generator. EPA believes numerous situations exist where CESQGs and LQGs under the same ownership could take advantage of this proposed change. For example, Army National Guard and Reserve units that may be CESQGs would have the opportunity to send their hazardous waste to an active Army base that is an LQG. The same situation applies to Air Force, Navy, and Marine Corps reserve units as well.

Additionally, many universities have engineering, medical, and science laboratories located on campus, with each laboratory building possibly qualifying as a CESQG. Allowing different laboratory buildings within a university or industrial environment that are CESQGs to send their hazardous waste to another university or industrial entity that is an LQG would provide both economic and environmental benefits. Furthermore, utilities, retailers, and remote oil and gas production facilities also represent examples of industrial sectors that may realize benefits from the intra-company transfer of hazardous waste from CESQGs to LQGs.

2. Scope

As discussed above, EPA is proposing to amend the regulations under the existing regulatory framework at § 261.5(f)(3) and (g)(3) to allow CESQGs to send hazardous waste to an LQG under the control of the same person.³⁸ "Person" is defined in § 260.10 to mean an individual, trust, firm, joint stock company, federal agency, corporation (including a government corporation), partnership, association, state, municipality, commission, political subdivision of a state or any interstate

³⁸ EPA is proposing to reorganize the regulations for CESQGs by moving provisions from § 261.5 to § 262.14. The proposed revision to allow CESQGs to send hazardous waste to LQGs under control of the same person can be found at § 262.14(b)(3)(viii).

body. For the purposes of this section, “control” would mean the power to direct the policies of the facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to “control” such facilities.

The Agency believes limiting transfers to facilities under control of the same person is appropriate because it ensures common control is maintained over both facilities and takes advantage of strong incentives to ensure the hazardous waste is safely managed. Additionally, if a CESQG sends hazardous waste to an LQG under the control of the same person, the LQG is likely to be familiar with the type of hazardous waste generated by the CESQG. Furthermore, questions regarding liability and responsibility for such hazardous waste are likely to be clearer than is the case with facilities from unrelated companies.

EPA is also proposing some labeling and marking standards for CESQG waste being transferred to LQGs under the control of the same person under this provision. Note that aside from these two conditions, the same standards for management of CESQG waste apply to materials going to an LQG under this provision as to other CESQG waste, including the exemption from the requirement to ship using a hazardous waste manifest. DOT shipping requirements do still apply.

3. Conditions for Exemption

Condition for Exemption for CESQGs

As part of this provision, CESQGs would be required to meet the following conditions for exemption, proposed at § 262.14(a)(viii).

Under control of the same person. As described above, the CESQG and the LQG would have to be under control of the same person, according to the existing definitions in § 260.10.

Labeling and marking of containers. The Agency is proposing that a CESQG transferring waste to an LQG under the control of the same person label its containers with (1) the words “Very small quantity generator hazardous waste”; (2) other words that identify the contents of the containers (e.g., the name of the chemical(s), such as “acetone” or “methylene dichloride” or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation (DOT) requirements at 49 CFR part 172 subpart D); (3) an indication of the hazards of

the contents of the container, such as the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association (NFPA) code 704; a hazard pictogram consistent with the United Nations’ Globally Harmonized System (GHS); or any other marking and labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers; and (4) the applicable EPA hazardous waste number(s) (EPA hazardous waste code) in subparts C and D of part 261 to assist the receiving LQG in managing the hazardous waste received. This condition is also consistent with the changes proposed for labeling and marking of containers in the revisions to 40 CFR parts 262, 263, and 268 discussed in various sections elsewhere in this preamble. A generator subject to DOT shipper/carrier packaging requirements should be familiar with and aware of the marking requirements at 49 CFR 172.301 and 49 CFR 172.304, as well as prohibited labeling and label visibility requirements at 49 CFR 172.401 and 172.406, respectively.

Because the hazardous waste generated and accumulated by a CESQG will be subsequently sent off site to an LQG under the same company in compliance with DOT hazardous material regulations, the CESQG may choose to use an appropriate DOT proper shipping name found in the 49 CFR 172.101 hazardous materials table to identify the contents of the container while hazardous waste is accumulating on site. That way, the generator will fulfill EPA and DOT requirements simultaneously; however, EPA is not proposing to require the use of the DOT shipping names while the hazardous waste is accumulating on site. We only suggest that the DOT shipping name may be one way that some generators may choose to identify the contents of the container.

EPA believes use of the DOT marking requirement should be sufficient in many situations involving DOT Class 9 hazardous materials that are also hazardous waste, with the DOT shipping name ending in N.O.S. (not otherwise specified). As noted at 49 CFR 172.301(b), generators using a DOT shipping name ending in N.O.S. must

also provide the technical name of the hazardous material in association with the proper shipping name. However, the Agency is requesting comment on examples of when the DOT shipping name would not meet EPA’s intent of “identifying the contents of the container” and suggestions for addressing this situation.

EPA believes that CESQGs should label and mark containers of hazardous waste sent to LQGs in order to communicate the contents of the containers to facility personnel that can then safely manage the hazardous waste in compliance with the LQG regulations. Since CESQGs already must make a hazardous waste determination to determine if and what types of hazardous waste they generate, the Agency does not believe this condition will pose an undue burden. In fact, if the CESQG was not required to provide this information, the burden to the LQG receiving the hazardous waste may increase because the LQG would then have to do so.

Conditions for Exemption for LQGs

EPA is proposing that LQGs receiving hazardous waste from CESQGs under the control of the same person comply with the following conditions for exemption, all proposed at § 262.17(g).

a. Notification. EPA is proposing that LQGs receiving hazardous waste from CESQGs under the control of the same person submit a notification to EPA or their authorized state using EPA form 8700–12 (i.e., the Site Identification (Site ID) form) 30 days prior to receiving the first shipment of hazardous waste from the CESQG. LQGs would be required to identify in the Comments section of the Site ID form the name(s), site address(es), and contact information for the CESQG(s) that will be transferring hazardous waste to the LQG. LQGs would also be required to submit an updated Site ID form within 30 days should the name, site address, or contact information for the CESQG change.

Notification in this instance serves to inform the regulatory authorities of which LQGs are receiving hazardous waste from which CESQGs under control of the same person. The Agency believes notification is necessary in order to communicate to inspectors the origin of the hazardous waste received by the LQG and to ensure that the received shipment is managed in compliance with the conditions of the provision. EPA also believes that notification by the LQG, rather than notification by the CESQG, is more efficient and less burdensome, because LQGs are already required to submit

Site ID forms as part of obtaining a RCRA Identification Number and as part of the biennial reporting process. Additionally, it is more efficient for one LQG to notify on behalf of many CESQGs.

EPA has recently made available an electronic interface for states and the regulated community to use to submit Site ID forms electronically, which will further reduce burden on LQGs. Facilities should check with their states regarding whether their state will use EPA's electronic submittal process.

b. Recordkeeping. LQGs would be required to maintain records for three years from the date the hazardous waste was received from the CESQG with the following information:

- The name, site address, and contact information for each CESQG; and
- A description of each waste shipment received from the CESQG, including the quantity, EPA hazardous waste number(s) of each waste received, and the date the hazardous waste was received.

EPA believes recordkeeping is necessary to ensure the requirement that the CESQG and LQG are under control of the same person is met, as well as to ensure that the hazardous waste from the CESQG is managed according to the other conditions for exemption of this provision, such as that LQGs are receiving shipments of hazardous waste from CESQGs in quantities commensurate with the CESQG's generator category. EPA believes this recordkeeping condition could be fulfilled through routine business records, such as a bill of lading, and would not present undue burden to the LQG. Additionally, the LQG could use this information in order to report the hazardous waste from the CESQG on its biennial report forms.

c. Labeling and marking of containers. The Agency is proposing that LQGs comply with the labeling and marking conditions for exemption under proposed § 262.17(a)(5), including the date accumulation started (*i.e.*, the date the hazardous waste was received from the CESQG). (Note: These are the same proposed standards that CESQGs must comply with in labeling and marking containers that they send to LQGs, as discussed above.) If the LQG is consolidating incoming hazardous waste from a CESQG with either its own hazardous waste or with hazardous waste from another CESQG, the LQG would be required to mark each container with the earliest date any hazardous waste in the container was accumulated on site.

Because the LQG must manage the hazardous waste it receives from

CESQGs according to the LQG regulations, EPA believes that the same labeling and marking regulations should apply to hazardous waste from a CESQG that is accumulated and managed by an LQG. EPA believes that it is important that employees, transporters, downstream handlers, emergency personnel, EPA, and the states know as much as possible about the potential hazards of the contents in containers that LQGs accumulate, transport, and manage.

d. Waste management. Under this proposal, an LQG would be required to manage all incoming hazardous waste from a CESQG in compliance with the regulations applicable to its LQG generator category. In other words, there would be no difference in how the hazardous waste from a CESQG was managed relative to the management of the LQG's own hazardous waste, although hazardous waste from a CESQG would not be eligible for management under the satellite accumulation regulations (proposed § 262.15).

4. Biennial Reporting

An LQG would also be required to report the hazardous waste it receives from CESQGs on its biennial report, as required under § 262.41. EPA plans to include a new source code in the biennial report instructions (if this provision is made final) that LQGs would use to identify the hazardous waste as being received from a CESQG (to differentiate from hazardous waste the LQG generates on site). Generators would be required to report hazardous waste they receive from CESQGs by type of hazardous waste. In other words, if an LQG receives the same type of hazardous waste from multiple CESQGs, it would only need to report the total quantity of that hazardous waste received from all CESQGs. This provision is consistent with the existing provision that LQGs must report information on the quantities and types of hazardous waste they generate as part of the biennial reporting process. It will also enable states and EPA to better understand the additional volumes and types of hazardous wastes managed at an LQG, which will assist in prioritizing compliance assistance.

5. No Maximum Limit of Hazardous Waste LQGs Receive From CESQGs

Because LQGs currently have no maximum limit on the amount of hazardous waste they can accumulate, and because the regulations that are applicable to LQGs are protective, the Agency believes there is no need to establish a maximum limit on the

amount or types of hazardous waste that an LQG could receive from CESQGs. In fact, we believe the more hazardous waste that is shipped to LQGs, the greater potential for reduced risk, since these hazardous wastes would be managed under the more comprehensive hazardous waste regulations, as opposed to potentially being sent to non-hazardous waste disposal facilities.

6. Enforcement

EPA believes the proposed conditions to allow CESQGs to send their hazardous waste to an LQG under the control of the same person are necessary to ensure protection of human health and the environment. Failure to meet one or more of the conditions could lead to potential mismanagement of the hazardous waste, potentially resulting in a release of hazardous waste or hazardous waste constituents to the environment. Persons taking advantage of the proposed provision that fail to meet one or more of the conditions for exemption would be subject to an enforcement action under RCRA section 3008 for violations of applicable independent requirements in part 264, 265, 267, 268, and 270. EPA and authorized states would also have the authority to cease certain transfers of hazardous waste from CESQGs to an LQG in the context of an enforcement action. EPA also notes that failure on the part of the LQG to meet one of the conditions for exemption would not mean that the CESQG is subject to permitting or other standards in 264, 265, and 270, provided that the CESQG met its conditions for exemption and vice versa.

7. Interstate Shipments

Under RCRA, authorized state programs may be more stringent than the federal program and thus states may choose not to adopt the proposed provision allowing CESQGs to send their hazardous waste to an LQG under the control of the same person. In the case of interstate shipments where a CESQG wants to transfer its waste to an LQG located in a different state than the CESQG, the CESQG must ensure that both states have adopted the provision in order to ship the hazardous waste to an LQG. Additionally, if a CESQG wants to transfer its waste through states that have not adopted the proposed provision, these transit states may also impose state requirements on the shipment while it is being transported through the state. Therefore, EPA recommends that generators contact any states through which the hazardous

waste will be shipped to ascertain their policy about such shipments.

8. Request for Comment

EPA requests comment regarding its proposal to allow CESQGs to ship their hazardous waste to an LQG under the control of the same person.

EPA is also requesting comment on whether to establish a process that would allow an entity (whether CESQG or LQG) to request approval from its EPA Regional Administrator or the authorized state to transfer hazardous waste from CESQGs to LQGs that are not under the control of the same person. For example, such inter-company transfers could occur between high school laboratories and university laboratories or other waste management companies, such as those assisting with school chemical clean-outs. While the Agency believes that this should not be allowed as a general matter, we also recognize that there may be instances where such an arrangement may be appropriate, and thus, are taking comment on allowing such arrangements on a case-by-case basis. EPA is interested in whether such inter-company transfers would produce the same benefits as for intra-company transfers in enabling greater control over the management of CESQG hazardous waste, thereby resulting in improved efficiency and reduced liability for the generator.

The request for approval submitted to the state or Regional office would have to include the name, address, and contact information for each entity involved in the arrangement, how the entities will assign responsibility for the safe management of the hazardous waste during transport to and accumulation by the LQG, as well as a description of the actual practices that will be followed by the CESQG and LQG to ensure the safe management of the hazardous waste. EPA does not believe that these requests for approval would need publication in the **Federal Register** and, instead, would either be approved or denied by the EPA Regional Administrator or the authorized state. If a request is granted by the EPA Regional Administrator or the authorized state, the CESQG(s) and LQG would need to comply with the conditions discussed above for those CESQGs and LQGs that are “under control” of the same person. In addition, the LQG would need to keep a copy of the request for approval, as well as EPA’s or the state’s approval for as long as the CESQG sends their hazardous waste to the LQG.

EPA is requesting comment on an additional variation for allowing LQGs to consolidate CESQG hazardous waste

when the generators are not under the control of the same person with a self-implementing request for approval. Under this variation, the implementing agency would have sixty days from the date the request was sent to approve or deny it. After sixty days, the generator may start consolidating regardless of whether it has heard back from the implementing agency. This option provides the state or Regional office the ability to deny requests that pose a risk to human health or the environment or that come from entities that have a history of not managing waste responsibly, but puts a limit on how long a generator must wait for a response to its request for approval.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The reorganization of the generator regulations would move the conditions for CESQGs from § 261.5 to § 262.14 and the conditions for LQGs from § 262.34 to § 262.17. The reorganization is discussed in section XIII of this preamble.

D. Requiring Biennial Reporting for Owners or Operators of Facilities That Recycle Hazardous Waste Without Storing It (40 CFR 261.6(c)(2))

EPA is proposing to modify 40 CFR 261.6(c)(2) to require owners or operators of facilities that recycle hazardous waste without storing it prior to recycling to comply with the biennial reporting requirements at 40 CFR 265.75. Because these entities receive hazardous waste using a hazardous waste transporter and hazardous waste manifest, similar to a permitted TSDF or a facility with interim status, the Agency is proposing to amend its regulations and instructions to specify that such facilities must complete and submit a biennial report to EPA. Without this information, the Agency and states may have an incomplete picture of which facilities recycle hazardous waste and the quantities of regulated hazardous wastes that are recycled, impeding their ability to provide adequate oversight for those facilities.

The Agency believes that only a few recycling facilities will be affected by this change. Additionally, considering that most facilities already have sophisticated information systems to manage and track incoming shipments of hazardous waste, we believe the burden imposed on such facilities should be minimal.

The Agency requests comment on this proposed change. Additionally, the EPA is interested in information regarding whether these facilities already routinely submit biennial reports or are

required by the states to submit biennial reports.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

VIII. Proposed Revisions to 40 CFR Part 262—Standards Applicable to Generators of Hazardous Waste

A. Proposed Addition of Terms Used in This Part and Changes to Purpose, Scope, and Applicability (40 CFR 262.1 and 262.10)

As previously discussed, one of the objectives of this proposal is to revise the hazardous waste generator regulations to make them more user-friendly and easily understood by both the regulated community and federal and state regulators. Currently, the hazardous waste generator regulations are located primarily in three different parts of the CFR (40 CFR parts 261, 262, and 265). In some cases, it is difficult to determine what components of the regulations apply to different categories of hazardous waste generators.

The proposed reorganization will address many of these problems by moving the regulations at § 261.5 and some of the technical standards of part 265 into part 262 and by organizing the regulations based on a generator’s category so generators can more easily determine which regulations they are subject to. That is, EPA is proposing that § 262.14 contain conditions for exemption for conditionally exempt small quantity generators, that § 262.15 contain conditions for exemption for satellite accumulation areas, that § 262.16 contain conditions for exemption for small quantity generators, and that § 262.17 containing conditions for exemption for large quantity generators.

In concert with the reorganization of the generator conditions for exemption, EPA is proposing to add some regulatory language to more clearly explain how the regulations work for generators and to lay out which provisions the various categories of generators are responsible for complying with. The proposed addition of § 262.1 and the proposed revisions to § 262.10 are meant to achieve these goals.

1. Proposed Addition of 40 CFR 262.1

One concern regarding the current generator regulations is that they are not sufficiently clear about the distinction between the two types of generator requirements: Those that a generator must meet because it is an entity that generates hazardous waste— independent requirements—and those that a generator must meet only if it

wants the benefits of an exemption from RCRA permitting—conditions for exemption. In order to make the regulations clearer regarding this distinction, EPA is proposing to include definitions for these terms in a new section of the regulations at § 262.1.

The difference between independent requirements and conditions for exemption, as discussed previously in this preamble, lies in the nature of each, and in the consequences that result when each is not met. An independent requirement is an unqualified or unconditional requirement imposed without reference or regard to obtaining an optional exemption from regulation. That is, independent requirements must be met whether or not the generator accumulates hazardous waste. An independent requirement is applicable and enforceable, independent of whether the generator is attempting to obtain an exemption.

A condition for exemption, on the other hand, is a requirement that is contingent in nature, in that it is only necessary to meet in order to obtain an optional exemption from other requirements. As an example, the regulations in § 262.34(a) introduce the conditions of the LQG exemption by stating that the LQG may accumulate hazardous waste on site for 90 days or less without a permit or without having interim status, provided that it meets the conditions listed in that paragraph.

This distinction is relevant because while an entity can “violate” and be penalized for violating an independent requirement, an entity cannot be penalized for not complying with a condition for an optional exemption. Instead, if the entity does not comply with the conditions of the exemption, that exemption no longer applies and the entity becomes subject to full regulation. Violation of an independent requirement, such as an SQG failing to obtain an EPA identification number, can result in a notice of violation and enforcement action for that particular provision. Noncompliance with a condition for exemption, such as an LQG accumulating hazardous waste for more than 90 days, however, can result in an entity losing its conditional status and becoming the operator of a non-exempt storage facility subject to the applicable requirements for storage facilities in parts 124, 264, 265, 267, 268 and 270, and for generators in part 262.

EPA is proposing to define an “independent requirement” as a requirement of any of part 262 that states an event, action, or standard that must occur or be met and that applies without relation to, or irrespective of, the purpose of obtaining a conditional

exemption from a permit or having interim status under § 262.14, 262.15, 262.16, or 262.17.

EPA is proposing to define a “condition for exemption” as any requirement in § 262.14, 262.15, 262.16, or 262.17, that states an event, action, or standard that must occur or be met in order to obtain a conditional exemption from any requirement in parts 124, 262 through 268, or 270, or from any requirement for notification under section 3010 of RCRA.

We will be using these terms throughout this preamble to distinguish between these two types of provisions for generators.

EPA is requesting comment on this proposed change to the regulations, particularly whether it clarifies implementation of the generator regulations by industry and the regulating entities.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

2. Proposed Changes to 40 CFR 262.10(a)

As part of the reorganization of the generator regulations, § 262.10(a), which addresses the purpose, scope, and applicability of the hazardous waste generator regulations, will list which generator provisions are independent requirements and which are conditions for a generator exemption from part 124, from the applicable standards of parts 264 through 268, from the permitting requirements of part 270, and from section 3010 of RCRA.

Specifically, EPA is proposing two changes to § 262.10(a): (1) Stating that a hazardous waste generator is subject to all the applicable independent requirements of part 262 and listing those independent requirements and (2) stating that a generator that accumulates hazardous waste on site is also considered to be a facility storing hazardous waste unless it meets the conditions for one of the generator exemptions in § 262.14, 262.15, 262.16, or 262.17.

a. Independent requirements. As stated above, under the RCRA hazardous waste program, certain regulations are independent requirements and certain regulations are conditions for exemption from RCRA permitting and the interim status standards.

To be clear about the distinctions between these types of standards, EPA is proposing to state at § 262.10(a)(1) that a person who generates a hazardous waste as defined by 40 CFR part 261 is subject to all the applicable independent requirements in the

subparts and sections listed, unless the person is a conditionally exempt small quantity generator (or “very small quantity generator,” in the terminology of the proposed rule) that meets the conditions for exemption in § 262.14. This new addition will reinforce to generators that they must meet these independent requirements whether or not they accumulate hazardous waste on site.

b. Conditional exemption for CESQG, SQG, and LQG. The RCRA hazardous waste generator regulations provide generators that accumulate hazardous waste on site with exemptions from the hazardous waste permitting standards and compliance with interim status standards in 40 CFR parts 264 and 265, provided certain conditions are met.

Therefore, EPA is proposing to state at § 262.10(a)(2) that a generator that accumulates hazardous waste on site is also considered a facility that stores hazardous waste, unless it is excluded because it meets the conditions of being a generator. The paragraph then lists the generator categories and where to find the relevant conditions for each, in § 262.14, 262.16, or 262.17.

These proposed changes to § 262.10 do not constitute substantive changes to the hazardous waste generator regulations. Rather, these changes simply reorganize the independent requirements and conditions for exemption applicable to all hazardous waste generators based on their generator category into one section of the regulations. EPA also believes these changes will reduce confusion for the regulated community in the context of enforcement actions. It has been the Agency’s longstanding position that generators that do not comply with a condition of a generator exemption fail to qualify for the exemption and, if they have not qualified for any other exemption, they would be considered an operating TSDF without a permit and/or in violation of the storage facility operating standards in parts 264 or 265. The Agency believes this proposed reorganization will improve the use of and compliance with the regulations.

EPA is requesting comment on these proposed changes.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The reorganization is discussed in section XIII of this preamble.

3. Proposed Deletion of § 262.10(c)

Section 262.10(c) of the hazardous waste regulations is a provision that describes the requirements for a generator who treats, stores, or disposes of hazardous waste on-site and includes

a list of provisions these generators must comply with. EPA believes that this provision in the regulation is outdated and confusing and can be removed. EPA is proposing to delete and reserve this paragraph.

When § 262.10(c) was initially promulgated on February 26, 1980, the hazardous waste generator regulations distinguished between the generators that sent hazardous waste to be managed off site and those that managed their hazardous waste on site. Generators that sent hazardous waste off site could manage it for 90 days in an accumulation area, but generators that managed hazardous waste on site were expected to manage it under their permits or under interim status regulations. The purpose of § 262.10(c) was to provide the list of requirements that generators managing hazardous waste were required to follow in addition to those permits or interim status requirements.

This distinction meant that the two types of generators had very different standards for the areas where newly generated hazardous waste was managed. Significantly, generators sending hazardous waste off site could easily make physical changes to their accumulation areas, whereas a similar generator managing hazardous waste on site under a permit had to go through the permit modification process to make the same kind of changes. EPA effectively eliminated the distinctions by revising these regulations (45 FR 76624, November 19, 1980 and 47 FR 1248, January 11, 1982). The final rule promulgated in January 11, 1982, made a change to § 262.10(c) that added the generator accumulation provisions at § 262.34 to the list of things a generator who treats, stores, or disposes of hazardous waste on site must comply with. Currently, the Agency does not make this distinction between generators that send waste for treatment off site and those that manage waste on site. This revision is therefore outdated and not well understood and can be deleted and reserved without disruption to the generator hazardous waste regulations.

EPA seeks comment on whether anyone is using this provision or has objection to its removal and what the reasoning for that objection is.

Effect of the Proposed Reorganization: This proposed deletion is not affected by the proposed reorganization.

4. Generators Are Subject To Enforcement of Applicable Requirements and Penalties Under Section 3008 of RCRA if They Fail To Meet the Independent Requirements Made Applicable by the Failure To Obtain a Conditional Exemption (40 CFR 262.10(g))

The existing regulation at § 262.10(g) states that a generator is subject to the compliance requirements and penalties prescribed in section 3008 of [RCRA] if it does not comply with the requirements of that part. However, this paragraph does not expressly state that a generator that is not meeting the conditions of its exemption—and is, therefore, an illegal TSDF—is liable under section 3008 of RCRA for failing to meet the requirements for TSDFs in parts 124, 264 through 268, and 270.

Therefore, EPA is proposing to revise § 262.10(g) to state that a generator is subject to enforcement of the applicable requirements and penalties under section 3008 of RCRA if it fails to meet its applicable independent requirements under part 262: § 262.11 (Hazardous waste determinations and recordkeeping), § 262.12 (Obtaining an EPA identification number), part 262 subpart B (Manifest), §§ 262.30 through 260.33 (Pre-transport) and part 262 subpart D (Recordkeeping and reporting). The new language would further explain that a generator is subject to enforcement of the applicable requirements and penalties under section 3008 of RCRA if it fails to meet the applicable requirements of parts 124, 263 through 268, and 270, including such requirements made applicable when such person is not meeting the conditions of the generator exemption.

EPA is requesting comment on these proposed changes.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

5. Proposed Deletion of Laboratory XL Project Regulations (40 CFR 262.10(j) and Part 262 Subpart J)

The Laboratory XL Project was created for Boston College, the University of Massachusetts, and the University of Vermont, and was finalized in the **Federal Register** on September 28, 1999 (64 FR 53292). Originally, the program was to expire on September 30, 2003. But on June 21, 2006, EPA extended the program and the new expiration date was changed to April 15, 2009 (71 FR 35550). Since the program has now expired, EPA is proposing to remove paragraph (j) from § 262.10, as well as part 262 subpart J.

EPA is requesting comment on this proposed change.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

6. Generators Shall Not Transport to a Non-Designated Facility

The Agency is proposing to add a new provision at § 262.10(a)(3) that would clearly and succinctly state that a generator cannot offer or otherwise cause its waste to be sent to a facility that is not authorized to accept it.

As the Agency has stated numerous times in the development and implementation of the RCRA hazardous waste program, a fundamental aspect of the program is the responsibility placed on the generator of hazardous waste to ensure its hazardous waste is properly managed from cradle to grave. Numerous existing regulatory provisions are designed to ensure that generators send their hazardous waste only to authorized TSDFs or other authorized facilities. See for example, §§ 262.12(c), 262.20(b), 262.40(a). However, from experience with the program, the Agency has found situations where a generator failed to send its hazardous waste to a facility authorized to receive that waste, thus creating both regulatory and potential hazardous waste mismanagement problems. The Agency believes this provision is necessary to ensure generators understand they have this obligation and, for that reason, is placing it in the initial provisions of the generator regulations.

This provision is being added to the regulatory framework and not replacing §§ 262.12(c), 262.20(b), 262.40(a), as those provisions are aimed at other aspects of the generator program (for example, ensuring manifests are properly completed).

The Agency requests comment on adding this new provision.

B. Waste Determinations (40 CFR 262.11)

EPA is proposing to revise the hazardous waste determination regulations at § 262.11 in order to provide a more complete explanation of the regulation and improve compliance by hazardous waste generators. The proposed changes are intended to provide more information about when a waste determination must be made, as well as to better explain the methods and procedures for generators to determine whether they have a listed hazardous waste or a characteristic waste. The proposed changes also address some deficiencies in the current recordkeeping regulations.

Specifically, the proposed changes discussed in this section are the following: (1) Confirming that a generator's waste must be classified at its point of generation and, for wastes potentially exhibiting a hazardous characteristic, at any time during the course of its management when the properties of the wastes may change; (2) revising the language on making a determination for a listed hazardous waste in § 262.11 to explain more fully how generators can make this kind of determination, including use of acceptable kinds of generator knowledge; (3) explaining more completely in the regulations in § 262.11 how a generator should evaluate its waste for hazardous characteristics; (4) moving the independent recordkeeping and retention requirements for hazardous waste determinations currently found at § 262.40(c) into § 262.11 to integrate this provision more directly into the hazardous waste determination regulations; (5) revising the hazardous waste determination recordkeeping regulations to require that SQGs and LQGs maintain records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years, including waste determinations where a solid waste (as defined in § 261.2) is found not to be a RCRA hazardous waste (as defined in § 261.3); (6) revising the hazardous waste determination regulations by copying § 262.40(d) into § 262.11 to address situations where an enforcement action has been initiated and the period of record retention (*e.g.*, three years from when the record was generated) must be extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator; and (7) making clear at the very beginning of § 262.11 that the hazardous waste determination must be accurate.

In addition, EPA is asking for comment in this section on two additional potential changes regarding the accuracy of hazardous waste determinations and the length of time records must be maintained.

Finally, EPA discusses the potential development of an electronic decision making tool for hazardous waste determinations and takes comment on whether that would be a helpful tool to generators.

The revisions proposed at § 262.11 are designed to improve compliance by generators in making a hazardous waste determination for their solid wastes. To a great extent, the success of the RCRA hazardous waste regulatory program

begins with and relies on generators making this determination. Failure to make an accurate hazardous waste determination may lead to mismanagement of the waste, with potential adverse consequences to human health and the environment. As described below, generators may have a difficult time making an accurate hazardous waste determination for a variety of reasons.

Many of the proposed changes at § 262.11 derive from policy statements and clarifications the Agency has made through the years in FR notices, guidance documents, and policy letters to help explain how hazardous waste determinations should be made. The proposed changes also derive from issues identified in EPA's 30 years of experience implementing the RCRA hazardous waste program.

1. Background

The regulations at § 262.11 require generators of solid waste (as defined at § 261.2) to determine whether their waste is also a hazardous waste. Under RCRA, a solid waste may be hazardous if it is either listed as hazardous or exhibits a hazardous waste characteristic. Listed hazardous wastes are wastes that the Agency has specifically evaluated and determined may present a risk to human health and the environment, if improperly managed. Such wastes can be generated by specific processes of particular industries or by many different types of industry (*e.g.*, spent degreasing solvents) or hazardous commercial chemical products being discarded as surplus, off specification, or for another reason. Wastes that exhibit any of the four hazardous characteristics (ignitability, corrosivity, reactivity, toxicity) are also classified as hazardous. Hazardous wastes are subject to a number of handling and disposal requirements intended to prevent them from damaging human health or the environment.

Once a generator has determined from § 261.2 that it has generated a solid waste, the regulations at § 262.11 currently provide the following method for a generator to determine if a waste is a hazardous waste:

(1) It should first determine if the waste is excluded from regulation under the exclusions found in 40 CFR 261.4.

(2) It must then determine if the waste is listed as a hazardous waste in subpart D of 40 CFR part 261. Note that even if the waste is listed, the generator still has an opportunity under 40 CFR 260.22 to demonstrate to the Administrator that the waste from his particular facility or operation is not a hazardous waste.

(3) For purposes of compliance with the land disposal restrictions in 40 CFR part 268, or if the waste is not listed in subpart D of 40 CFR part 261, the generator must then determine whether the waste is identified in subpart C of 40 CFR part 261 by either:

(A) Testing the waste according to the methods set forth in subpart C of 40 CFR part 261, or according to an equivalent method approved by the Administrator under 40 CFR 260.21; or

(B) Applying knowledge of the hazard characteristic of the waste in light of the materials or the processes used.

(4) Finally, if the waste is determined to be hazardous, the regulations state that the generator must refer to parts 261, 264, 265, 266, 267, 268, and 273 of this chapter for possible exclusions or restrictions pertaining to management of the specific waste.

A generator's responsibility begins with applying due diligence through knowledge of its processes, feedstocks, and wastes generated, and/or testing to make an accurate hazardous waste determination for the solid waste it has generated (see § 261.2). The Agency considers the application of the above information (*e.g.*, knowledge of the production processes, feedstocks, and wastes generated and/or information from testing) to be acceptable types of generator knowledge. Failure to consider any relevant types of knowledge could be viewed critically if a situation arose in which a particular generator's waste determination came under scrutiny. Once a determination has been made that a generator's solid waste is a hazardous waste, then the generator can initiate the process of quantifying the total amount of hazardous waste generated in a calendar month to determine its generator category, and from that, determine the regulations with which it must comply. If an incorrect hazardous waste determination is made (*i.e.*, a hazardous waste is identified as non-hazardous), there is a strong possibility that the waste will not be managed appropriately, potentially leading to environmental releases and damage.

From experience with the waste determination program, the Agency has found that there are a number of situations in which generators may misclassify their wastes. In some cases, generators overlook certain wastes that are unrelated to their production processes, discarding them in the trash without realizing that they have discarded a hazardous waste. In other cases, generators may not understand how the hazardous waste characteristics or listings regulations may apply to the waste. There are also instances in which

generators have not even known that RCRA and its regulations apply to their wastes.

States have also identified difficulties generators have in making hazardous waste determinations as a concern. A study conducted by the State of New Hampshire found that generators often overlooked hazardous wastes they had generated apart from their main production operations, for example, solvent-contaminated wipes and aerosol cans.^{39 40}

The Georgia Department of Natural Resources (GADNR) has also highlighted this problem in one of its publications, stating “Many solid waste streams at facilities tend to be overlooked as hazardous wastes because the solid waste usually does not resemble what one would think a hazardous waste looks like [*i.e.*, wastes that are not a liquid chemical waste (rags, absorbents, or filters); or wastes that are not directly generated in manufacturing process (universal wastes, computers, electronics, or sludge in drains or sumps); wastes that are newly regulated (electronics); or wastes that are similar to household hazardous wastes (mercury thermometers, aerosol cans, batteries, and lamps), which are excluded as hazardous waste in accordance with § 261.4(b)(1).]”⁴¹

The importance of generators making an accurate hazardous waste determination cannot be over-emphasized. In 2013, a contractor for EPA completed a third-party program evaluation of the hazardous waste determination regulations to better understand the reasons generators may have difficulty making reliable hazardous waste determinations.⁴² This study involved examining national compliance statistics associated with hazardous waste determinations and meeting with representatives of three state programs—Texas, Minnesota, and Colorado—and the regulated community in those states. Questions

³⁹ A final rule for solvent-contaminated wipes was published in the *Federal Register* on July 31, 2013. This rule provides an exclusion from the definition of solid waste for solvent-contaminated wipes that are recycled and an exemption from the definition of hazardous waste for discarded wipes provided specific conditions are met (78 FR 46447).

⁴⁰ Summary of Waste Determination Meetings with VT and NH State Officials on September 27–28, 2010.

⁴¹ “10 Most Common Hazardous Waste (RCRA) Violations in Georgia: 40 CFR 262.11 “Hazardous Waste Determination,” Georgia Department of Natural Resources https://epd.georgia.gov/sites/epd.georgia.gov/files/related_files/site_page/guidehwdet.pdf.

⁴² Hazardous Waste Determination Program Evaluation, IEC, April 2013. <http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf>.

focused on rates of non-compliance with the hazardous waste determination regulations, obstacles to generator compliance, the role of state waste management programs and the role of third parties, such as environmental services companies or industry trade organizations. The interviewers also solicited stakeholder recommendations for improvement of the waste determination regulations.

The evaluation reported the following findings. First, the average non-compliance rate with the RCRA hazardous waste determination regulations across the United States is approximately 34 percent. This figure is based on an analysis of hazardous waste determination violations during EPA compliance inspections recorded in EPA’s RCRAInfo data system from 2001 to 2011.⁴³ These results are supported by the results of other EPA analyses. For example, in a review of inspection reports of the foundry sector by EPA’s Office of Compliance, EPA found 26 of 69 facilities, or 38 percent, with hazardous waste determination violations.⁴⁴ Additionally, an EPA analysis of inspections at CESQG facilities conducted by the State of Kansas inspectors for the 2009–2012 time period found a waste determination non-compliance rate of 21 percent, and an EPA analysis of inspections of Iowa CESQG facilities conducted by EPA Region 7 inspectors for the same time period found a waste determination violation rate of 36 percent.^{45 46}

Probably the most comprehensive analysis involved examining all compliance evaluation inspections of LQs, SQGs, and CESQGs conducted by both the EPA Regions and the states for fiscal years 2008–2012.⁴⁷ Of the 62,003 compliance evaluation inspections conducted during that time period, EPA and the states found 8,148 waste determination violations, resulting in a non-compliance rate of 13.1 percent. While the estimates of waste determination violation rates vary somewhat across the studies examining them, all of them identify violation rates that are significant.

The evaluation also discussed a number of implementation challenges

⁴³ RCRAInfo is EPA’s national repository for hazardous waste generation and management data.

⁴⁴ “Review of RCRA Inspection Report Practices,” May 2007.

⁴⁵ EPA administers Iowa’s hazardous waste program.

⁴⁶ Iowa CESQG Inspections 2009–2012, October 2012; Kansas CESQG Inspections 2009–2012, December 2012.

⁴⁷ State Compliance Evaluation Inspections (CEI) for FY 2008–2012.

that lead to non-compliance with the hazardous waste determination regulations. The evaluation identified 30 recurring themes that describe various obstacles, challenges, and factors that influence hazardous waste generators’ compliance with the hazardous waste determination regulations. These 30 themes fall into three overarching categories: (1) Challenges related to the regulations; (2) challenges related to generators; and (3) challenges related to regulatory agencies.⁴⁸

The Agency is proposing changes intended to address the two challenges identified that are related to the regulations. These are (1) difficulty understanding the regulations as written and (2) difficulty interpreting and applying the regulations to specific circumstances. The proposed changes to § 262.11 are intended to elaborate on the meaning and intent of these regulations to make them easier for generators to understand. We believe the better understanding resulting from these changes will also make it easier to appropriately apply the requirements to a broader range of specific circumstances.

2. Improvements to the Existing Hazardous Waste Determination Regulations

EPA’s evaluation of the waste determination regulatory program noted that improving compliance in making accurate waste determinations is a multi-faceted problem. The Agency believes improving the clarity of the regulatory text is an important step because it represents the foundation from which all subsequent EPA and state outreach, technical assistance and enforcement efforts begin. In this regard, EPA identified several particular areas for possible improvements to the current regulations:

—Confusion about where and when to make a hazardous waste determination, particularly when further management of that material may result in a change in the hazardous waste determination.

—§ 262.11(b), which relates to whether or not a solid waste is a listed hazardous waste, does not describe how a generator should determine if the material in question is a listed hazardous waste.

—§ 262.11(c) states that a generator can either test its waste or use process knowledge or knowledge about its waste to determine whether a solid waste is a characteristic hazardous waste.

⁴⁸ Hazardous Waste Determination Program Evaluation, IEC, April 2013. <http://www.epa.gov/evaluate/pdf/waste/haz-waste-determination.pdf>.

However, there is little guidance in the regulation on using knowledge to classify waste.

—The existing regulatory text notes that test methods are included in the hazardous characteristic definitions in subpart C of part 261, but does not note that tests are not provided for all aspects of the hazardous characteristics identified there.

The Agency has provided guidance on these issues over the past 30 years and through these proposed regulatory revisions intends to incorporate key aspects of that guidance into the regulatory language.

Finally, EPA is proposing to address deficiencies in the recordkeeping for hazardous waste determinations. These deficiencies include both a lack of specificity regarding what materials used in a hazardous waste determination must be maintained and lack of a specific statement that the independent requirement to maintain records is extended when there is an unresolved enforcement action. In addition, there are large number of hazardous waste determinations for which records are not being kept because the generator determines that the material in question is not a hazardous waste. Failure to maintain records in these cases makes it difficult for regulatory agencies to determine how a generator made the determination and to quickly assess whether the determination is accurate.

3. When and Where To Make a Hazardous Waste Determination

To respond to generator concerns about identifying the most appropriate point at which to make a hazardous waste determination, EPA is proposing to revise § 262.11 to add a paragraph (a), which would state that a hazardous waste determination must be made at the point of waste generation (*i.e.*, when the material becomes a solid waste).⁴⁹ The RCRA statute makes clear that the term “hazardous waste generation” means the act or process of producing hazardous waste.⁵⁰ By requiring that the initial hazardous waste determination be made at the point of generation, the regulation clarifies that the determination cannot be made downstream in the process where other materials could be mixed with the waste or where the waste changed its physical characteristics simply as a result of time elapsing affecting the hazardous waste determination. This standard must be

met even in instances in which another entity, such as a waste management facility, makes the waste determination on behalf of the generator.

The 1980 preamble to the original hazardous waste regulations explicitly discussed this scenario, stating that a solid waste which is a hazardous waste because it is listed in part 261 subpart D must begin to be managed as a hazardous waste when it first meets the subpart D listing description. The preamble explains that most of the hazardous wastes listed in §§ 261.31 and 261.32 of subpart D (the F-list and the K-list) are process residues, emission control dusts, or wastewater treatment sludges and the point in time when they are created is generally well defined. For other hazardous wastes, such as spent solvents or those hazardous wastes listed in § 261.33, the point at which they meet the listing description is somewhat less well defined, but generally occurs when their intended use has ceased and they begin to be accumulated or stored for disposal, re-use, or reclamation. The preamble then goes on to provide several examples illustrating how this provision would operate in practice (45 FR 33095–96, May 19, 1980).

The 1980 regulatory preamble also addressed this issue for characteristic hazardous waste. In defining what waste is considered hazardous, § 261.3(b)(3) states that “a solid waste becomes a hazardous waste . . . when the waste exhibits any of the characteristics.” EPA elaborated on this regulatory definition in 1980 by noting that “paragraph (b) provides that a solid waste is a hazardous waste whenever it exhibits one or more of the characteristics. As a practical matter, this means that persons handling solid waste must determine whether they meet the characteristics whenever the management of the waste would be subject to EPA’s part 262–265 regulations” (45 FR 33095, May 19, 1980).

This implies that a generator’s waste characterization obligations may continue beyond the determination made at the initial point of generation. In the case of a non-hazardous waste that may, at some point in the course of its management, exhibit a hazardous waste characteristic, there is an ongoing responsibility to monitor and reassess its regulatory status if changes occur that may cause the waste to become hazardous. Thus, the generator must monitor the waste for potential changes if there is reason to believe that the waste may physically or chemically change during management in a way that might cause the waste, or a portion of the waste, to become hazardous.

The preamble to the final rule for the toxicity characteristic reiterated that the current rules require that the determination of whether a waste is hazardous is to be made at the point of its generation (*i.e.*, when the material becomes a solid waste).⁵¹ In the preamble to that rule, EPA stated that it believes that the determination of the regulatory status of a waste at the point of generation continues to be appropriate and that EPA was retaining the existing approach of requiring that a determination be made at the point of generation (55 FR 11830, March 29, 1990).

Thus, for determining whether a waste exhibits a hazardous characteristic, generators of solid waste are required to make a hazardous waste determination at the initial point of generation, in the form the waste is generated in (*i.e.*, “as is”), following the procedure described in § 262.11, which allows use of generator knowledge and/or testing, as appropriate. A generator’s hazardous waste determination at the initial point of generation is critical to ensure proper management of the waste not only by the generator, but also by transporters and TSDFs who rely upon the generator’s determination to allow them to safely manage the waste and provide appropriate treatment.⁵²

As an example, in a letter regarding a waste consisting of solvents mixed with water that separates and becomes biphasic over time, the Agency stated that in this situation, the generator must make the hazardous waste determination not only at the initial point of generation, but also after the waste separates into phases. This letter went on to say that a generator’s responsibility to make a hazardous waste determination may continue beyond the determination made at the initial point of generation. In the case of a nonhazardous waste that may, at some point in the future, exhibit a hazardous waste characteristic, there is an ongoing responsibility to monitor and reassess if changes occur that may cause the waste to become hazardous.

Again, if there is reason to believe that the waste may physically or chemically change during management in a way that might cause the waste, or portion of the waste, to become hazardous, the generator must monitor the waste for these changes. The generator should also notify any subsequent handlers of the waste so they are aware that they

⁵¹ A material must be a solid waste before it can be a hazardous waste under RCRA.

⁵² Note that making a solid and hazardous waste determination is also applicable for the exemptions identified at §§ 261.2 and 261.4 since such exemptions negate the determination.

⁴⁹ A material must be a solid waste before it can be a hazardous waste under RCRA.

⁵⁰ See Solid Waste Disposal Act, Sec. 1004, page 9.

should also monitor the waste for changes. This is analogous to and consistent with situations the Agency has discussed in the past such as when, over time, sludges that exhibit the characteristic of toxicity settle out of nonhazardous wastewaters managed in surface impoundments.⁵³

Therefore, to clarify that hazardous waste determination must be made at the point of generation, the Agency is proposing to revise the regulations at 40 CFR 262.11 by adding a new paragraph (a) that would state that a hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste.

This addition of paragraph (a) would change current § 262.11(a) into § 262.11(b) and bump all subsequent paragraphs in that section.

EPA requests comments on the proposed changes to § 262.11 and in particular is soliciting comment on whether the proposed new language is sufficient to improve the existing regulatory text and better assist generators in making effective hazardous waste determinations. Additionally, EPA is interested in comments regarding improvements the Agency could make to the proposed regulatory text.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

4. Determining Whether a Waste Is a Listed Hazardous Waste

a. Identifying listed hazardous wastes. As a general matter, determining whether a waste is a listed hazardous waste consists of comparing the waste that the generator generates to the hazardous waste listing descriptions in §§ 261.31 through 261.33. For many wastes, identifying the origin of the waste is sufficient to determine whether it is a listed waste and this determination is rather straightforward. However, this is not always the case. Sometimes additional information about the waste, the process that generated it (including production feedstocks), and the listing regulations is needed to make a reliable determination, including the following: (1) The regulatory language of

the hazardous waste listing; (2) the regulatory intent of the original hazardous waste listing (as evidenced by FR notices and technical support documents and interpretative letters from the original listings); and (3) facts specific to the waste stream at issue.⁵⁴

These three types of information can be considered as acceptable types of generator knowledge about a waste stream for making a hazardous waste determination. A November 20, 1997, **Federal Register** notice elaborates on the use of knowledge to make a listing determination—that is, determining whether a waste is a listed hazardous waste can be accomplished by comparing information on the waste stream origin with the RCRA listings set forth in 40 CFR part 261 subpart D. These listings are separated into four major categories or lists and are identified by EPA hazardous waste numbers starting with the letters K, F, P, or U, depending on the category of the waste. The hazardous waste numbers are associated with a specific waste description, specific processes that generate the wastes, or certain chemical compounds. For example, EPA hazardous waste number K103 is defined as “Process residues from aniline extraction from the production of aniline.” A generator that produces such residues should know, without any sampling or analysis, that these wastes are “listed” RCRA hazardous wastes by examining the K103 hazardous waste description in the hazardous waste lists and comparing this with the production process that generated the waste.

Other hazardous waste listings describe wastes generated from generic processes that are common to various industries and activities. They include, for example, waste solvents (e.g., EPA hazardous waste numbers F001–F005), which are often used in the degreasing or cleaning processes of manufacturing operations, and thus are widely generated. EPA hazardous waste number F001 is a listed waste from a non-specific source that is defined by providing a list of spent halogenated solvents at a particular concentration before use and stating that they are F001 when used in degreasing. Because this listed waste is from a non-specific source, the generator would compare this listing description to any industry

operation where solvent degreasing is conducted to determine whether this waste meets the specific listing description.

Note that these spent solvents are regulated as hazardous under RCRA, but only if the total of all the solvent constituents before use is greater than or equal to ten percent of the material’s volume. This adds a layer of complexity to the hazardous waste determination and requires that the generator have knowledge of the composition of the unused solvent before the waste is generated.

Finally, the hazardous waste regulations include the “derived from” and “mixture” rules, which state that any solid waste derived from the treatment, storage, or disposal of a listed RCRA hazardous waste, or any solid waste mixed with a listed RCRA hazardous waste, respectively, is itself a listed RCRA hazardous waste until delisted (see § 261.3(a)(2)(iv) and § 261.3(c)(2)(i), respectively) (62 FR 62082, November 20, 1997). The exception to these rules is when the waste is listed solely because it exhibits a hazardous waste characteristic, but the particular waste in question no longer exhibits any hazardous characteristic (§ 261.3(g)).

b. Proposal to provide further explanation in regulatory text about listed waste determinations. The current regulation at § 262.11(b) provides minimal information to generators for determining whether their waste is a listed hazardous waste. EPA is proposing that this paragraph be expanded and that it be redesignated as § 262.11(c) to make room for existing paragraph (a) of § 262.11, which would be redesignated as paragraph (b) under the proposed new regulatory framework at § 262.11 and which addresses the generator determination of whether the solid waste it has generated is excluded from regulation under 40 CFR 261.4.

The new § 262.11(c) would identify the types of acceptable information that the generator could consider in evaluating its waste against the hazardous waste listing descriptions and would assist them in determining if they have generated a listed hazardous waste. This proposed paragraph would state that if the waste is not excluded under 40 CFR 261.4, the person must then use knowledge of the waste to determine if the waste meets any of the listing descriptions under subpart D of 40 CFR part 261. Acceptable knowledge that may be used in making an accurate determination as to whether the waste is listed includes, but is not limited to, waste origin, composition, the process producing the waste, feedstock, and

⁵³ Letter from Betsy Devlin, Director of EPA’s Materials Recovery and Waste Management Division, to Gary Jones, Printing Industries of America, November 20, 2012, RCRA Online 14834.

⁵⁴ Note that once listed at §§ 261.31–33 wastes remain listed as hazardous wastes unless and until they are delisted in accordance with §§ 260.20 and 260.22 or unless they are specifically excluded from § 261.3, regardless of their actual composition and constituent concentrations even if the manufacturing and/or treatment processes do not use any of the constituents for which the wastes were listed.

other relevant information. If the waste is listed, the person may file a delisting petition under 40 CFR 260.20 and 260.22 to demonstrate to the Administrator that the waste from this particular site or operation is not a hazardous waste.

EPA requests comments on these proposed modifications to § 262.11(c).

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization, but the contents of the current § 262.11(b) are proposed to be revised and moved to § 262.11(c) to account for the proposed inclusion of a new § 262.11(a).

5. Determining Whether a Waste Is a Characteristic Hazardous Waste

The RCRA hazardous waste regulations identify four characteristics that can result in a hazardous waste classification: ignitability, corrosivity, reactivity, and toxicity. Wastes exhibiting any of these characteristics have EPA hazardous waste numbers starting with the letter “D” and the regulations defining these characteristics are at §§ 261.20 through 261.24. The current § 262.11 regulations identify two methods for determining whether a solid waste is hazardous because it exhibits a hazardous characteristic: (1) Testing of the waste or (2) using knowledge of the hazard characteristic and the materials and processes used in generating the waste. Further, even if a waste is a listed hazardous waste, the regulations require the generator to determine whether it also exhibits a hazardous characteristic to ensure that all waste treatment obligations under part 268 are met. This ensures that the waste can be treated to mitigate hazards posed by chemicals or properties for which it was listed, and also any characteristic hazards, which may be different from hazards that are the basis for listing.

a. Use of testing to identify waste exhibiting a hazardous characteristic. The current regulations at §§ 261.20 through 261.24 describe two different ways to determine whether a solid waste is a hazardous waste because it exhibits certain characteristics. In some cases, the regulations identify specific test methods, the results of which can be used directly to determine whether the waste exhibits that characteristic (although testing is not required, and knowledge may be used). These include for example, the pH test for the corrosivity characteristic, the flashpoint test for liquids for the ignitability characteristic, and the toxicity characteristic leaching procedure (TCLP) for the toxicity characteristic. Other hazardous characteristics are

defined narratively, such as the definitions for ignitable solids or oxidizers in the ignitability characteristic, and the reactivity characteristic. When there is no regulatory test, then knowledge of the waste’s origin, production processes, feedstocks, chemical composition, and other relevant information is acceptable and necessary for determining whether wastes exhibit one of these characteristics. Testing that may illustrate and support identification of the properties of the waste (even though it is not part of the regulation) can be part of the generators’ knowledge of the waste.

The proposed language associated with testing at § 262.11(d)(1) specifies that generators testing their waste must obtain a representative sample for testing, as defined at § 260.10 and as required by all of the hazardous characteristic regulations. For those characteristics that include a specific test as part of the regulation, the results of that test, when properly performed and compared with regulatory thresholds, are definitive for determining whether the waste is hazardous. The tests specified by the regulations are available in EPA’s “Test Methods for Evaluation Solid Waste, Physical/Chemical Methods,” EPA Publication SW-846. This document which contains all of OSWER’s analytical methods, is available on EPA’s Web site at: <http://www.epa.gov/epawaste/hazard/testmethods/index.htm>.

When evaluating a waste for one of the hazardous characteristics for which there is a regulatory test, generators are not required to use the test provided the generators’ knowledge about the waste is adequate to make a reliable determination about the RCRA status of the waste, as discussed in the next section. However, if a disagreement arises between a generator and an inspector about whether a particular waste is hazardous, we would recommend that the generator use the regulatory test, since the results of the test, when properly performed, should resolve such a disagreement.

For those characteristics that do not include a specific test, but provide a narrative definition, the generator can use appropriate tests, such as those identified in SW-846 that identify hazardous properties as part of their knowledge about the waste to help determine whether the waste exhibits the hazardous waste characteristic. In addition, test methods used by DOT, the National Fire Protection Association, or other third-party testing organizations may be useful or relevant for evaluating

a particular waste. However, the generator would need to show the relevance of the test to the waste evaluation.

The Agency has discussed the use or requirement of testing in various **Federal Register** notices, guidance documents, and letters. In promulgating the toxicity characteristic regulations in 1990, EPA considered whether to require TCLP testing. However, the Agency determined that the flexibility of the current approach resulted in a more effective and practical program overall and that liability for incorrect determinations would provide a strong incentive for generators to not misclassify their wastes as non-hazardous (55 FR 11829–30, March 29, 1990). In a 1992 letter, the Agency re-emphasized that generators are not required to test their waste to determine whether it is hazardous. As part of that letter, the Agency made clear that to ensure proper handling and treatment, the generator must identify all the hazardous characteristics a waste may exhibit as identified in part 261 subpart C.⁵⁵ In another letter, the Agency discussed the importance of testing a representative sample of the waste, as required by the hazardous characteristics regulations.⁵⁶ The introductory chapters (1–13) of SW-846 provide guidance on a number of important analytical issues, including development of sampling plans and sampling methods, as well as quality control and an overview of the different types of methods in the guidance.

b. Use of knowledge to identify waste exhibiting a hazardous characteristic. As we discussed previously with respect to the identification of listed hazardous wastes, EPA is also proposing to modify § 262.11 to include the acceptable types of information that a generator can consider when applying generator knowledge for making hazardous waste determinations for potentially characteristic hazardous waste. Much of this information has been discussed in **Federal Register** notices and other guidance documents over the past 30 years.

Specifically, several FR notices discuss what constitutes “process knowledge” for making a hazardous waste determination and include the following potential sources: (1) Waste analysis data or studies on wastes generated from processes similar to that

⁵⁵ Letter from Sylvia Lowrance, Director of EPA’s Office of Solid Waste to Basil Constantelos, Safety-Kleen, October 28, 1992, RCRA Online 13570.

⁵⁶ Letter from Sylvia Lowrance, Director of EPA’s Office of Solid Waste to James Maes, Blue Beacon International, Inc., May 1, 1991, RCRA Online 11603.

which generated the original waste;⁵⁷ (2) waste analysis data obtained by TSDFs from the specific generators that generated the waste and sent it off site, and (3) waste analysis data obtained by generators or TSDFs from other generators, TSDFs, or areas within a facility that test chemically identical wastes.⁵⁸ In addition, information about chemical and physical properties of manufacturing feedstocks or product contained in Material Safety Data Sheets (MSDS), or Safety Data Sheets (SDS) under OSHA's regulations implementing the UN Global Harmonized System of Classification and Labelling of Chemicals (GHS), or other reliable data sources may be used to assist the generator in determining whether any of the product's constituents or properties would make it a characteristic waste, when discarded.⁵⁹ Also, an FR notice from 2003 identifies still other information that the Agency has considered appropriate and useful in using knowledge to classify waste, including special handling of waste by the generator to temporarily prevent it from exhibiting a hazardous characteristic (e.g., keeping it either wet or dry to prevent reaction to air or water, respectively); testing using non-regulatory tests that may illustrate some of the waste's properties; classification under certain Department of Transportation hazardous material designations that may be similar to or overlap with RCRA hazardous characteristics, as well as identification of environmental damage attributable to mismanagement or disposal of the waste.⁶⁰⁶¹ All of the above examples are considered as acceptable types of knowledge that can be used by a generator.

Some states have also provided guidance to their generators on some of the challenges of only using process knowledge. For example, the Connecticut Department of Energy and Environmental Protection notes that although knowledge of process information can be very useful (especially in identifying hazardous constituents that are known to be

present), it may not always be adequate to fully and properly characterize a waste. In particular, knowledge of the process may not account for factors such as trace contaminants that may not be listed on an MSDS (only chemicals present at concentrations greater than 1% are typically identified), contaminants introduced during use, and cross-contamination from other wastes. As a result, some sampling may be required by the state to properly characterize a waste.⁶²

Similarly, the Georgia DNR has highlighted some of the challenges of only using process knowledge. In particular, a GADNR publication states, "Using [process] knowledge alone to make a hazardous waste determination may not always be adequate due to the variability of the waste, or the lack of knowledge of chemical processes in generating the waste. In those cases where the waste generated is variable, generators may choose to make a determination that the waste is hazardous waste rather than testing the waste each time it is generated. In addition, in the case of a hazardous waste that is always hazardous, but is characteristic for certain constituents at times, but not at others, the generator may choose to be inclusive of all potential waste codes, rather than test the waste each time it is generated. If the generator with a variable waste chooses not to treat the waste as described above in this paragraph, the waste must be tested as generated."⁶³

The Georgia DNR has also issued useful guidance for its generators regarding the testing and recordkeeping for waste, stating that, "If test methods are used to determine if the waste exhibits a characteristic, a description of how the waste was sampled to obtain a representative sample and copies of the analytical results for that sample should be included as documentation of the hazardous waste determination. The generator may apply knowledge of the waste and the generation process to determine which constituents/parameters to include in analyses, as well as where and when sampling is most appropriate. However, if the full suite of analyses is not applied, the generator must have sufficient documentation to demonstrate why only

certain analyses were applied, and not all. Adequate documentation includes a list of constituents/chemicals that make up the waste, their physical and chemical properties, the effects of the process on the product/materials in the waste, and whether the product/material picks up additional hazardous constituents (contaminants) in the process; all of which provide knowledge as to what constituents should be included in the analyses."⁶⁴ Other states have also issued guidance illustrating the need for generators to understand the wastes they generate and to consider all factors affecting waste composition and properties in making hazardous waste determinations.

c. Proposal on using process knowledge. In consideration of the above discussion and to better assist generators in making hazardous waste determinations, EPA is proposing to revise the regulations associated with using knowledge to identify waste exhibiting a hazardous characteristic currently found at § 262.11(c)(2). Under this proposed rule, § 262.11(c)(2) would move to § 262.11(d)(2) and would identify various types of information that EPA has identified in the past as potentially relevant and acceptable for making a RCRA waste determination, including information about chemical feedstocks and other inputs to the production process; knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the processor or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents.

A test other than a test method set forth in subpart C of 40 CFR part 261, or an equivalent method approved by the Administrator under 40 CFR 260.21, is also acceptable and may be used as part of a person's knowledge to determine whether a solid waste exhibits a characteristic of hazardous waste. However, such tests do not, by themselves, provide definitive results and the generator may need to identify why the test is relevant.

The Agency requests comments on the proposed changes associated with revising § 262.11(c) and moving it to

⁵⁷ 62 FR 62081-2, November 20, 1997; 58 FR 48111-12, September 14, 1993.

⁵⁸ 62 FR 62081-2, November 20, 1997.

⁵⁹ Letter from Matt Hale, Director of EPA's Office of Solid Waste, to Michael Beckel, 3E Company, June 6, 2008, RCRA Online 14790, and 68 FR 59940, October 20, 2003.

⁶⁰ 68 FR 59939-40, October 20, 2003.

⁶¹ Test methods developed by the UN Committee on Transport of Dangerous Goods, the National Fire Protection Association, or others may be useful and relevant for evaluating a particular waste. However, the generator must show the relevance of the test to waste evaluation.

⁶² See Connecticut Department of Environmental Protection Web site, Hazardous Waste Determinations/Knowledge of Process at http://www.ct.gov/deep/cwp/view.asp?a=2718&q=325422&deepNav_GID=1967.

⁶³ "10 Most Common Hazardous Waste (RCRA) Violations in Georgia: 40 CFR 262.11 "Hazardous Waste Determination," Georgia Department of Natural Resources https://epd.georgia.gov/sites/epd.georgia.gov/files/related_files/site_page/guidehwdet.pdf.

⁶⁴ "10 Most Common Hazardous Waste (RCRA) Violations in Georgia: 40 CFR 262.11 "Hazardous Waste Determination," Georgia Department of Natural Resources https://epd.georgia.gov/sites/epd.georgia.gov/files/related_files/site_page/guidehwdet.pdf.

§ 262.11(d). In particular, EPA requests comment on whether the proposed language is sufficient to improve the existing regulatory text and better assist generators in making more effective hazardous waste determinations or whether other improvements should be made to the proposed regulatory text.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization, but the contents of current § 262.11(c) are being revised and bumped to § 262.11(d) to account for the new § 262.11(a).

6. Documenting and Maintaining Records for Hazardous Waste Determinations

The Agency is proposing to make one organizational change and several revisions to the recordkeeping provisions associated with making a hazardous waste determination, a provision found currently at § 262.40(c). Section 262.40(c) currently states that a generator must keep records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. This independent recordkeeping requirement is applicable to SQGs and LQGs only. CESQGs are not affected by this section.

First, the Agency is proposing that this paragraph be moved to § 262.11(e) to integrate this provision with the hazardous waste determination regulations in that section. Additionally, EPA is proposing to revise the wording to better articulate the types of information acceptable to making an accurate hazardous waste determination that must be maintained and to emphasize the importance of this section.

These records must include, but are not limited to, the following types of information that have been used by the generator in making the waste determination: The results of any tests, sampling, or waste analyses; records documenting the tests, sampling, and analytical methods used and demonstrating the validity (or quality assurance/quality control) and relevance of such tests; records consulted in order to determine the process by which the waste was generated, information on the composition of the waste and the properties of the waste; and records which explain the basis for the generator's determination as described at § 262.11(d)(2).

Second, the Agency is also restating that these records must be maintained for at least three years from the date that the waste was last generated by the

facility and also stating that should the generator be involved in any unresolved enforcement action regarding a waste determination, then the periods of record retention are extended automatically or if requested by the Administrator. An "unresolved enforcement action" means any formal administrative, civil or criminal enforcement action which has been filed or issued against a generator by EPA or authorized state pursuant to RCRA subchapter III or VII and for which all rights of appeal have not been exhausted.

Additionally, EPA is proposing to revise the wording of the section to better articulate the types of waste determination information that must be maintained and to emphasize the importance of this section. In an effort to improve compliance with the hazardous waste determination regulations, and therefore improve environmental protection, EPA is proposing to revise the recordkeeping regulations to require small and large quantity generators making a waste determination to document and maintain records of all their hazardous waste determinations, including determinations where a solid waste is found not to be a hazardous waste.⁶⁵ In many respects, this proposed change also relates to the above proposed change in the regulations to clarify that generators must use due diligence in making a hazardous waste determination by applying process knowledge and/or testing results to the solid waste they generated. The Agency believes it is very important that generators make accurate hazardous waste determinations to avoid potential adverse impacts to human health and the environment from the possible mismanagement of hazardous waste. Therefore, we believe the benefits to human health and the environment far outweigh the minimal costs of requiring SQGs and LQGs to document hazardous waste determinations, including determinations where the solid waste was found not to be a hazardous waste.

CESQGs would not be affected by this change. However, maintaining a copy of their hazardous waste determinations may be beneficial to a CESQG to support any questions posed during an inspection by EPA or state inspector, as well as to support their waste generator category. In analyzing Kansas and Iowa inspection data of CESQG facilities, instances were found where the

generator failed to make an accurate hazardous waste determination resulting in the generator moving into a higher generator category and becoming subject to the regulations of either an SQG or LQG.

The hazardous waste determination process is the gateway to the hazardous waste generator regulatory program and, to a great extent, its ultimate success. If a generator can accurately identify the types of hazardous wastes it generates, it can then identify the applicable regulations it must comply with to ensure safe management of that waste. Conversely, if a generator fails to make an accurate hazardous waste determination, that failure can potentially lead to the mismanagement of hazardous waste and environmental damages. In addition, the generator could then be cited in an enforcement action not only for that violation, but also for failing to comply with other generator regulations, including operating without a RCRA permit (see § 262.34(a) and (d)).

The Agency made this point clear when it initially promulgated the hazardous waste generator rules in February 1980, where it stated, "The determination is the crucial, first step in the regulatory system, and the generator must undertake this responsibility seriously" (45 FR 12727, February 26, 1980). Unfortunately, as previously discussed, there is a high rate of noncompliance with the hazardous waste determination regulations.

Under the current regulations at § 262.40(c), a generator is required to document and maintain records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage, or disposal. When an inspector sees a container or other waste management unit, that inspector has the authority to ask the generator how it determined the regulatory status of the waste, and the generator should be able to articulate how that determination was made. In many instances, the inspector will also ask to see any documentation supporting a questionable determination that a material is not a hazardous waste in order to understand how the generator applied process knowledge or the results of testing the waste to support its non-hazardous waste determination.

The Agency strongly believes that documentation must be maintained for waste determinations, not only when a solid waste is a hazardous waste but also when a solid waste is determined by the generator to not be a hazardous

⁶⁵ As will be discussed later in this section, the Agency does not intend for this provision to apply to those generators that generate a solid waste that clearly has no potential to be a hazardous waste.

waste. The primary obligation for generators is to accurately determine whether or not a solid waste is a hazardous waste. Requiring documentation of this determination, regardless of the outcome, is critical in ensuring compliance with the current hazardous waste determination regulations.

The requirement that a generator maintain records of determinations that a solid waste is not a hazardous waste was originally discussed in the preamble to the 1978 proposed rule for the hazardous waste regulatory program. In fact, the Agency proposed the following at 40 CFR 250.10(d)(1)(iii): “Generators who determine that their waste is not hazardous shall retain copies of the evaluation performed and shall repeat the necessary evaluation or testing when there is a significant change in their feed material or operations which may alter the test results.” (43 FR 58955, December 18, 1978). In the February 26, 1980, final rule for hazardous waste generators, however, the Agency did not make this requirement final. Rather, the Agency simply promulgated the provision stating that a generator must keep records of any test results, waste analyses, or other determinations made in accordance with § 262.11 for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal (45 FR 12734), which could be interpreted to mean either that a generator was required to keep records or that a generator was not required to keep records of solid wastes that were not hazardous wastes. (This provision is currently located at § 262.40.)

The Agency next discussed this issue in a March 29, 1990, **Federal Register** notice which clarified the rules by stating that recordkeeping for determinations that a solid waste was not a hazardous waste was not necessary. Specifically, the preamble to this final rule stated, “If a waste is determined to be hazardous, the generator must keep records establishing the basis for that determination (40 CFR 262.40(c)). These records must be maintained for at least 3 years after the generator no longer handles the waste in question. Neither of these recordkeeping requirements, however, applies to solid waste generators who do not generate hazardous wastes” (55 FR 11829, March 29, 1990).

At the time the 1980 rules were finalized, the Agency had no experience with their implementation and whether documentation associated with determinations that a waste was not a hazardous waste was necessary. The

Agency now believes that the original approach was insufficient. We now have 30 years of experience and compliance data to support an independent requirement that, as part of their obligation to determine whether a waste is hazardous under § 262.11, generators need to keep records and documentation of their waste determinations, including determinations that a solid waste is not a hazardous waste.

As an example, Georgia DNR requires that, in using generator knowledge, the determination must be valid, correct, and supported by documentation, especially when that determination is that the waste is not a hazardous waste or does not carry certain waste codes (contain certain contaminants).⁶⁶ Even in cases where state regulations do not explicitly require documentation supporting a determination that a solid waste is not a hazardous waste, they will seek documentation supporting that determination when evidence suggests the material is a hazardous waste. Should documentation not be presented, EPA and the states will often take a sample to answer their own questions about waste status.

The Agency does not believe requiring generators to retain documents used to make their non-hazardous waste determinations will pose an undue burden. In a review of 26 state waste determination regulations as well as discussions with several state agencies, the Agency found that 17 states already require documentation and recordkeeping of a solid waste that is not a hazardous waste.⁶⁷ In EPA’s discussions with states, several states mentioned that they interpret the term “other determinations” at § 262.40(c) to mean determinations that a solid waste is not a hazardous waste. Further, generators should already have this information collected as part of their compliance with other parts of § 262.11.

An examination of biennial report data for a small sample of LQGs for both 2009 and 2011 reporting cycles demonstrated that the majority of generators generate the same hazardous waste streams from year to year. In other words, the Agency believes that, for the most part, SQGs and LQGs will make a hazardous waste determination once

⁶⁶ “10 Most Common Hazardous Waste (RCRA) Violations in Georgia: 40 CFR 262.11 “Hazardous Waste Determination,” Georgia Department of Natural Resources https://epd.georgia.gov/sites/epd.georgia.gov/files/related_files/site_page/guidehwdet.pdf.

⁶⁷ As an example, some states interpret the term “other determinations” at 40 CFR 262.40(c) to mean determinations that a solid waste is not a hazardous waste.

and will not need to make a new solid waste determination unless something changes in their process, thereby reducing the need to document waste determinations. This suggests that the burden of documenting a non-hazardous waste determination should be relatively minimal.⁶⁸

In light of the importance of making accurate hazardous waste determinations, and because of the high rates of non-compliance with § 262.11 among generators, the Agency is proposing to modify § 262.11 to specifically require that SQGs and LQGs document and maintain records of all determinations, including determinations that their solid waste is not a hazardous waste. Again, the Agency is not proposing to apply this independent requirement to CESQGs.

A key issue with this provision will be defining the scope of applicable entities for this requirement. First, documentation will not be required for entities that do not generate a solid waste, as defined by § 261.2, or that generate a solid waste that has been excluded or exempted from RCRA Subtitle C controls. However, all potential entities, with the exception of households, must determine whether they generate a solid waste as defined by § 261.2 for purposes of the existing RCRA hazardous waste regulations. Solid wastes under § 261.2 include spent materials, sludges, by-products, scrap metal, and commercial chemical products (CCPs) that are discarded. Specifically:

- Spent materials as defined in § 261.1(c)(1), include any material that has been used and as a result of contamination can no longer serve the purpose for which it was produced without processing.
- Sludge, as defined in § 260.10, means any solid, semi-solid, or liquid waste generated from a municipal, commercial, or industrial wastewater treatment plant, water supply treatment plant, or air pollution control facility.
- A by-product, as defined in § 261.1(c)(3), is a material that is not one of the primary products of a production process and is not solely or separately produced by the production process. Examples are process residues such as slugs or distillation column bottoms. The term does not include a co-product that is produced for the general public’s use and is ordinarily used in the form it is produced by the process.

⁶⁸ Assessment of the Potential Costs, Benefits, and Other Impacts of the Improvements to the Hazardous Waste Generator Regulatory Program, As Proposed, prepared for U.S. Environmental Protection Agency by Industrial Economics, Incorporated, May 2015, page 3–8.

- Scrap metal, as defined in § 261.1(c)(6), is bits and pieces of metal parts (e.g., bars, turnings, rods, sheets, wire) or metal pieces that may be combined together with bolts or soldering, which when worn or superfluous can be recycled.

- CCPs are those materials listed in § 261.33 or those CCPs which exhibit one or more of the hazardous waste characteristics. The term CCP includes those chemical substances which are manufactured or formulated for commercial or manufacturing use and consist of commercially pure grades of the chemical substance, any technical grades of the chemical substance that are produced or marketed, and all formulations in which the chemical substance is the sole active ingredient. CCPs do not include or refer to wastes, such as a manufacturing process residue, that contain any of the chemical substances.

Where there is a potential for a discarded material to be a hazardous waste listed under part 261 subpart D or when the material may contain hazardous constituents that would exhibit a characteristic of hazardous waste (i.e., ignitability, reactivity, corrosivity or toxicity) under part 261 subpart C, these entities must make a hazardous waste determination and document that determination, including for those solid wastes that are not hazardous wastes.

If an entity is generating a hazardous waste (and is, therefore, a hazardous waste generator) and if it is generating sufficient amounts of hazardous waste in a calendar month to be considered an SQG or an LQG, then these generators would be responsible for documenting determinations under this proposed revision.

We would note that the existing hazardous waste regulations already require every generator to make a waste determination and that the only additional provision that this proposal is addressing is that they document that waste determination, including for those wastes that are not hazardous waste. The focus of this provision is on solid wastes that have the potential to be hazardous wastes. Thus, for the purposes of this proposed provision, the Agency is not interested in entities that generate solid wastes that clearly have no potential to be hazardous, such as food waste, restroom waste, or paper products. There are literally hundreds of thousands of entities who generate such wastes. In addition, lawyers and accountants, business offices, religious organizations, governmental organizations, engineering and architectural firms, among other sectors,

are not meant to be impacted by this provision for everyday municipal waste that does not have the potential to be hazardous. Most elementary schools also should not be affected by this provision unless they have laboratories that use large amounts of hazardous chemicals where greater than 100 kilograms of non-acute hazardous waste (or 1 kilogram of acute hazardous waste) is discarded monthly or another source of potentially hazardous waste.

In addition, as noted previously, for the purposes of this proposed provision, the Agency is not interested in entities that generate 100 kilograms or less of non-acute hazardous waste or 1 kilogram or less of acute hazardous waste in a calendar month (e.g., CESQGs). The Agency requests comment on verifying the above sectors and identifying other industrial or non-industrial sectors where the probability is high that generators either do not generate solid wastes that would be identified or characterized as hazardous under RCRA, or if they do, they generate small enough amounts to most likely qualify as a CESQG.

The Agency does not believe the cost of documenting a waste determination, whether non-hazardous waste or hazardous waste, will be substantial. As previously discussed, generators may use either the results of testing their waste or process knowledge to make a hazardous waste determination. If a generator tests its waste or hires a third party to do so, then the written results of those tests will be the documentation. Similarly, if generator knowledge is used to make the waste determination, then a statement describing what the basis of that knowledge was (e.g., information about chemical feedstocks and other inputs to the production process and how those chemical feedstocks may change when introduced into the production process; knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the processor or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents) will most likely be sufficient.

In estimating the impact of requiring SQGs and LQGs to document their non-hazardous waste determinations, the Agency examined the relationship of the number of hazardous wastes generated per facility to non-hazardous waste generated per facility and established an

approximate relationship of 60% to 40%. As part of this analysis, the Agency also found from examining the biennial report data that 50 percent of LQGs generate from one to five hazardous waste streams annually and that many of these generators continue to generate the same waste streams from year to year.⁶⁹ Therefore, for most LQGs, the incremental cost to document their non-hazardous waste determinations should be minimal. The Agency believes that many SQGs also generate the same waste streams from year to year.

However, from examining biennial report data, the Agency is also aware of situations where a generator generates many different hazardous waste streams each year. Examples include academic and industrial laboratories, chemical manufacturers, and TSDFs. As an example, an analysis of the 2011 Biennial Report identified 843 LQGs reporting that they generated 41 or more hazardous waste streams. This analysis derived an average of 17 hazardous waste streams being generated by LQGs. EPA can infer that these entities also generate numerous types of solid, but not hazardous, waste streams.⁷⁰

Although TSDFs and chemical manufacturers may generate many different types of hazardous waste, many of them also have sophisticated protocols and testing procedures in place to make a hazardous waste determination. These processes should be sufficient to provide the proposed documentation to verify that the solid waste is or is not a hazardous waste. Other organizations may not and the Agency is interested in how best to address this important subject.

The Agency believes that requiring SQGs and LQGs to document their non-hazardous waste determinations is important to the success of RCRA hazardous waste program in protecting human health and the environment. Additionally, the Agency believes the proposed change will encourage generators to develop better internal processes and improve overall compliance with the RCRA hazardous waste regulations. At issue is how best to implement this provision in the most cost-effective manner possible. Therefore, the Agency seeks comment

⁶⁹ Assessment of the Potential Costs, Benefits, and Other Impacts of the Improvements to the Hazardous Waste Generator Regulatory Program, As Proposed, prepared for U.S. Environmental Protection Agency by Industrial Economics, Incorporated, May 2015, page 3-8.

⁷⁰ A more detailed discussion of this analysis can be found in the Regulatory Impact Analysis that accompanies this preamble and that can be found in the docket to this rulemaking.

on how to balance the burden of recordkeeping with the benefits from ensuring waste is properly identified and managed.

The Agency seeks comment from those generators that generate many new wastes each year, on ways that could be used to reduce burden while maintaining sufficient protection. The Agency also seeks comment on whether there are particular industrial sectors where many, if not most, solid wastes generated could be clearly determined not to be hazardous wastes and whether there are families of solid wastes where it is clear that they will not be hazardous wastes and thus can be eliminated from this provision.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization and is located at § 262.11(e) of the proposed regulation. The proposed reorganization is discussed in section XIII of this preamble.

7. Specifically Stating That the Hazardous Waste Determination Must Be Accurate

Generators have an obligation to apply due diligence in making an accurate hazardous waste determination by using either knowledge of their processes and waste and/or testing of their waste. As discussed above, RCRA inspectors often cite generators for “failing to make a waste determination” at § 262.11. By that we mean the generator failed to accurately identify a material that could be a solid waste, or failed to accurately make a hazardous waste determination. In both cases, the generator’s failure to make accurate solid and hazardous waste determinations may result in adverse impacts to human health and the environment.

As previously stated, at the core of the RCRA hazardous waste program is the need for generators to make an accurate hazardous waste determination. Therefore, to emphasize this point the Agency is modifying the regulatory text at 40 CFR 262.11 to emphasize and make clear that a generator who generates a solid waste, as defined in 40 CFR 261.2, must accurately determine if that waste is a hazardous waste.

A 1993 FR notice states that in the case where a generator sends waste off site for treatment, storage, or disposal, the TSDF may rely on process knowledge supplied by the generator as a basis for the TSDF’s waste characterization (40 CFR 264.13). The notice points out that while using process knowledge is “seemingly attractive because of the potential savings associated with using existing

information (such as published data), the facility must ensure that this information accurately characterizes applicable wastes” (58 FR 48111, September 14, 1993).

Generators often rely on a third party, such as a TSDF, to help them make a hazardous waste determination. Whether the generator uses a third party or not, the generator is responsible for that determination. As such, the generator should still apply its due diligence to ensure a solid waste is not a hazardous waste, and if a hazardous waste, that it is characterized accurately.

Also with respect to characterizing a hazardous waste accurately, a generator identifying all possible RCRA waste numbers (or RCRA hazardous waste codes) on its manifest or container marking does not satisfy the requirement to make an accurate waste determination. First, the TSDF will not be able to treat the waste effectively or efficiently to comply with land disposal restriction requirements because it will not know precisely what waste it needs to treat. Second, the generator clearly did not apply its due diligence seriously.

The Agency also realizes that generators, whether inadvertently or intentionally, often make a hazardous waste determination when the material is actually a non-hazardous solid waste. The intent of this proposed change would not impact such determinations. The generator is always free to manage its solid waste as a hazardous waste if it so desires. However, the Agency is concerned about other related situations, such as when a generator applied due diligence but still made an incorrect hazardous waste determination potentially posing a risk to the environment, or where a generator intentionally tried to circumvent waste determination requirements.

EPA specifically requests comment on reasons why it may not be feasible to require a generator’s solid and hazardous waste determinations to be accurate and how best the Agency can make clear that generators are responsible for making an accurate hazardous waste determination. EPA also requests comment regarding ways the proposed regulatory text could be improved to better assist generators in making more effective hazardous waste determinations.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

8. Taking Comment on Maintaining Records Until the Generator Closes

EPA is also using this notice to take comment on an additional revision to the hazardous waste determination regulations at § 262.11, but is not proposing any regulatory text for this change. The Agency requests comment on requiring SQGs and LQGs to maintain records of their waste determinations until the generator closes its site, rather than for at least three years from the date that the waste was last sent to on-site or off-site treatment, storage and disposal. Because an inspector may not be able to inspect every SQG and LQG within three years from when the solid or hazardous waste was first generated, a generator may discard its waste determination records prematurely. For practical reasons, the Agency believes a generator will want to maintain records of its solid and hazardous waste determinations to support and respond to any questions an inspector may have about a particular waste determination—even if it is more than three years from when it was first generated. Similarly, the Agency believes generators that generate large numbers of solid and hazardous waste streams annually will computerize their records, making it easy to store and retrieve them when necessary. For these reasons, the Agency does not believe requiring SQGs and LQGs to maintain records of their active solid and hazardous waste streams should be overly burdensome.

Finally, while the Agency is not proposing that CESQGs maintain documentation of their non-hazardous waste determinations, the Agency does seek comment on the economic costs and environmental benefits of potentially requiring CESQGs to maintain documentation of their hazardous waste determinations, including their non-hazardous waste determinations. The Agency realizes that the total number of CESQGs is very large—ranging from an estimated 293,000 to 463,000; however, the Agency believes that based on the number of waste streams generated by SQGs and LQGs that such generators should only be generating a few solid waste streams and in many cases using their knowledge of the process and process materials in making hazardous waste determinations. In other words, the burden of documenting their hazardous waste determination should not be that costly for each CESQG.

Conversely, the costs of not making an accurate hazardous waste determination could be significant environmentally and financially to the CESQG. For

example, in the case that a CESQG fails to make an accurate hazardous waste determination, resulting in the CESQG actually being either a SQG or LQG, hazardous wastes will likely be illegally managed. Hazardous wastes that should have been sent to a RCRA-permitted treatment, storage or disposal facility would instead be sent to a municipal solid waste landfill, potentially posing future environmental problems for that landfill and community. EPA requests comment on the potential environmental benefits that could be achieved if the Agency were to require that CESQGs document determinations that their solid waste is or is not a hazardous waste.

9. Hazardous Waste Determination Electronic Decision Tool

Building upon the above discussion and the importance of making accurate hazardous waste determinations, the Agency also seeks comment on the feasibility of developing a user-friendly electronic hazardous waste determination decision tool that generators could use to assist them in making a hazardous waste determination. This electronic tool would guide generators through a series of analytical decision-type (Yes or No) questions to assist them in determining whether the solid waste they have generated is also a hazardous waste subject to the applicable RCRA hazardous waste regulations. As part of this decision tool, generators would be able to document reasons why the solid waste is a hazardous waste, or conversely, why the solid waste is not a hazardous waste.

Given the large number and great variety of hazardous waste streams, a key challenge would be to determine how best to design this decision tool if the Agency went forward in developing it. Potential approaches include designing the tool conceptually around the following: (1) Industrial sectors; (2) families of industrial materials (*i.e.*, solvents, acids, metals, etc.); (3) broad type of hazardous secondary material (*i.e.*, spent material, by-product, sludge, etc.); (4) listed hazardous waste organized by specific industrial sector or non-specific sectors (*e.g.*, solvents, electroplating wastes, and characteristic hazardous waste), or (5) an eclectic approach that combined different aspects of the approaches in (1) through (4).

This decision tool could assist generators to make the following determinations under § 262.11:

- Whether the waste is excluded from regulation under § 261.4 [§ 262.11(a)]

- Whether the waste meets any of the hazardous waste listing descriptions in part 261 subpart D [§ 262.11(b)]

- Whether the waste exhibits one or more hazardous characteristics of hazardous waste, as identified in part 261 subpart C [§ 262.11(c)]

- What are all applicable EPA hazardous waste codes for wastes determined to be hazardous [§ 262.11(f)]

An electronic decision tool could also possibly provide a way for SQGs and LQGs to maintain records supporting their waste determinations [§ 262.11(e)].

Developing this decision tool would be a major investment on the part of the Agency and could take several years to fully develop, test, and make operational, with different components produced for use over time. However, even when completed (assuming it was a worthwhile Agency investment to pursue), this decision tool would never be able to account for all the industrial sector/family of industrial materials/type of hazardous secondary material possibilities that exist in industry. Therefore, scoping such a decision tool to capture as much of the most likely industrial sector/family of industrial materials/type of hazardous secondary material possibilities would be the Agency's goal.

Additionally, if such a decision tool were to be developed, the generator would still be ultimately responsible for making the hazardous waste determination, since no decision tool could ever account for its site-specific circumstances.

Hazardous waste determination software or tools could be web-based, off-the-shelf, or both. The software or tools could be developed by EPA, by authorized states and tribes, by private parties, or by public and private sector collaboration.

The Agency particularly requests comment on the feasibility of the private sector developing electronic application software (apps). An initial search for preexisting hazardous waste determination software identified no relevant, privately-developed, off-the-shelf software products to assist generators in making accurate waste determinations. However, EPA did identify a variety of state and academic internet-based hazardous waste determination tools and workbooks.⁷¹

⁷¹ See, for example, the Washington Department of Ecology created an Excel program titled "Designation Tool 2.0 for Excel 2007," to help business make accurate waste designations in the state of Washington. http://www.ecy.wa.gov/programs/hwtr/manage_waste/des_intro.html; the Texas Commission on Environmental Quality created an online hazardous waste determination tool, the "Waste Designation Decision Matrix."

At issue is whether there is a market for such an app and what EPA could do to facilitate software development. The Agency estimates the universe of hazardous waste generators to be approximately 400,000 to 500,000, with a large majority being conditionally-exempt small quantity generators that generate up to 220 pounds in a calendar month.

EPA is seeking comment on whether development of an electronic hazardous waste determination decision tool is feasible and by whom. The Agency requests comment on what circumstances would encourage the private sector to develop such a tool or app and on what generators would like to see in terms of components and organization that would facilitate a generator using it.

C. SQG and LQG Re-notification (40 CFR 262.12)

1. Background

Under existing 40 CFR 262.12, SQGs and LQGs are required to notify EPA using EPA form 8700-12 (Site ID form) in order to obtain an EPA identification number (EPA ID). Without such identification, a generator cannot treat, store, dispose of, or transport, its hazardous waste. Once a generator applies for and receives an EPA ID, information provided by the generator (*e.g.*, name, address, contact, industrial sector, EPA hazardous waste numbers) is entered into the state system and/or EPA's national data system (RCRAInfo) to support program management activities.

Subsequent to obtaining an EPA ID, there is no federal regulation requiring LQGs or SQGs to re-notify EPA to update their site information or confirm the information remains accurate. However, LQGs do update their site information as part of the biennial report.

EPA believes that about half the states require annual reporting by LQGs and some require periodic reporting by SQGs in order to determine user fees based on the amount of hazardous waste they generate. However, the data from these annual reports may not always be submitted to EPA's national RCRA database. Additionally, although many LQGs currently submit a Site ID form as part of their biennial report, this

<http://www.tceq.texas.gov/assistance/waste-matrix/matrixenter.html>, and The Connecticut Department of Energy and Environmental Protection's RCRA Help page provides a guide designed to help businesses and individuals figure out which hazardous waste requirements apply and how to comply with them. http://www.ct.gov/deep/cwp/view.asp?a=2718&q=434308&deepNav_GID=1967%20.

independent requirement does not apply to SQGs or to entities that initially notified as an LQG, but were an SQG during the biennial reporting year and, thus, were not required to submit a biennial report.

2. Problems With Outdated Information

The lack of re-notification at the federal level greatly impairs EPA's and the states' ability to use the information for compliance monitoring and programmatic purposes. This is because a one-time notification provides no assurance that the information collected in EPA's and the states' databases over time will accurately reflect which facilities are generating hazardous waste. For example, a recent examination of EPA's data reveals that there are thousands of SQGs who last notified over 20 years ago.⁷² EPA is concerned that the probability a generator that last notified prior to 1990 is still active and still an SQG is quite small. Because of the outdated information, it is difficult for EPA to ascertain even simple statistics, such as the number of SQGs currently operating, let alone information that can be reliably used for programmatic and compliance monitoring purposes.

Because of the lack of integrity in the data, the Agency and states must spend their limited resources to 'clean up' the data every time regulatory authorities try to use it, for example, to estimate regulatory burden and benefits to the regulated community, offer compliance assistance, or produce public reports on hazardous waste generation.

Furthermore, regulatory authorities may waste time and resources monitoring compliance at entities that no longer generate hazardous waste. This inefficient use of resources lowers the effectiveness of regulators to monitor compliance overall and could potentially increase the risk of environmental damage from mismanagement of hazardous waste. In summary, the Agency and many states have, for the most part, an outdated, incomplete, and inaccurate understanding of the LQG and SQG universe. Consequently, over time, this undermines the ability of EPA or the states to make effective programmatic decisions.

3. Proposed Periodic Re-Notification

EPA is proposing to add an explicit independent requirement to the regulations that both LQGs and SQGs re-notify EPA using the Site ID form (EPA

form 8700-12).⁷³ The intent of this re-notification provision is to provide basic information to the regulatory agencies about who is generating and managing hazardous waste. The information required in the Site ID form includes:

- Site name, address, contact information, and EPA ID number
- NAICS (North American Industry Classification System) code
- Information regarding the entity's legal owner and operator
- Type of regulated waste activity (e.g., hazardous waste generator category and whether the entity is a transporter, treater, storer, disposer, or recycler of hazardous waste)
- Universal waste activities
- Used oil activities
- Notification for opting into or withdrawing from managing laboratory hazardous waste under 40 CFR part 262 subpart K
- Description of hazardous waste, including a list of applicable federal and state hazardous waste numbers
- Notification of hazardous secondary material activity managed under certain definition of solid waste exclusions.
- Certification signed by the entity's legal owner, operator, or authorized representative.

The specific information included in the notification will enable regulatory agencies to monitor compliance adequately and to ensure hazardous wastes are managed according to the appropriate RCRA hazardous waste regulations. The information can be used to assist RCRA inspectors in determining which facilities may warrant greater oversight and provides a basis for setting enforcement priorities. Notification information is collected in EPA's RCRAInfo database, which is the national repository of all RCRA Subtitle C site identification information, whether collected by a state authority or EPA. EPA provides public access to this information through EPA's public Web site at <http://www.epa.gov/enviro/html/>.

Once an initial notification (to obtain an EPA ID number) is submitted, to re-notify, a generator need only review the previous notification and either make changes if necessary or confirm that the information remains accurate. Furthermore, EPA has recently made available an electronic system for the regulated community to use to submit Site ID forms electronically, which will further reduce burden on generators. Facilities should check with their states

regarding whether their state will use EPA's electronic submittal process.

The proposed rule would require LQGs, having first obtained an EPA ID number, to re-notify EPA using the Site ID form prior to March 1 of each even-numbered year. This time frame is the same as that for the biennial reports in 40 CFR 262.41. Adding this provision to § 262.12 in the existing regulations (which is § 262.18 in the proposed reorganization in this proposed rule) reflects existing processes by which LQGs already submit Site ID forms as part of the biennial reporting process. EPA also believes that the requirement to re-notify is particularly important considering generators may change regulatory status from LQGs to SQGs and vice versa.

EPA is also proposing that SQGs, having first obtained an EPA ID number, must re-notify EPA using the Site ID form prior to February 1 of each even-numbered year. We propose the two-year time frame to mimic the current biennial reporting process for LQGs; however, we propose to require that SQG re-notifications (due by February 1 of each even-numbered year) to occur one month prior to the due date for LQG re-notifications (due by March 1 of each even-numbered year) to help reduce the burden on states that must process the re-notifications. We are also taking comment on whether re-notifying every four years would be appropriate for SQGs.

EPA also considered whether to require SQGs to re-notify on alternate years—that is, by March 1 of each odd-numbered year, from LQGs, in order to further reduce the burden on states. However, this may complicate the regulations because a generator can change its generator category year-to-year. For example, it is possible that a generator who is an LQG during the SQG-reporting year and an SQG during the LQG-reporting year would not have to submit any notification to EPA. Furthermore, requiring SQG and LQG re-notifications during the same year enables EPA to include information regarding SQGs in its National Biennial RCRA Hazardous Waste Report.

EPA believes that requiring a set due date (i.e., February 1) will ease implementation and compliance with the re-notification provision. However, one alternative that the Agency seeks comment on is to allow for 'rolling' notifications, in that generators could re-notify at any time of the year as long as they re-notified within two years of the date of their last notification. EPA understands that this alternative may further reduce burden on the states that would process the re-notifications, in

⁷² Count of SQGs by Year of Last Notification Received, December 12, 2012. Developed from RCRAInfo data system using Form 8700-12 Site Identification Form information.

⁷³ To the extent that other parts of the RCRA regulations require the submittal of EPA form 8700-12, for example, used oil generators or handlers, the proposed re-notification provision would not impact them, unless they were also an LQG or SQG of hazardous waste.

that the state would receive the notifications throughout the year rather than all at once; however, it may also complicate compliance by the regulated community, as well as compliance monitoring by the states and EPA, as each LQG and SQG would have a unique 'due date' that must be individually tracked.

Another alternative to requiring periodic notification (*e.g.*, every two years) that the Agency seeks comment on would be for EPA to require an SQG or LQG to re-notify only in the event of a change to certain information, such as (1) change in ownership and (2) change in generator category.⁷⁴ The Agency believes that updating this specific information is particularly important because:

- Re-notifying when a generator has a change of ownership is important so that EPA and the states understand who is legally responsible for managing the generated hazardous waste.
- Re-notifying due to a change in generator category provides EPA and the state with information regarding what regulations apply to the generator and thus assist with compliance assistance and monitoring activities.

EPA notes that, because an EPA ID number is specific to a site location, a change in site address for an entity already requires the entity to apply for a new EPA ID number using the Site ID form.

In this case, EPA would require re-notification within 30 days of when the change occurred. Re-notification in the event of change to these two items may further reduce burden on LQGs and SQGs, because EPA assumes that these changes would happen fairly infrequently. However, EPA also notes that although LQGs and SQGs would only have to re-notify in the event of a change in its ownership or generator category, re-notification would require a complete submittal of all information included in the Site ID form. EPA understands that this alternative may also increase the complexity of implementing the regulation because it would be difficult for regulatory authorities to ensure that re-notifications were received according to the regulations. For example, if a facility last notified ten years ago, it would be difficult for EPA and the states to ascertain whether the generator has failed to re-notify in compliance with the regulations or that the generator's

information simply hasn't changed since its last notification. Additionally, EPA notes that re-notification based on a change does not result in data that is as reliable as data provided in periodic re-notifications because it provides no information on generators that have stopped operations.

4. Request for Comment

EPA requests comment on its proposed change to require re-notification for SQGs and LQGs, including information regarding the benefits and burden of such a provision. EPA also requests comment on whether such re-notification should be every two years or one of the other alternatives discussed above. Finally, EPA requests comment on any other alternatives for an independent re-notification requirement, including suggestions that would reduce the burden on states that must process re-notifications.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. EPA is proposing to move § 262.12 (EPA identification numbers) to § 262.18 and is proposing to revise the title of the section to read "EPA identification numbers and re-notification for large quantity generators and small quantity generators."

D. Determining Generator Category (Proposed New Section 262.13)

EPA is proposing a new section § 262.13, which would describe how a generator determines which generator category it would be subject to. Proposed § 262.13 discusses the framework for making a generator determination in paragraph (a) and stresses that the calculation is made monthly and that the generator category can change from month to month. The proposed regulatory text would state that a generator's category is determined each month by the amount of hazardous waste it generates and may change from month to month. The regulation sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month, as defined in § 260.10.

The discussion in § 262.13(a) is not a new requirement for generators, but these steps are not currently laid out in the regulations in as succinct a manner. EPA believes that the addition of the definitions of generator categories to § 260.10 and this paragraph on how to make a generator category determination should provide specific instructions on this matter for the regulated community and thereby improve compliance with the generator regulations.

Proposed paragraph (b) of § 262.13 would specifically address the situation in which a generator generates any combination of non-acute hazardous waste, acute hazardous waste, and the residues from the cleanup of a spill of acute hazardous waste. This paragraph presents a series of steps for a generator to follow when determining its generator category to ensure that it selects the appropriate category for the total amount and types of hazardous waste generated.

Proposed §§ 262.13(c) and (d) are existing provisions that we are proposing to move from §§ 261.5(c) and (d) of the existing regulations with a few small wording changes to reinforce that category determinations are made monthly and do not otherwise represent a change in the generator regulations.

EPA is requesting comment on the proposal to add this description of how a generator is to determine its generator category to the regulations.

Effect of the Proposed Reorganization: This section is partially affected by the proposed reorganization. Some of the language proposed for § 262.13 on what materials to count when determining generator category are moved from existing § 261.5, but much of this proposed regulation is new text.

E. Requiring Hazardous Waste Numbers When Marking of Containers Prior to Shipping Hazardous Waste Off Site to a Designated RCRA Facility (40 CFR 262.32)

The Agency is proposing to modify 40 CFR 262.32 to require SQGs and LQGs to mark their containers with the applicable EPA hazardous waste number (RCRA hazardous waste code) prior to transporting their hazardous waste off site to a designated RCRA facility for subsequent management. EPA is proposing this revision so that TSDFs can readily identify the contents of hazardous waste containers they are receiving from generators and effectively treat the wastes to meet land disposal restriction requirements (LDRs). As described elsewhere in this proposal, the Agency is proposing revisions to the marking and labeling of containers and other waste accumulation units in order for employees, inspectors, emergency responders, and waste handlers to better understand the potential hazards associated with the contents of hazardous waste contained in a unit.

This proposed provision should not increase burden on generators as it reaffirms commonly used waste management practices. Most generators, or their designated waste handlers, already mark their containers with the

⁷⁴ EPA is also proposing a notification requirement for (1) generators undergoing closure (section VII.G.); (2) LQGs that receive hazardous waste from CESQGs (section VII.C) and (3) episodic generators (section IX), which are discussed in other parts of this preamble.

applicable EPA hazardous waste numbers prior to transporting their hazardous waste off site. In fact, requiring that applicable EPA hazardous waste numbers be marked on containers decreases overall burden because it avoids the need for a TSDF to identify the hazardous waste or send it back to the generator for proper identification.

The Agency requests comment on this proposed change.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

F. Modifications to Management of Containers, Tanks, Drip Pads, and Containment Buildings (40 CFR 262.34(a)(2) and(3) and 40 CFR 262.34(a)(1))

The existing regulations for LQGs that address the conditions for exemption related to marking and labeling are at § 262.34(a)(2) and (3) for containers and at § 262.34(a)(3) for tanks. The marking and labeling condition for SQGs who accumulate hazardous waste in both tanks and containers are at § 262.34(d)(4), which references § 262.34 (a)(2) and (3). For practical reasons, there are no requirements to mark drip pads or containment buildings that accumulate hazardous waste other than requiring that documentation must exist that describes the procedures to ensure that each waste volume remains in the unit for no more than 90 days.

EPA is proposing to modify § 262.34(a)(2) to strengthen the marking and labeling conditions for exemption for containers and to modify § 262.34(a)(3) to strengthen and consolidate the marking and labeling conditions for exemption for hazardous waste tanks, drip pads, and containment buildings by LQGs. The Agency is also proposing to modify § 262.34(d) to strengthen the marking and labeling conditions of containers, tanks, drip pads, and containment buildings by SQGs.

The proposed changes are consistent with the applicable discussion of marking and labeling of containers in SAAs in section VIII.I. Where differences may occur is when the container may be shipped off-site as opposed to when the contents of the container are managed on-site, or temporarily managed on-site (e.g., when the container is moved from the SAA to a central accumulation area and then shipped off-site to a TSDF).

1. Container Marking and Labeling for LQGs and SQGs (40 CFR 262.34(a)(3))

Currently, § 262.34(a)(3) requires each container and tank to be labeled or

marked clearly with the words, "Hazardous Waste." However, while the words "Hazardous Waste" on containers and tanks provide some measure of information regarding the contents of these units, this information fails to describe the specific hazards of the contents and what risk these wastes could pose to human health and the environment. EPA believes it is important that employees, transporters, downstream handlers, emergency personnel, and EPA and state inspectors know as much as possible about the potential hazards of the contents in containers being accumulated, transported, and managed, whether on-site and/or off-site, so that the hazardous wastes are managed in an environmentally sound manner.

The Agency is proposing two modifications that would strengthen the labeling and marking conditions for LQGs and SQGs accumulating hazardous waste in containers. These changes are similar to those proposed for containers stored in satellite accumulation areas (see section VIII.I.) First, the Agency is proposing that SQGs and LQGs accumulating hazardous waste in containers mark their containers with both the words "Hazardous Waste" and other words that identify the contents of the containers that a third party, such as an emergency responder, co-worker unfamiliar with the material, or even the general public may recognize. Although the words "Hazardous Waste" are important to convey that the container contains a waste, as opposed to a product, and that a hazardous waste determination has been made for the contents, it does not convey more practical information regarding the contents of the container. Examples of other words that identify the contents of the container may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene dichloride"; or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents." Another option for complying with this provision is to use the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D. The Agency does not consider chemical formulas, such as CH₂Cl₂ for methylene dichloride, to be "words that identify the contents of the container" since chemical formulas may not be widely known among emergency responders, workers, and hazardous waste handlers other than chemists.

If the hazardous waste will subsequently be sent off-site for treatment and disposal, an SQG or LQG

may choose to use an appropriate DOT proper shipping name found on the hazardous materials table at 49 CFR 172.101 to identify the contents of the container while it is accumulating on-site. That way, the generator will fulfill EPA and DOT requirements simultaneously; however, EPA is not proposing to require the use of the DOT shipping names while the hazardous waste is accumulating on-site. We only suggest that the DOT shipping name may be one way that some generators may choose to identify the contents of the container.

EPA also believes use of the DOT marking requirement should be sufficient in many situations involving DOT Class 9 hazardous materials that are also hazardous waste, with the DOT shipping name ending in N.O.S. (not otherwise specified). As noted at 49 CFR 172.301 (b), generators using a DOT shipping name ending in N.O.S. must also provide the technical name of the hazardous material in association with the proper shipping name. However, the Agency is requesting comment on examples of when the DOT shipping name would not meet EPA's intent of "identifying the contents of the container" and suggestions for addressing this situation. EPA notes that additional pre-transport requirements, other than the DOT shipping name, apply when shipping hazardous waste off-site. We are not proposing to change EPA's existing requirements for pre-transport requirements that are currently found in §§ 262.30 through 262.33. Similarly, for packages subject to 49 CFR, the generator or shipper/ carrier should be familiar with and aware of the marking requirements at 49 CFR 172.304 and prohibited labeling and label visibility requirements at 49 CFR 172.401 and 172.406, respectively.

The second modification we are proposing for labeling containers in central accumulation areas is to add a provision that SQGs and LQGs mark and label their containers with an indication of the hazards of the contents of the containers. SQGs and LQGs will have flexibility in how to comply with this new provision. That is, generators can indicate the hazards of the contents of the container using any of several established methods, including, but not limited to an EPA hazardous waste characteristic(s) (ignitable, corrosive, reactive or toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with NFPA code 704; or a hazard pictogram consistent with the

United Nations' Global Harmonized System (GHS). Generators also may use any other marking or labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

EPA believes that placing both the appropriate label and marking on containers during hazardous waste accumulation will enable persons who may come in contact with it to be aware of the hazardous contents of the container with little or no additional cost to generators. In many instances, this proposed condition will already have been satisfied if the generator elects to move a container accumulating hazardous waste in a satellite accumulation area to a central accumulation area.

In summary, EPA is proposing to modify § 262.34(a)(3) and require LQGs and SQGs to mark containers with the following: (1) the words "Hazardous Waste," (2) other words that identify the contents of the containers, and (3) an indication of the hazards of the container's contents. We are not proposing to change § 262.34(a)(2), which requires LQGs and SQGs to mark clearly and visibly the date accumulation began on each container and make that marking visible for inspection.

The Agency requests comment on the proposed changes for container marking and labeling for LQGs and SQGs.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization in that the labeling and marking regulations would be moved from § 262.34 to § 262.16(b)(6) (for SQGs) and to § 262.17(a)(5) (for LQGs). The reorganization is discussed in section XIII of this preamble.

2. Tank Marking and Labeling for LQGs and SQGs (40 CFR 262.34(a)(3))

The Agency is proposing to modify the regulations at § 262.34(a)(3) to require LQGs and SQGs to use inventory logs, monitoring equipment, or records indicating the date the hazardous waste first entered the tank in order to support a generator's determination that it has not exceeded its 90 day accumulation time limit, or in the case of an SQG, its 180-day time limitation. Exceeding the 90- or 180-day time limitation for LQGs and SQGs, respectively, would be a violation of a condition for an exemption from permitting requirements. Records from tank level sensors also may be used which could be either automatically logged from the sensors to a computer record, or recorded as part of a tank's operational

daily inspection (see 40 CFR 265.195). Generators may also use any other methods that clearly demonstrate the date hazardous waste first entered the tank and show that the hazardous waste was subsequently emptied within 90 days of the date it first entered that tank, or 180 days in the case of an SQG (unless the hazardous waste must travel greater than 200 miles to a TSDF in which case 270 days is allowed). The generator must also use inventory logs to identify the hazardous waste contents and hazards of the tank.

With respect to the accumulation start date, in the preamble to the promulgation of the SQG regulations (51 FR 10160, March 24, 1986), EPA stated that § 262.34 contains the conditions for exemption for generators that accumulate hazardous waste on site. Under § 262.34(a), an LQG may accumulate hazardous waste on site in tanks or containers in any quantity for up to 90 days (and up to 180 days for a SQG unless the hazardous waste must travel greater than 200 miles to a TSDF in which case 270 days is allowed) without the need to have interim status or obtain a storage permit under RCRA, provided the generator complies with the conditions of § 262.34, which include marking the date upon which the period of accumulation begins. While the preamble mentions marking tanks and containers, the final regulation at § 262.34(a)(2) requires generators to mark the date upon which each period of accumulation begins only on containers.

As part of EPA's Hazardous Waste Technical Corrections and Clarifications Direct Final Rule (75 FR 12989, March 18, 2010), the Agency sought to correct this oversight by including what it thought to be the appropriate clarifying language. The proposed regulatory language required generators to mark the date upon which each period of accumulation begins on each container and tank, which would bring the regulation in line with the preamble to the 1986 rule. However, EPA received numerous adverse comments regarding this change and as a result withdrew that proposed change. The comments stated, among other things, that, unlike containers, the Agency failed to realize that generators do not actually mark their tanks with the date upon which each period of accumulation begins because the tank is often a fixture that is used and emptied repeatedly. Commenters argued that marking tanks would cause confusion since there would be numerous markings all over the tank making it difficult for the generator and inspector to identify when the last period of accumulation

began or could cause an extra effort of removing the old marking before applying a new one.

At least one commenter also cited an EPA letter clarifying § 262.34(a)(1)(ii) in connection with the turnover of hazardous waste stored in generator accumulation tanks.⁷⁵ In that letter, EPA stated that "LQGs utilizing a batch process must meet the requirements of § 262.34(a)(1)(ii). For example, the use of inventory records in conjunction with tank markings may provide confirmation that the tank has been emptied within an appropriate time period. Specifically, the inventory records typically show the dates and quantity of hazardous waste entering the tank, as well as the dates the tank was emptied. Shipping or hazardous waste manifest records also may be used to verify when the tank was emptied. Likewise, tanks accumulating hazardous wastes may have information indicating the time and date hazardous waste first entered the tank." The Agency went on to say that there may be other methods to demonstrate that a tank has been emptied, but any method used to confirm compliance with § 262.34(a)(1)(ii) must be reasonable and easily discernible to EPA or an authorized state.

Later in this letter, EPA stated that LQGs accumulating hazardous wastes through a continuous flow process must "demonstrate that the hazardous waste has not been stored for more than 90 days . . . For example, a generator could confirm that the volume of a tank has been emptied every 90 days by recording the results of monitoring equipment both entering and leaving a tank. This recordkeeping, in conjunction with the tank volume, would enable inspectors, as well as [site] personnel, to demonstrate compliance with § 262.34(a)(1)(ii). Likewise, in marking the tank, a generator could mark both the tank volume and estimated daily throughput to allow inspectors to determine the number of days that hazardous wastes resides in a tank to determine compliance with § 262.34(a)(1)(ii). As noted above, there may be other methods to demonstrate that the tank has been emptied, but any method or demonstration to confirm compliance must be reasonable and easily discernible to EPA or an authorized state."

Subsequent to withdrawing the provision at § 262.34(a)(2) as part of

⁷⁵ Letter from Matt Hale, Director of EPA's Office of Solid Waste to John Hopewell, National Paint and Coatings Association, February 16, 2007, RCRA Online 14764.

EPA's Hazardous Waste Technical Corrections and Clarifications Direct Final Rule due to adverse comment, EPA also confirmed with state officials that current operating practices do not include generators physically marking their tanks. Instead, generators are able to use inventory logs, monitoring equipment, or other methods to demonstrate that a tank has been emptied within 90 days of the date hazardous waste first entered the tank.

Therefore, with respect to the accumulation start date for tanks, EPA is proposing that generators may use inventory logs, monitoring equipment or records indicating the date the hazardous waste first entered the tank, as long as this information is immediately accessible for inspection. Records from tank level sensors also may be used that are either automatically logged from the sensors to a computer record or recorded as part of a tank's operational daily inspection (required by 40 CFR 265.195). Generators may also use any other methods that clearly demonstrate the date hazardous waste first entered the tank and was subsequently emptied within 90 days of the date hazardous waste first entered that tank.

The same issue potentially applies to a generator physically marking and labeling the contents of the tank and its associated hazards. If the contents and associated hazards frequently change, then physically marking the tank could result in numerous markings and labels on the tank, making it difficult for employees and others to identify its contents. Therefore, following the same logic, the Agency is proposing that generators use inventory logs or records to identify the contents of the tank and its associated hazards. The Agency is also proposing that such tank logs be immediately accessible by the generator should the need arise.

The Agency requests comment on the feasibility and effectiveness of using inventory logs or records to identify the contents and hazards of a hazardous waste tank. The Agency also requests comment on alternative methods of identifying the contents and hazards of a hazardous waste tank in a more cost-effective manner.

Consistent with the existing regulations for tanks at § 262.34(a)(3), the Agency will continue to require that hazardous waste tanks be labeled with the words "Hazardous Waste."

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The labeling and marking regulations would be moved from § 262.34 to § 262.16(b)(6) (for SQGs) and to § 262.17(a)(5) (for LQGs).

The reorganization is discussed in section XIII of this preamble.

3. Drip Pad and Containment Building Marking and Labeling for LQGs and SQGs (40 CFR 262.34(a)(3))⁷⁶

The existing regulations for drip pads at § 262.34(1)(iii)(A) and (B) require generators to produce a description of the procedures that will be followed to ensure that all wastes are removed from the drip pad and associated collection system at least every 90 days, and to produce documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal. Likewise, the existing regulations for containment buildings at § 262.34(1)(iv)(A) and (B) require the generator to produce a written description of the procedures to ensure that each waste volume remains in the containment building for no more than 90 days, a written description of the waste generation and management practices for the facility showing that they are consistent with respect to the 90-day limit, and documentation that the procedures are complied with. However, in both instances, the existing regulation explicitly fails to account for when the hazardous waste is first placed in or on the unit, which raises questions as to how a generator documents that it has met the 90-day limit.

Therefore, to address this shortcoming, and because the risks for accumulating hazardous wastes on drip pads and containment buildings are similar to those accumulating in tanks, and for purposes of consistency and uniformity with the marking and labeling provisions for tanks, the Agency is proposing the same marking and labeling regulatory framework for hazardous wastes accumulated on drip pads and in containment buildings that it is proposing for tanks.

Specifically, the Agency is proposing that hazardous waste accumulated on drip pads and in containment buildings be labeled in a conspicuous place near these units with the words "Hazardous Waste." The Agency is also proposing to revise the existing marking regulations and clarify that LQGs and SQGs document the date that the hazardous waste was first placed on the drip pad and the sump or collection system in order to verify that the removal or turnover of the hazardous wastes on the drip pad took place within 90 days or less in order to support a generator's

⁷⁶Note: Under a separate provision discussed in section VIII.J, the Agency is proposing to allow hazardous waste to be accumulated by SQGs in drip pads and containment buildings.

determination that it has not exceeded its 90-day accumulation time limitation. Exceeding the 90-day time limitation for LQGs and SQGs, respectively would be a violation of a condition for an exemption from permitting requirements. Note that this is also important because, as described in section VIII.J below, SQGs may move their wastes from one type of unit to another (e.g., drip pad to containers), and without knowing the start and end dates, the generator will not be able to confirm that it met the appropriate accumulation time limitations.

Consistent with current drip pad regulations in 40 CFR 262.34(a)(1)(iii)(A) and (B), these provisions will continue to include a description of the procedures to be followed by both SQGs and LQGs to ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days as well as documentation of each waste removal.

Finally, the Agency is proposing that generators use inventory logs or records to identify the contents of the drip pad and its associated hazards and that such logs and records be immediately accessible. The Agency believes that these requirements are necessary to ensure that workers and emergency responders handling or coming in contact with the waste understand the hazards and dangers that they may be exposed to.

In addition, as with the proposed changes for hazardous wastes accumulated in tanks and on drip pads, the Agency is proposing to clarify that LQGs and SQGs may use inventory logs, monitoring equipment, or any other effective means to document the date the hazardous waste was first placed in the containment building and the date when the hazardous waste was removed to verify that the waste was accumulated no more than 90 days at any one time.

Consistent with the existing regulation at § 262.34(a)(1)(iv)(A) and (B) for containment buildings, the proposed regulation for both LQGs and SQGs will state that the generator must maintain the following records and that they can do so by using inventory logs, records from monitoring equipment, or any other effective means:

(1) A professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the facility's operating record prior to operation of the unit; and

(2) A written description of procedures to ensure that each waste volume remains in the unit for no more

than 90 days by identifying the date hazardous waste first started to be accumulated, a written description of the waste generation and management practices for the site showing that they are consistent with respecting the 90 day limit, and documentation that the procedures are complied with; or

(3) Documentation that the unit is emptied at least once every 90 days.

Finally, the Agency is proposing that generators use inventory logs or records to identify the contents of the containment building and its associated hazards and that such logs and records be immediately accessible. As with the proposed changes to the marking and labeling of drip pads, the Agency believes that these requirements are necessary to ensure that workers and emergency responders handling or coming in contact with the waste understand the hazards and dangers that they may be exposed to.

As with the proposed changes to the tank marking and labeling regulations at § 262.34(a)(3), the Agency requests comment on the necessity and effectiveness of explicitly requiring generators to use inventory logs or records to identify the contents and hazards of hazardous waste accumulated on a drip pad or in a containment building. The Agency also requests comment on alternative methods of identifying the contents and hazards of a hazardous waste on a drip pad or in a containment building in a more cost-effective manner. Lastly, the Agency requests comment on how a generator can more effectively mark or label a drip pad or containment building with the words "Hazardous Waste."

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The labeling and marking regulations would be moved from § 262.34 to § 262.16(b)(6) (for SQGs) and § 262.17(a)(5) (for LQGs). The reorganization is discussed in section XIII of this preamble.

4. Request for Comment on Documentation of Waste Accumulation Unit Inspections

a. Container inspections at §§ 262.34. The Agency is requesting comment in this proposal on requiring both LQGs and SQGs, as a condition for exemption to record the results of their required "at least weekly" inspections to emphasize the importance of these inspections in preventing releases into the environment and to provide a measure of accountability that a generator inspection of its containers actually took place.

As part of the proposed reorganization to make the generator regulations more

user-friendly, the Agency is proposing to incorporate parts of the existing regulatory text at § 265.174 (Container Inspections) into § 262.34 (§ 262.16(b)(2) for SQGs and § 262.17(a)(1) for LQGs under the proposed reorganization) and to revise these paragraphs to incorporate the existing regulatory text at § 265.171 for remedial action that is required if deterioration or leaks are detected.

The requirement for container inspections at § 265.174 states that the owner or operator must inspect areas where containers are stored at least weekly and that the owner or operator must look for leaking containers and for deterioration of containers caused by corrosion or other factors.

Currently, neither SQGs nor LQGs are required to record the results of their weekly inspections. As a result, EPA and some states have no reliable way to verify that such inspections took place unless, by the rare chance, an inspector is inspecting a generator site at the same time that the "at least weekly" inspection occurs or an inspector notices a release from a container during an inspection. This problem is compounded by the fact that generators accumulating hazardous wastes in containers are not required to have any type of secondary containment for their containers. Therefore, should a release occur, these problems could be compounded if the "at least weekly" inspection fails to occur.

A review of state programs found that many states already require generators accumulating hazardous waste in containers to maintain records of their weekly inspections. Many of these states provide templates for generators to use to assist them in recording the results of their inspections.⁷⁷

EPA does not believe the burden imposed upon generators to record the results of its weekly inspections would be significant, particularly if generators use a template of some type to document the results of inspections (see examples of templates provided by states to generators to assist them in recording the results of inspections in the docket to this proposal).

The Agency also believes that best management practices for generators would already include documenting the results of their weekly inspections to not only prevent any releases, but also identify situations, such as a damaged container, that could lead to a potential release to the environment. That is, the Agency believes that the incremental cost of documenting the results of

weekly inspections would be less than the costs of having to clean up after a release.

The Agency is also seeking comment on modifying the generator accumulation conditions (the proposed language at §§ 262.16(b)(2)(iv) and 262.17(a)(1)(v) under the reorganization) to add a provision that generators document their weekly inspections of containers in central accumulation areas and keep the log of the inspections at the site for at least three years. The record of each inspection would document the following: the visual inspection of containers to identify any hazardous wastes accumulated in rusting, bulging, or leaking containers; a description of any discrepancies or problem areas encountered in the inspection and corrective actions taken; and the signature or initials of the inspector and the date of the inspection.

In requesting comment on documenting the results of "at least weekly" container inspections, the Agency is interested in the environmental and economic impacts of requiring all generators accumulating hazardous waste in containers to document weekly container inspection, as a condition for exemption. Additionally, the Agency requests comment on whether to require documentation of such inspections if the generator has a secondary containment system to control leaks in the event of a release of hazardous wastes or other such incidents. The Agency also requests comment on whether this documentation requirement should be limited to those generators that accumulate a certain amount of hazardous waste at any one time or generators that accumulate more than a certain number of containers in a central accumulation area at any one time. Lastly, the Agency also seeks comment from generators in states who already must maintain records of their container inspections on their experience with this provision and whether there are effective alternative options worth considering that achieve the same goals.

b. Tank inspections for SQGs at § 262.34(d)(3) with cross-reference to §§ 265.201(c) and (d). The Agency also requests comment on requiring small quantity generators accumulating hazardous waste in tank systems to document the results of their tank inspections in order to emphasize the importance of these inspections in preventing releases into the environment and to provide a measure of accountability that a generator inspection of its tanks actually took place. Unlike LQGs accumulating

⁷⁷ See *Sample of States With Container Documentation Requirements* in the docket for this rulemaking.

hazardous wastes in tanks, who must document the results of their inspections, SQGs have no such provision in part 262. EPA proposes to incorporate the regulatory text of § 265.201(c) and (d) into § 262.16.

The regulations at § 265.201(c)(1) through (5) state that SQGs must inspect discharge equipment, data from monitoring equipment, and levels of waste in a tank daily, unless the tanks have secondary containment and leak detection equipment or procedures, in which case these can be inspected at least weekly. In addition, SQGs must inspect the construction of tanks and of discharge confinement structures like dikes and the areas immediately surrounding them at least weekly.

Section 265.201(d) also requires that SQGs with full tank secondary containment to document in the facility's operating record when an alternative inspection schedule is used. However, neither § 265.201(c) nor (d) contains a requirement to document the results of any inspection findings. Therefore, the Agency requests comment on adding a paragraph to § 262.16 that would require that generators record in a log the daily and weekly results of inspecting their tanks and maintain a record of those inspections on site for at least three years.

Similarly, the Agency requests comment on adding a similar provision to § 262.16 to address tanks with secondary containment and leak detection systems or practices to ensure that leaks that are identified, that the generator would be required to record in a log the results of inspecting these areas, including any leakage that may occur and maintain a record of those inspections on site for at least three years.

In commenting on this matter, please consider, in particular, whether it is environmentally and economically worthwhile to require SQGs accumulating hazardous waste in tanks to document the results of daily and weekly tank inspections. The Agency also requests comment on whether to require the documentation of such inspections if the SQG has a secondary containment system to control leaks in the event of the release of hazardous wastes. Additionally, the Agency requests comment on whether this documentation requirement should be limited to those generators that accumulate a certain amount of hazardous waste at any one time or generators that accumulate hazardous waste in more than a certain number of tanks in a central accumulation area. Lastly, the Agency also seeks comment

from SQGs in states who already must maintain records of their tank inspections on their experience with this requirement and whether there are effective alternative options worth considering that achieve the same goal.

c. Drip pad inspections for both SQGs and LQGs at § 262.34. The Agency also requests comment on requiring both LQGs and SQGs accumulating hazardous waste on drip pads to document the results of their drip pad inspections. The current regulation in § 262.34(a)(1)(iii) references subpart W of part 265. Section 265.444 in subpart W currently requires that after installation, liners and covers must be inspected to ensure tight seams and joints and the absence of tears, punctures, or blisters and that while a drip pad is in operation, it must be inspected weekly and after storms to detect evidence of various types of damage to the drip pad or the systems that prevent and detect run-off and leakage.

As with hazardous waste accumulated in containers by LQGs and SQGs and hazardous waste accumulated in tank systems by SQGs, there is no regulation requiring them to document the results of drip pad inspections. Therefore, the Agency requests comment on modifying the generator accumulation conditions (§§ 262.16(b)(4) and 262.17(a)(3) in the proposed reorganization) to add a condition that the generator record in a log the results of weekly inspections and inspections after storms and that the records address deterioration, malfunctions or improper operation of run-on and run-off control systems; the presence of leakage in and proper functioning of leakage detection systems; and deterioration or cracking of the drip pad surface. The generator would be required to keep a record of the inspections on site for at least three years from the date of the last inspection.

In commenting, please consider whether it is environmentally and economically worthwhile to require SQGs accumulating hazardous waste on drip pads to document the results of weekly drip pad inspections. Additionally, the Agency requests comment on whether this documentation requirement should be limited to those generators that accumulate a certain amount of hazardous waste at any one time. The Agency also seeks comment from SQGs and LQGs in states who already must maintain records of their drip pad inspections on their experience with this provision, including whether it makes environmental and economic sense to ensure releases do not occur

and whether there are effective alternative options that achieve the same goals.

G. Generator Closure Regulations

EPA is proposing three changes to the closure conditions for exemption from permitting for LQGs in § 262.34(a)(1)(iv)(B). First, EPA is proposing to consolidate the closure regulations for LQGs accumulating hazardous waste at § 262.17(a)(8). This consolidation would include both the general performance requirements found at §§ 265.111 and 265.114 for containers, tanks, drip pads, and containment buildings, and the unit specific requirements found at § 265.197 for tanks, § 265.445 for drip pads, and § 265.1102 for containment buildings.

Second, EPA is proposing to strengthen the closure regulations for LQGs accumulating hazardous waste in containers in central accumulation areas that plan to stop hazardous waste accumulation in those containers by requiring them to meet the same type of closure regulations that apply for tanks, drip pads and containment buildings, including in those situations where a generator is not able to demonstrate that its contaminated soils can be practicably removed or decontaminated.

Third, EPA is proposing to require an LQG to notify EPA or the authorized state using EPA form 8700-12 at least 30 days prior to closing the generator's site or when the generator closes a unit accumulating hazardous waste. Additionally, EPA is proposing that an LQG notify EPA or their authorized state within 90 days after closing the site or the unit accumulating the hazardous waste. This notification would state that the LQG has clean closed or failed to clean close and therefore must close as a landfill.

1. Consolidation of Closure Regulations for LQGs in Part 262

EPA is proposing to consolidate all of the closure regulations for LQGs accumulating hazardous waste in tanks, drip pads, and containment buildings in the generator accumulation conditions (§ 262.17(a)(8) under the proposed reorganization). EPA believes that the current structure of these regulations can be confusing and difficult to follow.

Currently, the closure regulations for LQGs are found at § 262.34(a)(1). These regulations refer to the general performance requirements for closure at §§ 265.111 and 265.114. Section 265.111 references the unit specific closure regulations found at subpart J of part 265 (for tanks), subpart W of part 265 (for drip pads) and subpart DD of part 265 (for containment buildings). The

closure regulations for LQGs refer to the TSDf regulations because the waste accumulation units at LQGs (tanks, drip pads, and containment buildings) are similar to those at TSDf's and, thus, present the same potential for adverse impacts to human health and the environment if closure is not conducted properly.

However, while §§ 265.111 and 265.114 cite the specific closure regulations for different types of units, missing from § 265.111 is a reference to drip pads and missing from § 265.114 is a reference to both drip pads and containment buildings. The Agency believes these are inadvertent oversights where EPA failed to make the appropriate conforming changes when the regulations for drip pads and containment building were promulgated in 1990 and 1992, respectively.⁷⁸

Furthermore, as with other parts of the hazardous waste generator regulations, the accumulation regulations at § 262.34 often reference the detailed technical regulations of part 265 to reduce duplication. Part 265 describes the technical regulations for interim status TSDf's. Usually, the technical requirements in part 265 are clear in distinguishing the generator standards from standards for interim status TSDf's (e.g., § 265.201 specifies that the provisions of that paragraph are only for SQGs); however, this is not the case for the LQG closure regulations.

Finally, EPA believes the closure regulations are unnecessarily confusing. For example, the tank system regulations for LQGs at § 262.34(a)(1)(ii) make clear that the requirements of § 265.197(c) do not apply to LQGs. Yet, LQGs must comply with § 265.111, which in turn, at paragraph § 265.111(c) requires LQGs to comply with § 265.197, which includes paragraph (c). One commenter wrote about this confusion when the Agency proposed to clarify the closure regulations for LQGs as part its March 18, 2010, Hazardous Waste Technical Corrections and Clarifications Direct Final Rule (75 FR

12989).⁷⁹ The Agency has made clear in guidance that generators are not subject to § 265.111(c), except if the facility cannot clean close its waste accumulation unit(s), but we believe that a regulatory change would make this even more clear.⁸⁰

Therefore, as a first step in improving the usefulness of the closure regulations for LQGs accumulating hazardous waste in containers, tanks, drip pads, and containment buildings, EPA is proposing to consolidate and integrate all relevant closure provisions for LQGs accumulating hazardous waste in tanks, drip pads, and containments buildings at § 262.17(a)(8). The closure regulations include the following: (1) the general closure performance standards found at § 265.111(a) and (b); (2) a modified version of the standards found at § 265.114 (Disposal or decontamination of contaminated equipment, structures, and soils) that incorporates regulatory language applicable to containers, tanks, drip pads, and containment buildings undergoing closure; (3) the unit-specific closure regulations relevant to tanks, drip pads, and containment buildings found at §§ 265.197(a) and (b), 265.445(a) and (b), and 265.1102(a) and (b), respectively;⁸¹ (4) a provision addressing the disposition of any hazardous waste generated in the process of closing either the generator's site or unit(s) accumulating hazardous waste, and (5) a provision addressing the situation when a waste accumulation unit or site cannot clean close and must close as a landfill. This includes situations where an LQG accumulating hazardous wastes in containers cannot clean close. More specifically, the proposed new closure regulations in the generator accumulation conditions at § 262.17(a)(8)(ii) would require LQGs at closure to close the waste accumulation unit or site in a manner that achieves all of the following:

(1) Minimizes the need for further maintenance by controlling, minimizing, or eliminating, to the extent necessary to protect human health and the environment, the post-closure

escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere;

(2) Properly disposes of or decontaminates all contaminated equipment, structures and soil and any remaining hazardous waste residues from waste accumulation units including containment system components (pads, liners, etc.), contaminated soils and subsoils, bases, and structures and equipment contaminated with waste. Any hazardous waste residues remaining in the unit(s) being closed must be removed from the unit(s). Any leakage must also be decontaminated or removed and managed as a hazardous waste unless § 261.3(d) applies;

(3) Manages any hazardous waste generated in the process of closing either the generator's site or unit(s) accumulating hazardous waste in accordance with all applicable requirements of parts 260 through 270, including removing any hazardous waste contained in these units within 90 days of generating it and managing these wastes in a RCRA Subtitle C hazardous waste permitted or interim status treatment, storage and disposal facility or interim status facility; and

(4) Ensures that if the generator demonstrates that all contaminated soils cannot be practicably removed or decontaminated as required in this section, then the generator must close the waste accumulation unit(s) and perform post-closure care in accordance with the closure and post-closure care regulations that apply to landfills (§ 265.310). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the standards for landfills specified in subparts G and H of part 265.

2. Closure Regulations for LQGs Accumulating Hazardous Waste in Containers

As an additional condition to qualify to accumulate hazardous waste without a permit or interim status, EPA is proposing to require LQGs accumulating hazardous wastes in containers in central accumulation areas that plan to stop hazardous waste accumulation in those containers to meet the same type of closure regulations discussed above—that is, the closure regulations for tanks, drip pads, and containment buildings. This includes situations where an LQG accumulating hazardous wastes in containers can demonstrate that any

⁷⁸ Memo from Robert Springer, Director of EPA's Office of Solid Waste, to RCRA Directors, September 24, 2003, RCRA Online 14681; Drip Pad Closure Notification and Certification Requirements, November 1, 1997, RCRA Online 14130; and RCRA/Superfund Hotline Monthly Report, December 1998, RCRA Online 14321, that states: "LQGs are subject to the most stringent requirements, which include general closure provisions and unit-specific ones. The general closure requirements appear in Section 265.111 and Section 265.114 (Section 262.34(a)(1))." Additionally, the report states: "LQGs storing or treating waste in tanks, on drip pads, or in containment buildings are also subject to closure requirements specific to these types of units."

⁷⁹ Comments from the National Mining Association, May 3, 2010. Docket ID No: ID EPA-HQ-RCRA-2008-0678.

⁸⁰ RCRA/Superfund Hotline Monthly Report, December 1998, RCRA Online 14321.

⁸¹ Note: During the partial and final closure periods, all contaminated equipment, structures and soil must be properly disposed of, or decontaminated unless specified otherwise in § 265.197, 265.228, 265.258, 265.280, or 265.310. By removing all hazardous wastes or hazardous constituents during partial and final closure, the owner or operator may become a generator of hazardous waste and must handle that hazardous waste in accordance with all applicable requirements of part 262.

contaminated soils cannot be practicably removed or decontaminated and as a result, the generator must close the waste accumulation unit(s) and perform post-closure care in accordance with the closure and post-closure care requirements that apply to landfills (§ 265.310). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the requirements for landfills specified in subparts G and H of part 265.

Supporting these proposed regulations are damage cases by generators who accumulated hazardous wastes in containers. An examination of Superfund removal actions shows LQGs accumulating hazardous waste in containers have sometimes closed their doors or abandoned their sites, resulting in environmental problems.⁸² Most LQGs use containers to accumulate hazardous wastes. Some LQGs may generate relatively small quantities of hazardous waste and therefore may not need many containers to accumulate their hazardous wastes, but other generators generate a sufficient quantity of hazardous waste to require the use of a large number of containers each day. Not ensuring that these sites are closed properly increases the risk of more damage cases.

For LQGs that accumulate hazardous waste in containers or container units, EPA is proposing closure regulations that replicate the regulations in paragraphs § 262.17(a)(8)(ii), mentioned above. The Agency believes the closure regulations are applicable to LQGs who have accumulated hazardous waste in containers as well as to LQGs who have accumulated hazardous waste in tanks, drip pads and containment buildings in order to prevent adverse impacts to human health and environment. Therefore, as with LQGs that accumulate hazardous wastes in tanks, drip pads, and containment buildings, should a generator decide to close a container or stop accumulating hazardous waste in containers at the site altogether, it would be responsible for complying with the regulations proposed at § 262.17(a)(8)(ii) and removing all relevant hazardous wastes accumulated within 90 days of generating it and any hazardous wastes that also may have been accumulated in SAAs. Otherwise, the generator would fail to meet the conditions for the exemption from permitting and would be subject to the requirements of 40 CFR

parts 264, 265, 267 and the permit requirements of part 270.

3. Notification by LQGs Upon Closure of their Hazardous Waste Accumulation Units

EPA is also proposing that an LQG notify either EPA or its authorized state at least 30 days prior to closure of a hazardous waste accumulation unit, such as a container, tank, drip pad, or containment building, or closure of the site altogether. EPA is also proposing that such generators subsequently notify EPA or its authorized state no later than 90 days after closure of the site or a hazardous waste accumulation unit that they have either clean closed (*e.g.*, complied with the applicable generator closure regulations) or, if they cannot clean close, that they must close as a landfill. If these changes are finalized, EPA will amend EPA form 8700-12 to incorporate collection of this information.

The hazardous waste regulatory program is a “cradle to grave” system in which any hazardous waste generated by an LQG (or SQG) must be subsequently managed, either on site or off site at an appropriate RCRA destination facility. Missing from the current regulatory framework is knowledge by the regulatory authority that the LQG, upon closing either a waste accumulation unit or closing the site altogether, properly closed the accumulation unit in compliance with the applicable closure regulations. Without this knowledge, regulatory authorities do not know whether generators have abandoned the site, leaving behind hazardous waste that could subsequently result in a release to the environment and adverse impacts to human health and the environment. Thus, these closure notifications are important to ensure that LQGs close their waste accumulation unit, or site, in compliance with the applicable closure regulations. Fail to properly close would be a violation of the waste accumulation exemption.

4. Request for Comment

EPA requests comment regarding its proposal to consolidate the closure regulations for hazardous waste generated by LQGs in § 262.17(a)(8) and whether this approach would improve the readability/understandability of the rules, and thus, improve compliance. EPA also requests comment on whether parts of the proposed closure regulations at § 262.17(a)(8) should be modified.

EPA also requests comment regarding its proposal to strengthen the closure

regulations for LQGs accumulating hazardous waste in containers.

In addition, EPA requests comment on whether it should require LQGs to notify EPA regarding closure both prior to closure (*e.g.*, at least 30 days prior to closure) and after closure (*e.g.*, notify no later than 90 days after the site has closed one or all of its hazardous waste accumulation units either by clean closure or closed as a landfill) or whether EPA should just require notification only once—that is, after closure (*e.g.*, no later than 90 days after closure). Requiring notification only after closure of the hazardous waste accumulation unit or site reduces the generator’s paperwork burden in half and allows EPA and the state to focus on results. However, requiring notification both before and after closure creates greater visibility for this important activity. The notification creates an incentive for the generator to take all appropriate actions once the unit or site is closed and also provides notice to EPA and the state to be aware of this important activity and to plan for a possible inspection to verify clean closure has successfully occurred or determine if additional closure efforts are needed. EPA is currently of the opinion that the additional environmental benefits accrued from requiring both notifications will exceed the additional paperwork costs to the generator. In conjunction with an LQG notifying EPA no later than 90 days after closure, EPA is also requesting comment on whether, as part of the closure notification requirements, LQGs should be required to certify that they have clean closed or failed to clean close all applicable hazardous waste accumulation units. This type of notification would have the added benefit of ensuring EPA knows that an LQG performed their due diligence in closing and can certify to either clean closing or closing as a landfill.

Because there are no federal regulations for closure of a waste accumulation unit or site closure by SQGs, SQGs are not required to comply with the clean closure regulations, as well as notify when they close any or all waste accumulation units. Unlike LQGs, which have no waste accumulation limits as long as they remove any hazardous waste within 90 days of generating it, SQGs do have a waste accumulation quantity limitation of 6,000 kilograms. Given this waste accumulation quantity limitation, EPA sees no reason at this time to propose requiring SQGs to clean close or close as a landfill if they cannot clean close. However, EPA sees a potential benefit in having SQGs notify EPA when SQGs

⁸² See EPA’s On Scene Coordinator (OSC) Web site: <http://www.epaosc.org>.

close to allow the regulatory authority to follow-up and ensure that all hazardous waste was removed and properly managed. Therefore, EPA is requesting comment regarding whether SQGs that stop accumulating and close any or all of their hazardous waste accumulation units should notify EPA within 60 days after closing.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The LQG closure regulations would move to § 262.17(a)(8). The reorganization is discussed in section XIII of this preamble.

H. Changes to the Preparedness, Prevention, and Emergency Procedures Provisions (40 CFR 262.34(a)(4) and 262.34(d)(4) and (5))

EPA is proposing a number of modifications to the conditions for exemption for both SQGs and LQGs regarding preparedness, prevention and emergency procedures. The conditions for SQGs are found at §§ 262.34(d)(4) and (5) (which refer to the technical standards at 40 CFR part 265 subpart C) and the conditions for LQGs are found at § 262.34(a)(4) (which refers to the technical standards at part 265 subparts C and D).

The proposed revisions are organized in this section as follows: (1) Revising the scope of the contingency planning and emergency procedures regulations; (2) revising § 265.37(a) to state that when making arrangements with local authorities regarding emergency procedures, an SQG or LQG must first attempt to make emergency preparedness and procedures agreements with its Local Emergency Planning Committee (LEPC), and, if this attempt is not successful (or there is no LEPC in the area), the generator must make an arrangement with its local fire department and other emergency responders; (3) modifying the regulations for contingency plans for LQGs in §§ 265.52 and 265.53 to add an executive summary to the plan that a new LQG would submit to the LEPC and to adjust the content of an element of the required contingency plan; (4) making two revisions to the technical standards regarding required equipment that are part of the preparedness and prevention regulations in part 265 subpart C that are applicable to both SQGs and LQGs; (5) modifying the preparedness and prevention provisions for SQGs at § 262.34(d)(5) regarding posted emergency coordinator information and responsibility for cleaning up a spill; (6) modifying the personnel training provision for LQGs; (7) taking comment on what personnel

should have mandated personnel training, and (8) taking comment on whether any of these proposed revisions would be appropriate for TSDFs in addition to generators.

Recent catastrophic chemical accidents in the United States, such as the 2013 West, Texas, fire and explosion that killed 15 people, the 2010 explosion and fire at Tesoro Refinery in Anacortes, Washington, that killed seven employees, and the 2012 Chevron Refinery hydrocarbon fire in Richmond, California, that affected 15,000 people in the surrounding area, highlight the need for continued improvement in a number of areas related to chemical facility safety. To address these concerns, the President issued Executive Order 13650—Improving Chemical Facility Safety and Security (EO) on August 1, 2013.⁸³ The EO directed the Department of Homeland Security, EPA, the Department of Labor, the Department of Justice, the Department of Agriculture, and the Department of Transportation to identify ways to improve operational coordination with state, local, tribal, and territorial partners; enhance federal agency coordination and information sharing; modernize policies, regulations, and standards to enhance safety and security in chemical facilities; and work with stakeholders to identify best practices to reduce safety and security risks in the production and storage of potentially harmful chemicals.

One of the key goals the EPA is addressing through this effort is enhancing and providing additional support to State Emergency Response Commissions (SERCs) and LEPCs to assist them in collecting and analyzing the chemical information they receive from local facilities and developing local emergency response plans to mitigate or prevent a devastating chemical disaster. Several of the proposed requirements are aligned with these EO efforts and will assist in furthering this goal and with those of the EO in general because they update the regulations to make them compatible with the current infrastructure of emergency planning and response by referencing LEPCs. Additionally, these revisions would provide a more usable contingency plan to emergency responders en route to a time-sensitive emergency at a generator of hazardous waste. Before finalizing these provisions, EPA will ensure that they are aligned with the efforts to

⁸³ <http://www.whitehouse.gov/the-press-office/2013/08/01/executive-order-improving-chemical-facility-safety-and-security>.

improve chemical plant safety and security under the EO.

This preamble also discusses how EPA might incorporate modern technology into the emergency planning and procedures regulations for generators in order to provide information more quickly to emergency responders when faced with an event at a generator.

In addition to the changes listed above, as part of the reorganization of the preamble discussed in section XIII, EPA is proposing to copy the preparedness and prevention regulations for SQGs into § 262.16 and to create a new subpart in part 262—subpart M—that would contain the more extensive preparedness, prevention, and emergency procedures regulations for LQGs. Copying a version of these regulations into part 262 allows most of the preparedness, prevention, and emergency procedures regulations for generators to be easily found without accessing part 265 and with minimal cross-referencing.⁸⁴

As part of this reorganization, our proposed regulation has replaced the word “facility” in the regulations with “site” because “facility” is defined in § 260.10 as specific to TSDFs. Another small revision that we propose because of the reorganization of these regulations is folding the “comment” in § 265.55 into the body of the corresponding proposed regulation at § 262.264. We are proposing this because **Federal Register** style no longer permits this kind of comment in new regulations.

1. Areas Subject to Preparedness, Contingency Planning, and Emergency Procedures Regulations

The current preparedness and emergency procedures regulations do not clearly state whether they are applicable to the entire generator site or only to areas where hazardous waste is generated and accumulated on site (or where allowable treatment may occur in accumulation units) and when transported off site for subsequent treatment, storage, and disposal. EPA is proposing that the regulations for preparedness and prevention and for contingency planning and emergency procedures apply only to those areas of a generator's site where hazardous waste

⁸⁴ Note that throughout this section, although we are referring to the regulations by their current citations, the fact that we are also proposing in most cases to reorganize those requirements and copy them into the generator requirements in part 262 means that the revisions discussed in this section would not automatically apply to interim status TSDFs, as the proposed revisions only apply to the version of these regulations that is being proposed to be in part 262.

is generated and accumulated and, where applicable, to those areas where allowable treatment may occur in accumulation units.

The Agency is proposing to explicitly state that the RCRA preparedness and emergency procedures regulations are limited strictly to areas where hazardous waste is generated and accumulated.

The Agency has previously signaled that these requirements do not apply to the entire generator site. In a November 7, 2006, letter, EPA stated that the 40 CFR part 265 regulations for LQGs set forth in § 262.34(a)(4) apply to units accumulating hazardous wastes. The letter states that in order to comply with the part 265 requirements referenced in § 262.34(a)(4), LQGs only need to address those tanks, containers, drip pads, and containment buildings that accumulate hazardous wastes and are subject to the 90-day generator accumulation provision. As an example, the letter states that when developing a contingency plan, LQGs would only need to include those 90-day accumulation units involving the on-site management of hazardous waste.⁸⁵

It makes sense to limit the applicability of these regulations only to these areas because several other statutes already address the development and implementation of contingency plans associated with other areas of a generator site, such as the storage of chemical materials other than hazardous wastes. We also note that considerable overlap exists in the requirements in the various statutes and, since 1997, the federal government has encouraged facilities to develop integrated contingency plans and has provided guidance for doing so in the **Federal Register**. The integrated contingency plan is discussed further in section VIII.H.3, below.

The language EPA is proposing to change currently appears in §§ 265.30 and 265.50, though we are proposing to move it to a new part 262 subpart M to make it specific to generators. EPA proposes that subpart M apply only to those areas of a large quantity generator where hazardous waste is generated and accumulated on site in accordance with the conditions in § 262.17. This proposal includes a parallel change for the emergency procedures regulations for small quantity generators in § 262.16.

The Agency requests comment on making it explicit in the regulations that the preparedness, prevention, and

emergency procedures regulations apply only to those areas of the generator's site where hazardous waste is generated and accumulated, and where applicable, those areas where allowable treatment may occur in accumulation units.

Effect of Proposed Reorganization: This section is affected by the proposed reorganization. The proposed revisions would appear at § 262.250 in a new subpart M of part 262 and would not appear in part 265. The reorganization is discussed in section XIII of this preamble.

2. Making Arrangements With the Local Emergency Planning Committee

Sections 262.34(a)(4) and (d)(4) set forth conditions for LQGs and SQGs that accumulate without a permit. Both these paragraphs include references to part 265 subpart C, which contains a reference to § 265.37. Section 265.37(a) states that "The owner or operator must attempt to make the following arrangements, as appropriate for the type of waste handled at his facility and the potential need for the services of these organizations" and goes on to list the types of local emergency officials that should be informed about hazardous waste at a facility, such as fire departments and emergency response teams, and the information the generator should provide them.

The Agency is proposing to revise this provision for generators to state that SQGs and LQGs must first attempt to enter into agreements with their LEPC, but if there is no LEPC in the area or if the LEPC does not respond or is unwilling to enter an agreement, the generator must enter into an agreement(s) with the local fire department and other emergency responders. This proposed revision would add to the regulations both a reference to LEPCs and an explicit statement that generators must enter into an agreement with emergency planning officials, rather than just attempt to enter into an agreement.

a. Local emergency planning committees. The Agency is proposing to revise regulations that were finalized in 1980. The national and local infrastructure for emergency planning and response has changed significantly since that time, but these regulations have not been updated to reflect those changes. The proposed revision to specifically name LEPCs in this regulation addresses that deficiency.

The Superfund Amendments and Reauthorization Act (SARA) was enacted in 1986. Title III of SARA is also known as the Emergency Planning and Community Right-To-Know Act (EPCRA). EPCRA helps increase the

public's knowledge and access to information regarding chemicals at individual facilities, their uses, and releases into the environment. States and communities, working with facilities, can use the information to improve chemical safety and protect public health and the environment. EPCRA requires both small and large entities to report chemical information to the SERC, the LEPC, the local fire department, and tribal nations.

EPCRA requires LEPCs to prepare a comprehensive plan for local communities designed to help them prepare for and respond to emergencies involving extremely hazardous substances (EHS). Facilities covered by EPCRA planning provisions are required to cooperate in emergency plan preparation and designate a facility emergency coordinator to participate in the planning process as well as notify their SERC and LEPC within 60 days of becoming subject to the emergency planning requirements (when an EHS is first present at the facility from a shipment or production). Additionally, as part of the community-right-to-know provisions of EPCRA, facilities that have hazardous chemicals for which they must have or prepare an MSDS or SDS and have at or above the threshold amount of those chemicals must also annually complete and submit an Emergency and Hazardous Chemical Inventory form (also known as a Tier II) to the LEPC, to the SERC, and to the local fire department by March 1. These facilities must send copies of their MSDS, SDS, or a list of hazardous chemicals to the LEPC, to the SERC, and to the fire department.⁸⁶

In turn, LEPCs must develop an emergency response plan, review it at least annually, and provide information about chemicals in the community to citizens. These plans are developed by LEPCs with stakeholder participation. There are more than 3,000 designated local emergency planning districts, although not all of these districts have functioning LEPCs. The LEPC membership must include (at a minimum) elected state and local officials; police, fire, civil defense, and public health professionals; environment, transportation, and hospital officials; facility representatives; and representatives from community groups and the media. Although in many areas the LEPCs are the main organizing entities for emergency response, the RCRA hazardous waste regulations do not

⁸⁵ Memorandum from Matt Hale, Director of EPA's Office of Solid Waste, to RCRA Division Directors, November 7, 2006, RCRA Online 14758.

⁸⁶ The regulations implementing the emergency planning and notification requirements of EPCRA can be found at 40 CFR part 355.

mention them or their role in contingency planning.

The proposed language directly references LEPCs, stating that the generator must make arrangements with the Local Emergency Planning Committee for the types and quantities of hazardous waste handled at the site.⁸⁷ This modification merely updates the RCRA hazardous waste regulations to match the current emergency planning landscape.

Consistent with this proposed modification at § 265.37, the Agency is also proposing that when the language in current § 265.52(c) is copied into part 262, it state that the plan must describe arrangements agreed to with the Local Emergency Planning Committee. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, then the large quantity generator must make arrangements with its local fire department and other relevant emergency responders (e.g., police and hospitals) to coordinate emergency services, pursuant to § 262.256.

The Agency requests comment on this proposal to modify the language in §§ 265.37(a) and 265.52(c) when they are copied into part 262.

Effect of Proposed Reorganization: These sections are affected by the proposed reorganization. The proposed regulation would appear in the SQG standards at § 262.16(b)(8)(vi) and in the new part 262 subpart M for LQGs at § 262.256 for arrangements and § 262.261(c) for the content of the contingency plan. The reorganization is discussed in section XIII of this preamble.

b. Making required arrangements. The other proposed modification to the language currently in § 265.37(a) when it is copied into part 262 addresses the ambiguity of the current language, which requires only that the owner or operator “attempt to make” arrangements with local emergency response authorities.

Section 265.37(a) states that the owner or operator must attempt to make arrangements with local fire and emergency organizations, as appropriate for the type of waste handled at the facility and the potential need for the services of these organizations.

⁸⁷ Although much of the discussion of these provisions for the purposes of this rule revolves around hazardous waste generators, because the provisions are located in part 265 for interim status hazardous waste TSDFs, they will refer to the persons regulated as “owner or operator” and the entity being regulated as the “facility.”

Paragraph (a)(1) makes clear that these arrangements involve familiarizing these organizations with the layout of the facility, properties of the hazardous waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes. Because an SQG is not required to submit a contingency plan, this language suggests that SQGs need only invite local officials to visit and familiarize themselves with the site as compared to LQGs, which are required to develop a written contingency plan and provide it to local officials.

Given the importance of emergency preparedness and planning, EPA is proposing to require that an SQG or an LQG must make direct arrangements with its LEPC as part of this condition. The Agency believes the LEPCs, in turn, will work with their local responders to integrate the activities of SQGs and LQGs into the overall emergency response plan.

Many SQGs and LQGs may already have arrangements with their LEPCs because most SQGs and LQGs either have EHSs that require reporting to the LEPC, which triggers EPCRA emergency planning requirements, or use chemicals that require an SDS, triggering the EPCRA community right-to-know requirement to report to LEPCs. However, in the case that a hazardous waste generator does not have a relationship with the LEPC, that LEPC may view working with non-EPCRA facilities as outside the scope of their authority. Alternatively, there may be a hazardous waste generator in a location where there is no organized LEPC. Therefore, as part of this regulation, EPA proposes to require that an SQG or LQG attempt to make formal arrangements with its LEPC unless there is no LEPC, the LEPC does not respond, or the LEPC determines that it is not the appropriate organization to make an arrangement with. In this case, the SQG or LQG would be required to make arrangements with its local fire department, as well as with other relevant emergency responders, such as the police department and local hospitals.

The proposed regulatory text for this condition would state that the generator must make arrangements with the Local Emergency Planning Committee for the types and quantities of hazardous waste handled at the site, as well as the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment

suppliers, and local hospitals.⁸⁸ Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, then the generator must make arrangements with the local fire department and other relevant emergency responders (e.g., police and hospitals).

EPA is also proposing regulatory text that describes procedures for how a facility that is not able to make arrangements with the LEPC would make such arrangements with the fire department and other local emergency services. Much of this language corresponds with the existing standards for making arrangements with emergency responders. These mandated steps are not necessary in the case of arrangements with the LEPC because that group is likely to have standardized procedures of its own to follow to make these arrangements with facilities.

The Agency requests comment on its proposal to require an SQG or an LQG to enter into arrangements with its LEPC unless there is no LEPC, the LEPC does not respond, or the LEPC determines that it is not the appropriate organization to make arrangements with, in which case the SQG or LQG would enter into an arrangement with its local emergency responders.

EPA is also proposing to add new language to supplement this condition because current § 265.37(a) does not specify the frequency that hazardous waste generators must make arrangements with local authorities. For example, should arrangements be updated according to a set schedule or only when modification is needed. Considering that some SQGs and LQGs may already coordinate with their LEPCs annually as part of their EPCRA requirements, the Agency is of the opinion that it is not necessary to include time frames for updating in this rule. The Agency requests comments on whether the regulations should mandate how frequently a generator must communicate with its LEPC or local fire department if it has not otherwise communicated with them.

Effect of Proposed Reorganization: This section is affected by the proposed reorganization. The proposed regulation would appear in the SQG standards at § 262.16(b)(8)(vi) and in the new part 262 subpart M for LQGs at § 262.256. The reorganization is discussed in section XIII of this preamble.

⁸⁸ This condition is being proposed at § 262.16(b)(8)(vi)(A) for SQGs and § 262.256 for LQGs due to the proposed reorganization.

c. Documenting arrangements. As noted above, the EPA thinks it is important for both SQGs and LQGs to make arrangements with their LEPCs. In addition, EPA believes that documentation of these arrangements would be useful in ensuring that generators have taken the necessary steps to prepare for an emergency and have a clearly defined plan with the LEPC for emergency response.

Therefore, when EPA copies this condition into part 262, EPA is proposing to modify the language to state that the generator shall maintain records documenting the arrangements with the Local Emergency Planning Committee, or if appropriate, with the local fire department as well as any other organization necessary to respond to an emergency. This documentation may include a certified letter or any other documentation that confirms such arrangements actively exist.

One alternative suggested as part of the 2004 Program Evaluation of the hazardous waste generator regulatory program would be to require hazardous waste generators to list the emergency response agencies that have agreed to respond in the event of an emergency with some documentation confirming that the arrangements exist. In addition to helping generators prepare for emergencies, documentation of these arrangements would provide the necessary information for inspectors when determining compliance. The Agency believes this alternative may be the most effective approach to addressing the ambiguity that exists with the existing regulations at § 265.37(b).

The Agency seeks comment on this proposed change to documentation, in particular whether local ordinances already require generators to have documentation of arrangements with local emergency response organizations.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The proposed regulation would appear in the SQG standards at § 262.16(b)(8)(vi) and in the new part 262 subpart M for LQGs at § 262.256(b). The reorganization is discussed in section XIII of this preamble.

d. Request for comment on emergency procedures at large facilities with internal emergency teams. Many large organizations, particularly those that operate 24 hours a day, such as airports and military bases, have their own emergency response capabilities. This raises the question of whether and under what circumstances arrangements with local authorities would not be needed to ensure effective emergency response. The Agency seeks comment

on the feasibility of providing a waiver from requiring either an SQG or LQG to enter into arrangements with an LEPC or, if appropriate, other local authorities when they have 24-hour on-site emergency response capabilities, particularly under what circumstances a waiver would be granted.

3. Changes to Contingency Plan Regulations for LQGs

Under § 262.34(a)(4), LQGs are required to comply with 40 CFR part 265 subpart D, §§ 265.50–265.56, which describes the regulations on contingency planning and emergency procedures. These regulations address the purpose of the contingency plan, what it must contain, who receives copies, how to amend the contingency plan, and responsibilities of the facility's emergency coordinator and emergency procedures. One important thing to note is that the owner or operator of the facility can develop one contingency plan that meets all the regulatory standards for the various statutory and regulatory provisions for contingency planning:

- EPA's Oil Pollution Prevention Regulation (SPCC and Facility Response Plan Requirements) at 40 CFR 112.7(d), 112.20, and 112.21;
- EPA's Risk Management Programs Regulation at 40 CFR part 68;
- EPA's Resource Conservation and Recovery Act Contingency Planning Requirements at 40 CFR part 264 subpart D, 40 CFR part 265 subpart D, and 40 CFR 279.52;
- Department of Interior's Bureau of Safety and Environmental Enforcement (BSEE) Facility Response Plan Regulation at 30 CFR part 254;
- Pipeline and Hazardous Materials Safety Administration (PHMSA) Response Plans for Onshore Oil Pipelines at 49 CFR part 194;
- U.S. Coast Guard's (USCG) Facility Response Plan Regulation at 33 CFR part 154 subpart F;
- OSHA's Emergency Action Plan Regulation at 29 CFR 1910.38(a);
- OSHA's Process Safety Standard at 29 CFR 1910.119; and
- OSHA's HAZWOPER Regulation at 29 CFR 1910.120.

EPA recommends that generators base their contingency plan on the National Response Team's Integrated Contingency Plan Guidance (One Plan), discussed in the **Federal Register** on June 5, 1996, at 61 FR 28642.

In this action, EPA is proposing three modifications to the contingency planning regulations for generators: One is meant to improve the ability of emergency response teams to respond to an emergency at an LQG and the other

two are technical changes to the content of the contingency plan.

a. Submitting a contingency plan executive summary to emergency management authorities. The Agency is proposing to require that a new LQG, as of the effective date of the rule, submit an executive summary of its contingency plan to the emergency management authorities. As part of this revision, EPA proposes to change the language of the regulation to include LEPCs, as discussed above in section VIII.H.2.

The current regulations at § 265.53 state that a copy of the contingency plan must be submitted to all local police departments, fire departments, hospitals, and state and local emergency response teams that may be called upon to provide emergency services.

In discussions with EPA, emergency management professionals indicated that the length of the facility contingency plans prevents first responders from being able to fully review a facility's contingency plan when responding to an emergency.⁸⁹ Instead, they need readily available information that describes what they must confront when they arrive at the scene. Once the incident is under control, the first responders can then review the detailed contingency plan to determine their next steps, if applicable. Thus, the Agency believes that a shorter document, such as an executive summary of the contingency plan would be more effective for an emergency responder when responding to an incident at a facility accumulating hazardous waste. As currently happens in practice, once the incident is under control, then the emergency responders can review the more detailed contingency plan if necessary for long-term responses.

A review of the information required as part of a RCRA contingency plan in § 265.52, as well as information required by the local fire department, identified certain components that would be useful in an executive summary and EPA used this information in developing this proposed regulation. Specifically, the Agency is proposing to require that the following information be included in an executive summary to assist emergency responders in the event of an incident: (1) The types/names of hazardous wastes in layman's terms and the associated hazard associated with each waste present at any one time (e.g., toxic paint wastes,

⁸⁹ Notes from discussion with Phil Oakes and Jim Narva, International Association of Fire Marshalls, concerning Contingency Planning and Emergency Response Regulations, July 2012.

spent ignitable solvent, corrosive acid); (2) the estimated maximum amount of each waste that may be present at any one time; (3) the identification of any hazardous wastes where exposure would require a unique or special treatment by medical or hospital staff; (4) a map of the site showing where hazardous wastes are generated and accumulated and routes for accessing these wastes; (5) a street map of the facility in relation to surrounding businesses, schools, and residential areas to understand how best to get to the facility and also evacuate citizens and workers; (6) the locations of water supply (e.g., fire hydrant and its flow rate, drafting locations); (7) the identification of on-site notification systems (e.g., a fire alarm that rings off-site, smoke alarms); and (8) the name of the emergency coordinator and 24/7 emergency telephone number.

EPA believes these are the appropriate elements for the executive summary but is taking comment on them. In addition, for identification of the hazardous waste under element (1), EPA is taking comment on whether providing the name of the waste in layman's terms is sufficient for ensuring that first responders will be able to identify the appropriate actions to take in response. A reference to the material in the North American Emergency Response Guide, where appropriate, would likely reduce the time it takes for first responders to get the necessary information for managing the situation. EPA is interested in whether this type of reference would be useful to first responders and whether generators can easily access this information to add to their contingency plans.

EPA is also taking comment on whether the executive summary should add to element (3) a requirement that the generator provide information on the medical information for exposure to those hazardous wastes that do require special treatment. EPA is specifically interested in whether this information is readily available to the generator to be included in the executive summary of the contingency plan and whether first responders would find this additional information useful for responses.

Under the proposed condition for contingency plans at LQGs, EPA is proposing that an LQG that becomes subject to this rule after the rule's effective date be required to develop and submit an executive summary of its contingency plan to the LEPC in addition to the full contingency plan. The Agency is not proposing to require that an LQG that has already developed and submitted a contingency plan to local emergency responders develop an

executive summary because of the additional burden that would be imposed on existing LQGs to go back to their contingency plans and develop this summary. The Agency has determined that developing the executive summary during the initial writing of the contingency plan would not be a significant extra step. However, we recommend that an LQG that is not required to develop an executive summary of its contingency plan may want to do so and submit that executive summary to the LEPC when doing a periodic update on its contingency plan to ensure that the emergency responders have the appropriate information on hand in the event of an emergency.

EPA, therefore, is proposing to modify the condition regarding copies of the contingency plan to require that a copy of the contingency plan and all revisions to the plan must be maintained at the large quantity generator's site and the large quantity generator must submit a copy of the contingency plan to the Local Emergency Planning Committee. If there is no Local Emergency Planning Committee, if it does not respond, or if the Local Emergency Planning Committee determines that it is not the appropriate organization to make arrangements with, the facility must then submit the copy to the local emergency responders.

We are proposing to list in the regulations the eight elements described above as the most valuable items for emergency responders.

The Agency requests comment on this proposed revision. In addition, EPA requests comment on whether an existing LQG that has already provided its full contingency plan should also be required to submit an executive summary to the LEPC or, if appropriate, the fire department or other emergency responders.

The Agency also requests comment on whether an SQG should be required to develop an executive summary of a contingency plan. The major differences between the preparedness, prevention, and emergency procedures regulations applicable to SQGs and those applicable to LQGs are the development and implementation of a contingency plan and more rigorous responsibilities for the LQG emergency coordinator. Realizing that many SQGs may already have developed contingency plans to comply with other statutory and regulatory requirements, however, many of the elements of an executive summary may already be available and that the only addition would be summary information on the types and quantities of hazardous waste on site,

their associated risks, and their location within the facility. Therefore, requiring SQGs to provide an executive summary of a contingency plan to first responders could provide information that is critical during emergencies with little extra effort by the SQGs.

Effect of Proposed Reorganization: This section is affected by the proposed reorganization. These proposed regulations would appear in the new part 262 subpart M for LQGs at §§ 262.261 and 262.262. The reorganization is discussed in section XIII of this preamble.

b. Eliminating employee personal information in LQG contingency plans. As stated above, the condition for exemption for LQGs at § 262.34(a)(4) references part 265 subpart D, which includes a list of what the contingency plan must contain. The Agency is also proposing to modify the language currently at § 265.52(d) when it is copied into part 262 to now allow an LQG the flexibility to eliminate unnecessary employee personal information that is currently required in the contingency plan. This would protect those individuals' privacy, but still provide necessary information to address emergencies. Section 265.52(d) currently states that the plan must list names, addresses, and phone numbers (office and home) of all persons qualified to act as emergency coordinator (see § 265.55), and requires that this list be kept up to date. It specifies that where more than one person is listed, one must be named as primary emergency coordinator and others must be listed in the order in which they will assume responsibility as alternates. The proposed revision would remove the unnecessary references to addresses in this language and change the reference to home and office telephone numbers to "emergency telephone number."

Also as part of this revision, the Agency is proposing revisions to address situations where the facility has an emergency coordinator on duty 24 hours every day of the week. In those situations, the plan may list the staffed position (e.g., operations manager, shift coordinator, shift operations supervisor), as well as an emergency telephone number that can be guaranteed to be answered 24 hours a day, 7 days a week, 365 days a year. The EPA proposes to add language stating that in situations where the generator site has an emergency coordinator continuously on duty because it operates 24 hours per day, every day of the year, the plan may list the staffed position (e.g., operations manager, shift coordinator, shift operations supervisor,

or some other similar position) as well as an emergency telephone number that can be guaranteed to be answered at all times.

The Agency requests comment on this proposed modification.

Effect of Proposed Reorganization:

This section is affected by the proposed reorganization. The proposed regulation would appear in the new part 262 subpart M for LQGs at § 262.261(d). The reorganization is discussed in section XIII of this preamble.

c. Request for comment to include alternative evacuation routes in contingency plan (40 CFR 265.52(f)). The Agency also requests comment on modifying the condition on alternative evacuation routes in a contingency plan, currently found at § 265.52(f). This paragraph currently states that the plan must include an evacuation plan for facility personnel where there is a possibility that evacuation could be necessary and that this plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

At issue is whether a contingency plan must contain information about alternative evacuation routes or whether a different approach for addressing alternative evacuation routes would be more effective. As part of the 2004 Program Evaluation of the hazardous waste generator regulatory program, the Agency received a comment stating that it does not make sense to include in the contingency plan the hundreds of possible evacuation routes that may be present at a facility depending on its configuration. The commenter argued that the regulation should be modified to require that evacuation routes be posted and drills be conducted but that the regulations should not require the routes to be in the contingency plan.⁹⁰

The Agency does not believe the current regulation requires all potential evacuation routes be identified and believes emergency responders may need this type of information in order to determine the most efficient and timely approach to reach the facility, which raises the question of whether the regulation should be modified in this way. However, the Agency seeks comment on whether the commenter's proposal to require the posting of evacuation routes and holding annual evacuation training and drills would be

an effective substitute to maintaining alternative evacuation routes in the contingency plan. The Agency also seeks comment on whether this paragraph of the regulations should discuss shelter-in-place as part of contingency plans.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. Under the reorganization, the proposed regulation would appear in the new part 262 subpart M for LQGs at § 262.261(f). The reorganization is discussed in section XIII of this preamble.

d. Request for comment on the usefulness of a potential electronic RCRA contingency planning application.

The Agency requests comment on whether contingency plans should be submitted electronically to emergency responders to enhance their ability to respond safely and effectively to an emergency at an LQG and what EPA's role should be in electronic submittals. Currently EPA makes numerous electronic databases and tools available for helping first responders with emergency management. These tools include CAMEO (Computer-Aided Management of Emergency Operations), which assists with data management requirements under EPCRA, such as the required annual submittal of an Emergency Hazardous Chemical Inventory Form to the LEPC. EPA is taking comment on whether an additional tool to manage contingency plans under RCRA would be a useful addition to this software suite and whether it would assist LEPCs by integrating the contingency plan with their existing data on facilities, making the information available to the first responders in the most usable way.

Specifically, we request comment on the feasibility and effectiveness of private sector parties or non-profit or governmental entities developing software that LQGs could use to provide important information to emergency responders in responding to an emergency. Building on the concept of a standard list of information to be included in a contingency plan executive summary that was discussed above, private sector or non-profit parties could design electronic software to identify the appropriate information emergency responders quickly need to assess an emergency. In turn, LQGs would then input that information into the application and provide that information to their local LEPC or emergency response organization for use should an emergency arise. The objective would be to allow emergency responders to more quickly and

effectively analyze and respond to emergencies rather than having to review a lengthy document.

4. Technical Changes Applicable to Both SQGs and LQGs

The Agency is proposing two additional clarifications and modifications to the existing preparedness, prevention, and emergency procedures regulations for SQGs and LQGs and is taking comment on one more.

The Agency is proposing revisions based on 30 years of experience with these rules, feedback from stakeholders as part of the Agency's 2004 Program Evaluation of the hazardous waste generator regulatory program and discussions and communication with stakeholders. EPA believes these clarifications will foster improved compliance without adversely affecting the protection of human health and the environment.

a. Proposed technical changes to introductory paragraph on required equipment. Sections 262.34(a)(4) and (d)(4) include the condition that LQGs and SQGs comply with part 265 subpart C, which includes § 265.32. Section 265.32 requires that all facilities must be equipped with certain types of equipment unless none of the hazards posed by waste handled at the facility could require that particular kind of equipment. The paragraph goes on to list required equipment such as an internal communications system, a telephone or radio, fire extinguishers, and access to adequate water. The existing regulation is not clear as to whether the required equipment must be placed in those areas of operation where hazardous waste is generated and accumulated, (or treated, stored and disposed in the case of an interim status TSDF) or whether other parts of the facility could store this equipment—that is, where hazardous waste is not generated or accumulated.

The Agency believes it may not always be appropriate or safe to have this equipment stored in the actual waste generation or accumulation area and instead, we are proposing that the regulation state that the hazardous waste generator should have this equipment located where it can be immediately accessed without jeopardizing a timely and effective response to any emergency. For example, the waste generation area may be in an enclosed room. Should a fire occur in the enclosed room, it might be more appropriate to exit the room and call the fire department rather than stay inside and be exposed to smoke inhalation and other risks. EPA believes

⁹⁰ Summary of Hazardous Waste Generator Regulatory Program Evaluation, November 2004. See also public comments in Docket ID No. RCRA-2003-0014.

the existing regulatory text should be revised to explain that while this equipment applies to only those areas applicable to the generation and accumulation (and treatment, as appropriate) of hazardous waste, the generator has the flexibility to store this equipment in other areas of the facility to address those situations where it is infeasible or inappropriate for safety reasons to have the equipment immediately next to hazardous waste generation and accumulation areas.

Therefore, EPA is proposing to modify the introductory paragraph to provide generators subject to subpart C of part 265 the flexibility to determine the most appropriate locations within the facility to locate equipment necessary to prepare for and respond to emergencies.

The proposed regulation would state that all areas where hazardous waste is either generated or accumulated must be equipped with the listed types of equipment (unless none of the hazards posed by waste handled at the site could require a particular kind of equipment or the actual waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment). It would also state that a generator may determine the most appropriate locations within its generator site to locate equipment necessary to prepare for and respond to emergencies.

The Agency requests comment on its proposal to modify § 265.32.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The proposed regulation would appear in the SQG standards at § 262.16(b)(8)(ii) with some changes to make it specific to SQGs and in the new part 262 subpart M for LQGs at § 262.252. The reorganization is discussed in section XIII of this preamble.

b. The meaning of “immediate access.” Sections 262.34(a)(4) and (d)(4) include the condition that LQGs and SQGs comply with part 265 subpart C, which also includes § 265.34. Section 265.34(a) states that whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required under § 265.32. At issue is whether the phrase “immediate access” is clearly understood or whether additional clarity is necessary. As part of the Agency’s 2004 Program Evaluation of the hazardous waste generator program, stakeholders raised a

concern about whether the regulated community has a sufficient understanding about what this phrase means and we are proposing to address that concern here.

In the interest of clarity, the Agency is proposing to modify this language to read, “immediate access (e.g., direct or unimpeded access).” The Agency believes that adding this parenthetical example provides further guidance on the meaning of “immediate access.” This phrase is used again in the next paragraph in a similar context and EPA is proposing to add the words “(direct or unimpeded access)” in that case as well.

The Agency requests comment on the usefulness of modifying this language.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The proposed regulation would appear in the SQG standards at § 262.16(b)(8)(iv) and in the new part 262 subpart M for LQGs at § 262.254. The reorganization is discussed in section XIII of this preamble.

5. Technical Changes Applicable to SQGs

Current preparedness and prevention standards for SQGs are found at § 262.34(d)(5). SQGs must comply with the following:

- § 262.34(d)(5)(i)—have at least one employee either on the premises or on call with the responsibility for coordinating all emergency response measures (e.g., the emergency coordinator);
- § 262.34(d)(5)(ii)—post specified information next to the telephone, including the name and telephone number of the emergency coordinator; the location of fire extinguishers and spill control material, and, if present, fire alarm; and the telephone number of the fire department, unless the facility has a direct alarm;
- § 262.34(d)(5)(iii)—ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal facility operations and emergencies; and
- § 262.34(d)(5)(iv)—have the emergency coordinator or his designee follow the specified procedures in the event of a fire, spill, or explosion.

EPA is proposing changes to two of these provisions.

a. Require certain information be posted “next to the telephone” (40 CFR 262.34(d)(5)(ii)). The Agency is proposing to revise § 262.34(d)(5)(ii) in order to facilitate improved compliance on the part of SQGs. This language requires, among other items, that certain information be posted “next to the

telephone,” such as the name and telephone number of the emergency coordinator and the location of fire extinguishers and spill control material. Based on experience and feedback received from the regulatory community, the Agency believes it is unclear in this description where in the facility this information should be posted. A facility may have many operations and components that have no relationship with the generation and accumulation of hazardous waste.

Stakeholders have recommended deletion of § 262.34(d)(5)(ii) because, in this age of near-universal 911 availability, they state it is simply not important from a regulatory point of view to have emergency telephone numbers posted. They argue that locations of fire extinguishers, spill control material, fire alarms, etc., should be conveyed to relevant employees and displayed in a worker break area rather than the facility office and that posting the name and telephone number of the emergency coordinator is also not necessary. For the majority of the SQG universe, the emergency coordinator is the owner or shop supervisor.⁹¹

EPA disagrees with eliminating this provision because we believe that posting this information is important for workers and others to have readily available information so that they would know what to do and where to go in the case of an emergency. However, the Agency believes that the regulation should be modified to state clearly that the pertinent information should be posted where hazardous waste is generated and accumulated, since facility personnel can quickly seek assistance from it there.

Also unstated is whether the telephone number refers to the emergency coordinator’s home phone or business phone. Over the years the Agency has received requests that we modify this provision to ensure that personal information not be used or distributed, particularly to individuals or organizations that could use such information to cause harm to the individual.⁹² With cell phones and other means of instant communication now prevalent, EPA is proposing to clarify this provision to provide the hazardous waste generator with the necessary flexibility to allow its emergency coordinator to perform specified responsibilities effectively

⁹¹ Summary of Hazardous Waste Generator Regulatory Program Evaluation, November 2004. See also public comments in Docket ID No. RCRA-2003-0014.

⁹² Letter to Jim O’Leary from Derek Swick, American Petroleum Institute, September 28, 2011.

using the emergency telephone number of the emergency coordinator.

Therefore, EPA is proposing that § 262.34(d)(5)(ii) be modified to state that the small quantity generator must post the name and emergency telephone number of the emergency coordinator next to telephones or in areas directly involved in the generation and accumulation of hazardous waste. Section 262.34(d)(5)(ii)(B) and (C) are unchanged.

EPA requests comment on this proposed change.

Effect of the Reorganization: This section is affected by the reorganization and would move to § 262.16(b)(9)(ii)(A). The reorganization is discussed in section XIII of this preamble.

b. Allow containment and cleanup to be conducted by a contractor (40 CFR 262.34(d)(5)(iv)(B)). Section 262.34(d)(5)(iv)(B) currently reads, “In the event of a spill, contain the flow of hazardous waste to the extent possible, and as soon as is practicable, clean up the hazardous waste and any contaminated materials or soil.” If such a spill were considered an emergency under OSHA’s regulations in 29 CFR 1910.120, an SQG would be required to take a minimum of eight hours of initial training with an annual refresher, and in certain circumstances additional hours of training. Feedback from stakeholders suggests that most SQGs would hire a spill cleanup contractor to provide such services, if needed, rather than train employees to perform the response. We would agree that allowing an SQG to hire a contractor that is trained to address hazardous waste spills would certainly be appropriate. However, the regulations in § 262.34(d)(5)(iv)(B) arguably do not provide this flexibility.⁹³

Therefore, the Agency is proposing to modify § 262.34(d)(5)(iv)(B) and place the responsibility on the SQG to either perform the necessary cleanup of hazardous wastes or contract out the cleanup. The proposed language would state that in the event of a spill, the small quantity generator is responsible for containing the flow of hazardous waste to the extent possible, and as soon as is practicable, cleaning up the hazardous waste and any contaminated materials or soil. The proposal would allow such containment and cleanup to be conducted either by the small quantity generator or by a contractor on behalf of the small quantity generator.

The Agency requests comment on the proposed revision to

§ 262.34(d)(5)(iv)(B) and whether any unintended consequences arise from providing SQGs with this flexibility.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization and would move to § 262.16(b)(9)(iv)(B). The reorganization is discussed in section XIII of this preamble.

6. Technical Changes on Personnel Training Applicable to LQGs

The Agency is proposing to modify the condition regarding personnel training for LQGs, currently found at § 262.34(a)(4), which refers to § 265.16. The proposed modification would allow a generator to use online computer training, in addition to classroom instruction and on-the-job training, to complete the personnel training requirements. Since the personnel training regulations were promulgated in the 1980s, use of computerized training has become a common practice for generators to teach their workers about the management of hazardous waste. In fact, many generators already use this method for training workers and this modification would simply bring the hazardous waste personnel training regulations up to date with existing industry practices.

The proposal would modify the first sentence of this provision by adding the words “online training” and would state that site personnel must successfully complete a program of classroom instruction, online training, or on-the-job training that teaches them to perform their duties in a way that ensures compliance with this part.

The Agency requests comment on the proposed modification.

Effect of the Proposed Reorganization: This section would be affected by the proposed reorganization. Under the reorganization this provision would be found at § 262.17(a)(7)(i)(A). The proposed reorganization is discussed in section XIII of this preamble.

7. Taking Comment on Applicability of Personnel Training

The Agency seeks comment on clarifying what positions within an LQG must be responsible for receiving training associated with the management of hazardous waste, as well as identifying those positions for which a written job description is necessary. Under the current regulations, LQGs are responsible for complying with § 262.34(a)(4), which references, among other technical requirements, the personnel training provisions in § 265.16. Under the proposed reorganization discussed in section XIII,

this condition for LQGs would move into 40 CFR 262.17.

The current regulations are not specific about which personnel at an LQG must complete the hazardous waste training. Other than stating that under § 265.16(a)(3) personnel must be able to respond effectively to emergencies by familiarizing them with emergency procedures, emergency equipment, and emergency systems, no other areas of hazardous waste management are cited.

At issue is the scope of these training standards and the applicability of the training provision to employees that are not assigned to work in the 90-day accumulation areas. The Agency is considering whether to require training and a written job description for specific types of employees working in areas of hazardous waste management related to 90-day accumulation areas. This clarification would have the benefit of assisting LQGs in determining more readily the scope of their hazardous waste training program.

The Agency, with the assistance of staff from the states of Vermont, Connecticut and New York,⁹⁴ have identified the following areas of hazardous waste management for which personnel training and a written job description should be required: Anyone who (1) completes and/or signs the hazardous waste manifest, (2) manages hazardous waste in areas where hazardous wastes are accumulated, (3) maintains hazardous waste inventory, (4) conducts daily or weekly inspections of areas where hazardous wastes are accumulated, and (5) plans or responds to emergencies that involve hazardous wastes.

The Agency seeks comment on whether the regulations should specifically identify positions at LQGs where hazardous waste training would be required and for which a written job description is necessary and what those areas should be. In addition, the Agency seeks comment on whether personnel involved in handling or managing hazardous wastes in SAAs should be required to undergo hazardous waste training. Current Agency guidance excludes staff working in satellite accumulation areas from the training requirements.⁹⁵ The Agency is of the

⁹⁴ Correspondence between Steve Simoes, State of Vermont, with Ross Bunnell and Bill Yeman, from Connecticut and New York, respectively, a copy of which is found in the docket to this proposal.

⁹⁵ Memorandum from Robert Springer, Director of the Office of Solid Waste to RCRA Directors, EPA Regions 1–10, “Frequently Asked Questions about Satellite Accumulation Areas,” March 17, 2004, RCRA Online 14703 <http://yosemite.epa.gov/osw/>

Continued

⁹³ Summary of Hazardous Waste Generator Regulatory Program Evaluation, November 2004. See also public comments in Docket ID No. RCRA–2003–0014.

opinion that such personnel have a similar need to know the risks associated with hazardous wastes as personnel working in central accumulation areas.

8. Taking Comment on Applying Emergency Planning and Procedures Revisions to Parts 264 and 265

The proposed revisions discussed throughout this section of the preamble on the emergency planning and procedure regulations would only pertain to generators, as the proposed language would be found in the expanded generator regulations in part 262. However because many of the preparedness and emergency procedure provisions discussed in this section are taken from part 265 with only slight revisions, we are taking comment on whether these same proposed revisions should also be made in the applicable paragraphs of parts 264 and/or 265 as well to ensure consistency between the generator regulations and those for permitted facilities or facilities operating under interim status. The Agency requests comment on whether these revisions for consistency would be helpful and appropriate for facilities operating under part 264 or part 265 or whether the regulations should remain unchanged despite the result that generators and TSDFs would be left with some regulations that are very similar but not exactly the same.

I. Revisions to Satellite Accumulation Area Regulations for SQGs and LQGs (40 CFR 262.34(c))

The Agency is proposing a number of changes that would revise and strengthen the conditions for exemption for satellite accumulation areas (SAA) at § 262.34(c). These include (1) requiring SQGs and LQGs accumulating hazardous waste in SAAs to comply with the special requirements for incompatible wastes found at § 265.177; (2) providing limited exceptions to the regulation requiring generators to keep containers closed at all times; (3) strengthening the marking and labeling standards for SAAs (note these marking and labeling changes are the same as those proposed for containers in central accumulation areas); (4) confirming that three days means three consecutive calendar days, not business days; (5) providing a maximum weight for the accumulation of acute hazardous waste in SAAs in addition to a volume; (6) rewording the regulations for when the maximum volume or weight is exceeded

in an SAA; (7) rescinding a guidance memo regarding the accumulation of reactive (D003) hazardous waste away from the point of generation; and (8) providing examples in the preamble to help generators better understand the term “under the control of the operator,” which is used in the SAA regulations.

In addition to these proposed changes, the SAA regulations would be moved as part of the proposed reorganization. These regulations would all be found together in § 262.15. The reorganization is discussed in section XIII of this preamble.

Using an SAA is not required of hazardous waste generators, but the regulations allowing them and setting the conditions for their use are designed to assist generators who generate and accumulate small amounts of hazardous waste in different parts of their facilities. SQGs and LQGs, however, may choose to accumulate hazardous waste only in central accumulation areas (CAAs) rather than SAAs or they may accumulate up to 55 gallons of non-acute hazardous waste and/or one quart of acute hazardous waste within each facility's SAAs and once that threshold has occurred, ship the hazardous waste to a designated facility. A generator may also accumulate hazardous waste within an SAA(s) and never move the waste to a CAA once the 55 gallons limit is reached, but instead, ship the waste directly to a RCRA designated facility.

1. Requiring SQGs and LQGs to Comply with the Special Requirements for Incompatible Wastes for Containers Accumulating Hazardous Wastes in SAAs

Under the current regulations in § 262.34(c)(1)(i), generators accumulating hazardous waste in SAAs must meet the conditions for exemption, including complying with the container requirements at §§ 265.171, 265.172, and 265.173(a). These container requirements include accumulating hazardous waste in containers of good condition, ensuring the waste is compatible with, or will not react with, the contents of the container, and ensuring that the container accumulating hazardous waste is closed, except when it is necessary to add or remove waste. We are proposing to modify this part of the SAA container management standards by requiring that hazardous wastes not be mixed or be placed in the same container with other hazardous waste that are incompatible and could potentially result in fires, explosions, gaseous emissions, leaching,

or other discharge of hazardous waste or hazardous waste constituents.⁹⁶

The Agency believes that in developing the regulations for SAAs, it inadvertently failed to account for the potential for accumulating incompatible wastes, especially since the current regulations already prohibit placing hazardous waste in containers that it may react with and that impair the containers ability to contain the hazardous waste. Therefore, the Agency is proposing that SQGs and LQGs accumulating hazardous waste in SAAs also comply with the part 265 subpart I container management standards for incompatible hazardous wastes at § 265.177. The Agency believes most generators already are aware of and comply with this best management practice at their SAAs since they must comply with this regulation when they move the SAA container(s) into a 90-day or 180-day central accumulation area.

The Agency requests comment on this proposed modification.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to § 262.15(a)(1)(iii). The reorganization is discussed in section XIII of this preamble.

2. Limited Exceptions to Keeping Containers Closed at all Times in SAAs

As noted in the previous section, the current regulation in § 262.34(c)(1)(i) for generators accumulating hazardous waste in SAAs requires containers accumulating hazardous waste to be kept closed, except when it is necessary to add or remove waste. The SAA regulations reference the requirement in § 265.173(a) that containers be closed while accumulating hazardous wastes at interim status treatment, storage and disposal facilities. We are proposing to modify this provision from § 262.34(c)(1)(i) in the new section for SAA conditions at § 262.15, but only as it pertains to SAAs; it will not affect the requirements for container management at interim status treatment, storage and disposal facilities. Because this modification is only meant to apply to containers accumulating hazardous waste in SAAs, and not to containers being stored at interim status treatment, storage, or disposal facilities, we are proposing to modify this requirement by eliminating the reference in the SAA regulations in part 262 to the container management standards for interim status treatment, storage or disposal facilities at § 265.173(a) and

rcra.nsf/0c994248c239947e85256d090071175f/0ac9e15424b2897d8525770600609793?Open Document.

⁹⁶ See Comment in § 265.177.

incorporating the closed container provision directly into the SAA regulations in § 262.15, under the proposed reorganization.

Specifically, we are proposing to modify the standard in order to allow containers of hazardous waste in SAAs to remain open under limited circumstances. Specifically, we are proposing that containers of hazardous waste in SAAs may be open when it is necessary either for the operation of equipment to which the SAA container is attached or to prevent dangerous situations, such as the build-up of extreme pressure or heat because closing a container can be more dangerous than keeping it open temporarily in those situations. Stakeholders have identified situations where keeping SAA containers closed can interfere with the operation of equipment when the container is attached directly to the equipment via piping or tubing. Stakeholders have also identified situations in which closing a container can be more dangerous than keeping it open temporarily; for example, when the hazardous waste is very hot.

Therefore, EPA is proposing to modify the regulations to allow containers to be vented in such situations. However, we are also proposing that when the danger passes (*e.g.*, the contents cool), then the requirement to keep the container closed applies and when the equipment is not in operation, the requirement to keep the container closed applies.

As noted above, the flexibility proposed for containers to remain open in specific situations applies only to containers in SAAs since that is where hazardous waste initially accumulates. The Agency does not anticipate that it is necessary to extend this flexibility to containers of hazardous waste in central accumulation areas.

The Agency requests comment on this proposed modification.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to § 262.15(a)(1)(iv). The reorganization is discussed in section XIII of this preamble.

3. Strengthening the Marking and Labeling Provisions for Containers in SAAs

Currently, the regulations for SAAs in § 262.34(c)(1)(ii) require a generator to mark “his containers either with the words ‘Hazardous Waste’ or with other words that identify the contents of the containers” [emphasis added]. The Agency is proposing two modifications

that would strengthen the labeling and marking regulations for containers accumulating hazardous waste in SAAs. First, EPA is proposing to change the “or” to an “and” and thus require that generators mark containers in the SAA with both the words “Hazardous Waste” and other words to identify the contents of the container that are accumulated in SAAs.

Second, EPA is proposing that generators also indicate the hazards of the contents of the containers. EPA believes these proposed changes will alert workers, emergency responders, and others to the potential hazards posed by its contents. Identifying the hazard increases awareness to workers and others who might come into contact with the hazardous waste container and reduces potential risks to human health and the environment from container mismanagement. As discussed previously in section VIII.E, these changes are similar to those proposed for containers stored in central accumulation areas.

Specifically, EPA is proposing to modify the marking and labeling regulations for SAAs to require LQGs and SQGs to mark containers with the following: (1) The words “Hazardous Waste”; (2) other words that identify the contents of the containers. Examples may include, but are not limited to the name of the chemical(s), such as “acetone” or “methylene dichloride,” or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (3) an indication of the hazards of the contents of the container. Examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the DOT requirements at 49 CFR 172 part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the NFPA code 704; or a hazard pictogram consistent with the United Nations’ GHS. Generators also may use any other marking and labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

The pre-transport requirements of part 262 subpart C already require hazardous waste generators to comply with the DOT labeling/marking requirements of 49 CFR part 172. By requiring generators

to include other words that identify the contents of the containers, the Agency is proposing that generators perform a task that is already required when preparing the container prior to transporting the hazardous waste off site for subsequent waste management. In addition, the Agency is proposing to modify the marking and labeling of containers prior to shipping the hazardous waste. We are proposing that SQGs and LQGs can use the DOT hazard class labels to comply with the new labeling and marking regulation for containers in SAA. Alternatively, they may choose another method to indicate the hazards of the container that suits them better, as noted above.

The Agency requests comment on these proposed changes.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to § 262.15(a)(1)(v). The reorganization is discussed in section XIII of this preamble.

4. Clarify What Is Meant by “Three Days”

The current regulations at § 262.34(c)(2) state that a generator who accumulates either hazardous waste or acutely hazardous waste must, with respect to that amount of excess waste, comply “within three days” with paragraph (a) of that section or other applicable provisions of the chapter. The Agency is proposing to state in the regulations that the term “three days” means three consecutive calendar days, not three business days or three working days. The Agency has already clarified this term in a memo, which was based on preamble discussions from the proposed and final SAA regulations.^{97 98} As stated in the memo, “Originally, the Agency had proposed to use 72 hours as the time limit but realized that determining when 72 hours had elapsed would have required placing both the date *and* time of day on containers. In the final rule the Agency switched to using three days so that generators only need to date containers that hold the excess of 55 gallons of non-acute hazardous waste (or 1 quart of acute hazardous waste).”

The Agency requests comment on this codification of an existing interpretation.

⁹⁷ Memorandum from Robert Springer, Director of EPA’s Office of Solid Waste, to RCRA Regional Directors, “Frequently Asked Questions About Satellite Accumulation Areas,” March 17, 2004, RCRA Online 14703.

⁹⁸ Proposed rule: January 3, 1983 48 FR 118; Final rule: December 20, 1984; 49 FR 49569.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to § 262.15(a)(2)(i). The reorganization is discussed in section XIII of this preamble.

5. Providing a Maximum Weight for the Accumulation of Acute Hazardous Waste in Containers at SAAs

Currently, the regulations at § 262.34(c)(1) impose maximum volumes of hazardous waste that may be accumulated in an SAA without requiring a permit, complying with interim status standards, or complying with the generator accumulation standards. For non-acute hazardous waste, the maximum volume is 55 gallons. For acute hazardous waste, the maximum volume is 1 quart. When the SAA regulations were finalized, EPA explained that 55 gallons was selected for non-acute hazardous waste in part because it is the size of the most commonly used accumulation container.⁹⁹ EPA also explained that 1 quart was chosen for acute hazardous waste because it is the volumetric equivalent to 1 kilogram of acute hazardous waste used elsewhere in the regulations and commenters expressed opposition to using a weight measure. Since then, however, stakeholders have indicated that the 1-quart volume maximum is not a practical way to measure the accumulation of some wastes, particularly non-liquid acute hazardous wastes. Therefore, we are proposing to add a weight measurement to the SAA regulations for the maximum accumulation of acute hazardous wastes. Specifically, we are proposing that 1 quart or 1 kilogram (2.2 pounds) of acute hazardous waste may be accumulated in an SAA. Generators that accumulate acute hazardous waste in SAAs will have the choice of whether to use 1 quart or 1 kilogram, but they will be required to identify which metric they choose to use.

We are not proposing to add a similar weight equivalent to the 55-gallon threshold for non-acute hazardous waste since stakeholders have not expressed a similar need. However, we request comment on whether it would be useful to have a maximum weight for the accumulation of non-acute hazardous waste in SAAs.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to

§ 262.15(a)(1). The reorganization is discussed in section XIII of this preamble.

6. Modifying the Language for When the Maximum Volume or Weight Is Exceeded in an SAA

Currently, the regulation at § 262.34(c)(2) states that when the maximum volumes are exceeded in an SAA, a generator “must, with respect to that amount of excess waste, comply within three days with paragraph (a) of this section or other applicable provisions of this chapter.” The Agency is rewording this regulation in order to more clearly state the generator’s options for managing the materials that exceed the limit. The proposed regulatory text states that a generator who accumulates either non-acute hazardous waste or acute hazardous waste listed in § 261.31 or § 261.33(e) in excess of the amounts listed in paragraph (a)(1) of this section at or near any point of generation must remove the excess from the satellite accumulation area within three calendar days either to a central accumulation area, an on-site interim status or permitted treatment, storage, or disposal facility, or an off-site designated facility. Similarly, during the three-calendar-day period the generator must continue to comply with paragraphs (a)(1)(i) through (iv) of this section and must mark the container(s) holding the excess accumulation of hazardous waste with the date the excess amount began accumulating.

The Agency does not view this as a substantive change to the SAA regulations. Nevertheless, the Agency solicits comments on this proposed change.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. The SAA regulations are currently at § 262.34(c). We are proposing to move this provision to § 262.15(a)(6). The reorganization is discussed in section XIII of this preamble.

7. Rescinding a Memo Regarding Accumulating Reactive Hazardous Waste Away From the Point of Generation

In a memo dated January 13, 1988, EPA wrote that a storage shed that is outside of a building where a reactive hazardous waste (D003) is initially generated, could be considered an SAA.¹⁰⁰ EPA is proposing to revoke this interpretation. EPA acknowledges that in some instances it is safer to

accumulate hazardous waste away from the initial point of generation, such as with hazardous wastes that are explosive. However, because SAAs are subject to less stringent conditions than CAAs, EPA believes it is not appropriate for such dangerous hazardous wastes to be stored in SAAs. Rather, EPA believes that if a generator accumulates hazardous waste that is so dangerous it needs to be accumulated away from the point of generation, it should be accumulated under the more rigorous accumulation standards for central accumulation areas.

The Agency requests comment on proposing to revoke this interpretation of the SAA regulations.

8. Examples of the Meaning of “Under the Control of the Operator”

The SAA regulation at § 262.34(c)(1) uses the term “under the control of the operator.” EPA has not defined this term in the regulations, nor have we discussed it in preamble or guidance letters. However, over the years, the Agency has received inquiries about what constitutes “under the control of the operator.” In an effort to assist generators to better understand this term and to foster improved compliance with the SAA provisions, the Agency is providing examples in this preamble of what constitutes “under the control of the operator.” For example, EPA would consider waste to be “under the control of the operator” if the operator controlled access to an area, building, or room that the SAA is in, such as with entry by access card, key or lock box. Another example would be if the operator accumulates waste in a locked cabinet and controlled access to the key, even if the cabinet is stored inside a room to which access is not controlled.

The Agency requests comment on additional practices that would constitute “under the control of the operator.”

J. SQGs Accumulating Hazardous Waste on Drip Pads and in Containment Buildings (40 CFR 262.34(d))

EPA is proposing to modify the regulations at § 262.34(d) to require SQGs that accumulate hazardous waste for 90 days or less on drip pads without a permit or interim status to comply with the technical standards of 40 CFR part 265 subpart W and with all other conditions for an exemption associated with the accumulation of hazardous waste by an SQG.

Additionally, EPA is proposing to modify the conditions for an exemption currently at § 262.34(d) to require SQGs that accumulate hazardous waste for 90 days or less in a containment building

¹⁰⁰ Letter from Marcia E. Williams, Director of EPA’s Office of Solid Waste, to Michael E. Young, Atlantic Research Corporation, January 13, 1988, RCRA Online 11317.

⁹⁹ December 20, 1984; 49 FR 49569–70.

without a permit or interim status to comply with the technical standards of 40 CFR part 265 subpart DD and with all other conditions for exemption associated with the accumulation of hazardous waste by an SQG.

1. Accumulation of Hazardous Waste on Drip Pads

On December 30, 1988, EPA issued a proposed rule listing three additional hazardous wastes from wood preserving operations that use chlorophenolic, creosote, and/or inorganic (arsenic and chromium) preservatives, and listing one hazardous waste from surface protection processes that use chlorophenolics (53 FR 53282). As part of this rule, the Agency proposed additional standards “applicable to drip pads in treated wood storage yards and in kick back areas used in managing hazardous wastes at wood preserving and surface protection facilities. These standards are intended to provide for proper handling of treated wood drippage” (53 FR 53308).

In terms of the types of RCRA facilities this regulation would apply to, the proposed rule identified and discussed the regulatory requirements for two groups: Hazardous waste TSDFs subject to the part 264 permitting standards and LQGs subject to the part 265 interim status drip pad standards. More specifically, the preamble stated that “in the event that drippage is collected and is moved from the drip pad within 90 days following generation, generators may avail themselves of the 90-day accumulation standards of 40 CFR 262.34, and would not need Part B permits for their drip pads or tanks (consistent with § 264.1(g)(3), 265.1(c)(7), and 270.1(c)(2)(i)) provided that they comply with the Part 265 standards, as required by 40 CFR 262.34” (53 FR 53309).

When EPA promulgated the final rule for these hazardous wastes (55 FR 50450, December 6, 1990), the discussion addressed the same universe of facilities (*i.e.*, hazardous waste TSDFs subject to the part 264 permitting standards and LQGs subject to the part 265 interim status drip pad standards).

Pursuant to § 262.34(a), LQGs may accumulate the hazardous waste they generate without having to obtain a RCRA permit provided they comply with several specified conditions, including the technical standards for containers, tanks, drip pads, or containment buildings found at part 265 subparts I, J, W, and DD, respectively. Similarly, pursuant to § 262.34(d), SQGs may accumulate the hazardous waste they generate without having to obtain

a permit, provided they comply with several specified conditions, including the technical standards for containers and tanks found at part 265 subparts I and J, respectively. Although there is no explicit condition for SQGs accumulating and managing their hazardous waste on drip pads, EPA intended SQGs accumulating hazardous wastes on drip pads either to comply with all of the conditions for exemption, as well as any associated independent requirements for LQGs at part 265 subpart W, or else obtain a Part B permit for their drip pads (consistent with §§ 264.1(g)(3), 265.1(c)(7), and 270.1(c)(2)(i)).

EPA has consistently interpreted this regulatory requirement to apply to SQGs. For example, as stated in the wood preserving technical guidance document issued by EPA in 1996, a copy of which is found in the docket, “this 90-day limit applies to both large quantity and small quantity generators. While small quantity generators may normally accumulate hazardous waste in accumulation units for up to 180 days, this is not the case for small quantity generators accumulating waste on Subpart W drip pads. Owners/operators of wood preserving facilities who generate between 100–1,000 kilograms of hazardous waste per calendar month and who accumulate the waste on drip pads are not eligible for the reduced standards normally provided for small quantity generators. Instead, these generators must comply with all the management conditions for large quantity generators accumulating hazardous waste on drip pads.”¹⁰¹

Similarly, the RCRA training module for drip pads, a copy of which is found in the docket to this proposal, reinforced this principle by stating the following: “Under § 262.34(d), small quantity generators (SQGs) are subject to a reduced set of requirements when accumulating hazardous wastes in tanks or containers meeting the interim status unit standards. SQGs who accumulate wood-preserving wastes on drip pads do not qualify for this partial exemption. Consequently, all generators of more than 100 kilograms of waste per month who manage wood-preserving wastes on drip pads must comply with the requirements applicable to LQGs in § 262.34(a). As a result, the maximum generator accumulation time period on drip pads is 90 days.”¹⁰²

¹⁰¹ “Wood Preserving Resource Conservation and Recovery Act Compliance Guide—A Guide to Federal Environmental Regulation,” U.S. EPA, EPA-305-B-96-001, June 1996, Section 5-8.

¹⁰² “Introduction to Drip Pads (40 CFR parts 264 and 265, subpart W),” RCRA, Superfund & EPCRA

At the end of the same paragraph, the document states, “Generators using drip pads must also comply with the requirements that apply to large quantity generators for personnel training, development of a full contingency plan, and biennial reporting,” suggesting that SQGs accumulating hazardous waste on drip pads must comply with all of the conditions and independent requirements for LQGs, and not just the accumulation time limits.

Because of this statement, the Agency believes that confusion may potentially exist about the applicability of the regulations. As stated above, if an SQG accumulates hazardous waste in containers, it can comply with a reduced set of regulations, including accumulation of hazardous waste for up to 180 days, whereas if the SQG accumulates hazardous waste on drip pads, it must comply with the regulations for LQGs. The Agency believes a more effective and efficient approach is to require SQGs accumulating hazardous waste on drip pads to comply with the technical standards of part 265 subpart W, including compliance with the LQG 90-day accumulation limit (as opposed to the SQG 180-day accumulation limit), but to otherwise comply with less stringent conditions for SQGs found at 40 CFR 262.34(d). EPA notes that hazardous waste that is generated elsewhere at the wood preserving facility and accumulated in tanks or containers (*i.e.*, not accumulated on drip pads) will remain subject to the SQG accumulation limits. Only waste that is accumulated on drip pads must comply with the LQG accumulation limits.¹⁰³

Because both the monthly generation quantities (*e.g.*, greater than 100 kg and less than 1,000 kg) and accumulation total (*e.g.*, not to exceed 6,000 kg at any one time) for SQGs are significantly less than the generation and accumulation quantities for LQGs, the Agency believes that SQGs complying with the less stringent conditions at § 262.34(d) (*e.g.*, personnel training, contingency plan) will be protective of human health and the environment. Other than complying with the management standards at 40 CFR part 265 subpart W, the Agency sees no difference in the risks associated with hazardous wastes accumulated in tanks or containers. Therefore, EPA is proposing to modify the SQG regulations to require SQGs who

Call Center Training Module, U.S. EPA, EPA530-K-02-008I, October 2001, page 7.

¹⁰³ “Wood Preserving Resource Conservation and Recovery Act Compliance Guide—A Guide to Federal Environmental Regulation,” U.S. EPA, EPA-305-B-96-001, June 1996, Section 5-8.

accumulate hazardous waste on drip pads to comply with the technical standards of 40 CFR part 265 subpart W, with the 90-day accumulation limit for that hazardous waste, and with all of the other hazardous waste accumulation standards for an SQG currently found at § 262.34(d).

Situations may also occur where an SQG initially accumulates hazardous waste on a drip pad but subsequently transfers this waste to a container or tank for subsequent management. Similarly, the opposite situation may occur where hazardous wastes are generated and first accumulated by an SQG in a tank or in containers and then transferred to a drip pad. The Agency is proposing that the SQG have up to a total of 180 days to accumulate the hazardous wastes, which includes both the time the waste is on a drip pad and when it is in a tank or container, but that the total amount of time to accumulate the hazardous waste on the drip pad must not exceed 90 days. For example, if an SQG accumulates hazardous wastes on a drip pad for 80 days prior to transferring its waste to a tank, the SQG would be able to accumulate waste up to 100 days in the tank before it would be required to send it off-site for subsequent waste management, or conversely, treat and dispose of the waste on-site in compliance with all applicable RCRA regulations under parts 262 through 268 and 270.

In the case of an SQG first accumulating a hazardous waste in a tank or container and then transferring the waste to a drip pad, the generator would still have up to a total of 180 days, depending on the circumstances, to send the waste off-site for subsequent waste management, or conversely, treat and dispose of the waste on-site in compliance with all applicable RCRA regulations under parts 262 through 268 and 270. However, under the proposal, the amount of time allowed for the SQG to accumulate the hazardous waste on a drip pad may not exceed 90 days. For example, if an SQG first accumulated hazardous wastes in a tank or container for 100 days and then transferred the waste to a drip pad, the SQG would be able to accumulate up to 80 days more (for a total of 180 days) to accumulate the waste on the drip pad before the generator would be required to send the waste off-site for subsequent waste management, or conversely, treat and dispose of the waste on-site in compliance with all applicable RCRA regulations under parts 262 through 268 and 270.

However, if an SQG first accumulated hazardous wastes in a tank or container

for 80 days and then transferred the waste to a drip pad, the SQG would only have 90 days more (or a total of 170 days) to accumulate the waste on the drip pad before the generator sent the waste off-site for subsequent waste management, or conversely, treat and dispose of the waste on-site in compliance with all applicable RCRA regulations under parts 262 through 268 and 270.

EPA solicits comments on these proposed revisions. In particular, EPA requests comment on whether SQGs accumulating hazardous waste on drip pads should be subject to the accumulation time limit of 180 days, similar to SQGs accumulating hazardous wastes in containers and tanks. Conversely, EPA is seeking comment on whether SQGs accumulating hazardous waste on drip pads should be subject to all applicable conditions and requirements for LQGs, and not just the 90-day accumulation time limit.

The Agency also requests comment on the procedures for documenting and ensuring hazardous wastes are removed from the sump or collection system 90 days or less from being first placed on the drip pad and also for situations where hazardous waste accumulation involves both drip pads and containers or tanks.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. As part of the reorganization in this action, EPA is proposing to move the conditions for exemption for SQGs accumulating hazardous waste from § 262.34 to § 262.16. The proposed drip pad conditions for SQGs can be found at § 262.16(b)(4). The reorganization is discussed in section XIII of this preamble.

2. Accumulation of Hazardous Waste in Containment Buildings

Consistent with the changes proposed for hazardous wastes accumulated on drip pads by SQGs, the Agency is also proposing that SQGs that accumulate hazardous waste in containment buildings for 90 days or less without a permit or interim status must comply with the technical standards of part 265 subpart DD and with all other conditions associated with the accumulation of hazardous waste by SQGs currently found at § 262.34(d).

Similar to the drip pad regulations, the containment building regulations promulgated in 1992 (August 18, 1992, 57 FR 37194) did not discuss the possibility of an SQG accumulating hazardous wastes in a containment building, but instead only discussed

TSDFs and LQGs accumulating hazardous waste in containment buildings (57 FR 37212). Thus, under the current regulations, SQGs that choose to manage hazardous wastes in containment buildings can only do so if they comply with the LQG requirements or obtain a Part B permit for their containment building.

EPA is proposing to modify the regulations to allow SQGs to accumulate hazardous wastes in containment buildings for 90 days or less without a permit or without having interim status provided they comply with the technical standards of part 265 subpart DD and comply with all other conditions associated with the accumulation of hazardous waste by an SQG found at § 262.34(d). As with wastes accumulated by SQGs on drip pads, the Agency believes that SQGs complying with the less stringent conditions at § 262.34(d) (e.g., personnel training, contingency plan) will be protective of human health and the environment and other than complying with the management standards at 40 CFR part 265 subpart DD, the Agency sees no difference in the risks associated with hazardous wastes accumulated in tanks or containers.

As with drip pads, situations may potentially arise where hazardous wastes are first accumulated in a containment building and then transferred to containers for subsequent accumulation, or vice-versa. The Agency is proposing the same framework as described in the discussion on drip pads above for how long SQGs may accumulate hazardous wastes in a containment building to maintain their hazardous waste accumulation exemption.

EPA solicits comments on this proposed revision. In particular, EPA requests comment regarding whether SQGs accumulating hazardous waste in containment buildings should be subject to the accumulation time limit of 180 days, similar to SQGs accumulating hazardous wastes in containers and tanks or, conversely, whether SQGs accumulating hazardous waste in containment buildings should be subject to all applicable conditions for an exemption and independent requirements for LQGs, and not just the 90-day accumulation time limit. EPA also seeks comment on situations where hazardous waste accumulation involves both containment buildings and containers or tanks.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization. As part of the reorganization in this action, EPA is proposing to move the conditions for

exemption for SQGs accumulating hazardous waste from § 262.34 to § 262.16. The proposed containment building regulations for SQGs can be found at § 262.16(b)(5). The proposed containment building regulations for LQGs can be found at § 262.17(a)(4). The reorganization is discussed in section XIII of this preamble.

K. Deletion of Performance Track Regulations

EPA launched The National Environmental Performance Track in 2000 to provide regulatory and administrative benefits to Performance Track members. Performance Track was a public-private partnership that encouraged continuous environmental improvement through use of environmental management systems, community outreach, and measurable results. In order to provide regulatory benefits to members, EPA made changes to the RCRA hazardous waste regulations, among others, that specifically referenced members of Performance Track.

EPA terminated the Performance Track program in 2009. Therefore, EPA is proposing to remove obsolete references to Performance Track in the RCRA hazardous waste regulations as a part of this rulemaking. In some cases, a whole paragraph of regulation will be removed and in other instances we will remove just the part of the paragraph that references Performance Track. The deleted paragraphs would then be reserved to reduce the possibility of confusion by replacing them with other regulations. The references that would be removed would be the following:

- § 260.10: Definition of Performance Track member facility;
- § 262.34(j), (k), and (l): Regulations for accumulation of hazardous waste by LQGs in Performance Track;
- § 262.211(c): Two parenthetical references to § 262.34 (j) and (k) in the regulations for academic labs in subpart K of part 262;
- §§ 264.15(b)(4) and 265.15(b)(4): References to the requirements for inspection of areas of the facility subject to spills in §§ 264.15(b)(5) and 265.15(b)(5), respectively;
- §§ 264.15(b)(5) and 265.15(b)(5): Requirements for Performance Track member facilities that reduce inspection frequency for areas subject to spills;
- §§ 264.174 and 265.174: References to Performance Track requirements for inspections of areas where containers are stored;
- §§ 264.195(e), 265.195(d), and 265.201(e): Requirements for Performance Track member facilities for inspections of tank systems;

- §§ 264.1101(c)(4) and 265.1101(c)(4): Requirements for Performance Track member facilities for reduced inspections of containment buildings;

- § 270.42(l): Procedures for permit modifications for Performance Track member facilities; and
- Appendix 1 to § 270.42—Classification of Permit Modification, Section O.1: Indication that a permit modification for reduced inspections for a Performance Track member facility is a Class 1 permit modification.

The provisions that EPA is proposing to remove were added to the regulations in the National Environmental Performance Track Program final rule, dated April 22, 2004 (69 FR 21737), the Resource Conservation and Recovery Act Burden Reduction Initiative final rule, dated April 4, 2006 (71 FR 16862), and the Academic Laboratories final rule, dated December 1, 2008 (73 FR 72912). The Agency is requesting comment on whether there are additional references to the Performance Track program in the RCRA hazardous waste regulations that should be removed as a part of this rulemaking.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

L. Clarification of Biennial Reporting Requirements (40 CFR 262.41)

EPA is proposing to modify the biennial reporting regulations for generators found at 40 CFR 262.41 in order to make the regulations consistent with Agency guidance, including its biennial report instructions and forms. More specifically, the Agency is proposing the following revisions: (1) Only LQGs need to submit biennial reports; (2) LQGs must report all of the hazardous waste they generate for the entire reporting year, not just the month(s) the generator was an LQG; (3) LQGs completing a biennial report must report all hazardous wastes they generated in the reporting year, regardless of whether they transferred the waste off site during the reporting year; and (4) a reference to the biennial report form (EPA form 8700–13) at § 262.41 rather than the list of specific data elements in currently at that citation.

Additionally, EPA is proposing to modify the title of subpart D from “Recordkeeping and Reporting” to “Recordkeeping and Reporting Applicable to Small and Large Quantity Generators” in order to highlight which entities need to comply with this subpart.

1. Biennial Report Requirements Are Only Applicable to LQGs

The first proposed change is to modify the biennial reporting regulations in § 262.41 to make these only applicable to LQGs (and thus not applicable to SQGs and CESQGs). Currently, the biennial report regulations at § 262.41(a) and (b) refer to “a generator” and “any generator,” but do not further specify which categories of generators must complete and submit a biennial report. However, current EPA guidance, as well as a 1986 FR notice, states that only LQGs must complete and submit a biennial report to EPA.¹⁰⁴ To reduce confusion between the regulations and EPA’s current guidance regarding the applicability of biennial reporting requirements, EPA is proposing to modify § 262.41 to state that only LQGs are required to complete and submit a biennial report. This proposed change would not result in a substantive change to the existing regulations, but would make clear who is required to submit the biennial report. Additionally, EPA is proposing to modify the phrase “prepare and submit” which is the existing language in § 262.41, to “complete and submit” because the Agency believes that “complete and submit” more accurately reflects that LQGs must complete all applicable elements of the biennial report forms.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

2. LQGs Must Report All Hazardous Waste Generated During the Reporting Year, Not Just for the Month(s) the Generator Was an LQG

The second proposed change is to modify the biennial reporting regulations to require LQGs to report all of the hazardous waste they generate for the entire reporting year, not just the month(s) the generator was actually an LQG. (Additionally, if EPA were to make final the proposed provision allowing an LQG to receive hazardous waste from a CESQG under control of

¹⁰⁴ The **Federal Register** notice states, “the Agency is today finalizing the proposed exemption from the biennial report requirements of § 262.41 for generators of 100–1000 kg/mo, including an exemption from the provisions of this section requiring a description of efforts taken during the reporting year to minimize waste generation.” (51 FR 10160, March 24, 1986). Additionally, EPA’s Hazardous Waste Report Instructions and Forms specify that only LQGs (as well as facilities that treat, store, or dispose of RCRA hazardous waste on-site) must complete and file the biennial report (<http://www.epa.gov/osw/inforesources/data/biennialreport/index.htm>).

¹⁰⁵ Both EPA and the states have received questions from generators regarding whether they must submit a biennial report.

the same person, an LQG would also have to report the waste it received during the reporting year. See section VII.C of the preamble for discussion of this provision.) The Agency is proposing this change since there have been different positions provided by EPA regarding whether LQGs must report on the amount of hazardous waste generated and managed for the entire reporting year or only for those months they were an LQG, and, thus, were subject to the LQG standards, including biennial reporting. In addition, although the vast majority of states require LQGs to report the total amount of hazardous waste they generate for the entire reporting year, even if they were an LQG for only one calendar month, there are at least two states that only require LQGs to report the amount of hazardous waste generated and managed for those months they were an LQG.¹⁰⁶

Specifically, in a 1980 **Federal Register** notice, the Agency stated, “The recordkeeping and reporting requirements of part 262 apply, however, only to those periods in which the generator’s hazardous waste is subject to full regulation under part 262. Thus, for example, the annual report of a generator whose waste is subject to full regulation under part 262 for three months in a year would cover the generator’s activity only for those three months” (45 FR 76621, November 19, 1980). However, current EPA guidance in the Hazardous Waste Report Instructions and Forms instructs generators to report the total quantity of hazardous waste generated during the reporting year. The regulations in § 262.41 are silent on this issue.

In the interest of national consistency, EPA proposes to modify the regulations at § 262.41 to require LQGs to report the total amount of hazardous waste generated during the entire reporting year. EPA believes that this change will ensure a more complete and reliable estimate on the total amount of hazardous waste generated in order to support various RCRA program development and implementation efforts by EPA and the states.

The Agency does not anticipate significant added burden from this provision. First, EPA knows of only two states (Idaho and Kentucky) that currently require generators to report only those hazardous wastes generated

during the months the generator was an LQG. Thus, this modification will only affect a small percentage of the LQG universe that in certain months are not LQGs. Second, these LQGs are already completing a biennial report, so the change in burden will be in reporting the additional amounts of hazardous waste they generate for the remaining months of the reporting year that they were not an LQG. Third, generators are already required under § 261.5(c) and (d) to count the amount of hazardous waste they generate monthly to determine their regulatory status and thus would be counting hazardous waste during months they are not LQGs. Fourth, most generators transfer the hazardous waste they generate off site and, thus, should be able to use their hazardous wastes manifests to calculate the total amount of hazardous wastes they generate annually.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

3. LQGs Must Report All Hazardous Waste Generated During the Reporting Year, Regardless of When the Waste Was Transferred Off Site

The third proposed change requires LQGs completing a biennial report to report all hazardous wastes they generated during the reporting year, regardless of when the hazardous waste was transported off site. Although the current biennial report instructions clearly state that LQGs should report the total quantity of hazardous waste that was generated during the reporting year, the regulations do not address cases in which the generator generates hazardous waste during the reporting year, but ships the waste off site during the next calendar year.

For purposes of completeness and to be consistent and avoid confusion with the current biennial report and its instructions, the Agency is proposing to state in § 262.41 that LQGs must report all hazardous wastes they generate in the reporting year, regardless of when the generated hazardous waste was transferred off site. The Agency believes that this change will not pose a significant burden since the information is already available; it is simply stating clearly in which year the data is reported.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

4. Replace the List of Specific Data Elements With an Independent Requirement To Complete and Submit All Data Elements Required in the Biennial Report Form (EPA Form 8700–13)

EPA is proposing to modify the regulations at 40 CFR 262.41 to eliminate the specific list of data elements and to require the completion and submission of all data elements contained in the biennial report form (EPA form 8700–13).

Section 262.41(a) currently requires that the biennial report include a specific list of data elements, including the name, address, and EPA ID number of the generator and each transporter and TSDf, the EPA hazardous waste number for each hazardous waste shipped off site, and a signed certification, among other things.

In the nearly three decades since the biennial report regulations were first promulgated, EPA’s biennial report form and instructions have evolved to enable better data analysis and to reduce burden, where possible. Thus, the regulations at § 262.41 no longer accurately reflect the data elements currently listed in EPA’s biennial report instructions and forms. For example, current EPA guidance for biennial reporting requires generators to identify their hazardous wastes using not only the EPA hazardous waste number, but also using source, form, and management method codes. Additionally, EPA no longer requires the collection of the name and EPA identification number of each transporter in the biennial report. In order to maintain consistency between the regulations at § 262.41 and the EPA biennial report instructions and forms, EPA is proposing to remove the list of specific data elements currently in the regulations and to simply require completion and submission of all the data elements required in EPA form 8700–13. This change eliminates the need to update the list of data elements in the regulations, which would require periodic rulemakings, every time that changes were made to the information to be provided.

At least every three years, EPA’s biennial report instructions and forms are reviewed and approved through the information collection request (ICR) process under the Paperwork Reduction Act (PRA). The PRA requires EPA to issue proposed and final notices in the **Federal Register** and to provide opportunity for public comment, thus ensuring that the regulated community is informed and has the opportunity to comment on the report instructions and

¹⁰⁶ Relatedly, EPA is also proposing to allow CESQGs and SQGs that generate additional amounts of hazardous waste in response to an episodic event that would have required a bump up in generator category to maintain their generator category provided certain conditions are met. See section IX of this preamble for more information.

form. The PRA also requires approval by the Office of Management and Budget. Eliminating the list of specific data elements currently in the regulations therefore does not eliminate public input and avoids duplication with the review and approval processes established under the PRA.

EPA does not believe this change in any way affects the enforceability of the biennial reporting regulations. Generators must complete and submit all information required by EPA form 8700–13. EPA also notes that this approach is similar to the current regulations at § 262.12, which require generators to obtain an EPA identification number using EPA form 8700–12 (Site ID form). Section 262.12 does not contain an itemized list of specific data elements contained in EPA form 8700–12. Instead, it requires the completion and submission of the specified form.

EPA also notes that some states develop their own biennial report forms, based on the federal forms. EPA does not believe this proposed change would impact the biennial reporting processes in these states. Authorized states that use a different form for collecting biennial report information would simply refer to their authorized state form in their state regulations.

5. Request for Comment

The Agency requests comment on the proposed changes to § 262.41. EPA also specifically requests whether commenters believe the proposed change to eliminate the specific data elements in § 262.41 will ease compliance and understanding of the current biennial reporting procedures.

M. Provision Prohibiting Generators from Disposing of Liquids in Municipal Solid Waste Landfills (Proposed § 262.14 and § 262.35)

EPA is proposing to add a paragraph at § 262.14 (for CESQGs) and § 262.35 (for SQGs and LQGs) that hazardous waste generators are prohibited from disposing of liquid hazardous wastes in landfills. This is not a new requirement; it is a reflection of existing regulations found at § 258.28 for municipal solid waste landfills (MSWLFs), and §§ 264.314 and 265.314 for permitted and interim status hazardous waste landfills. The Agency believes it is important to emphasize that the responsibility for complying with this provision not only resides with municipal and hazardous waste haulers and landfill operators, but also with hazardous waste generators.

The restriction for disposal of liquid hazardous waste in MSWLFs has been

in place since 1991 at § 258.28 and specifically restricts “bulk or noncontainerized liquid wastes, except (1) household wastes (other than septic wastes), and (2) leachate and gas condensate that is derived from the MSWLF unit where the unit is equipped with a composite liner and a leachate collection system. . . . designed and constructed to maintain less than 30 centimeters of leachate over the liner” (56 FR 51055, October 9, 1991).¹⁰⁷

In the same preamble, EPA went on to state that liquids restrictions are necessary because the disposal of liquids into landfills can be a significant source of leachate generation and that restricting the introduction of liquids into landfills would minimize the leachate generation potential of landfills and reduce the risk of liner failure and subsequent contamination of the ground water.¹⁰⁸ The special requirements for bulk and containerized liquids in part 264 address similar concerns about the management of liquids in landfills.¹⁰⁹

Under current practices and operations, the primary onus for seeing that hazardous waste liquids are restricted from landfills generally resides with the hauler. Should a random inspection at a landfill of the hauler’s waste find liquid hazardous waste, the landfill operator cannot accept the hauler’s waste without violating its landfill permit. As a result, the hauler would be required to transport its waste back to the generator or to a RCRA-permitted treatment facility and pay the significantly higher tipping fees for any required treatment prior to disposal. While the waste management hauler or transporter can provide a measure of oversight, ultimately the hauler must rely on the due diligence and waste management practices of the hazardous waste generator to avoid such an outcome. In other words, the hazardous waste generator is responsible for ensuring that hazardous waste liquids are not disposed of in landfills.

Considering the importance of restricting liquid hazardous wastes in landfills, the Agency believes including a mirror provision in the 40 CFR part 262 hazardous waste generator regulations would increase awareness, and thus compliance, by generators with the liquids restriction that currently exists in §§ 258.28, 264.314(a) and 265.314(a). Therefore, the Agency is proposing to incorporate this provision

¹⁰⁷ The prohibition on liquid wastes in MSWLFs applies to all liquid wastes and not just liquid hazardous wastes.

¹⁰⁸ 56 FR 51055, October 9, 1991.

¹⁰⁹ 40 CFR 264.314(a) and 265.314(a).

into the generator regulations at part 262.

Effect of the Proposed Reorganization: This section is affected by the proposed reorganization in that we are proposing to include the provision as a condition in § 262.14 for CESQGs, as well as in § 262.35 for SQGs and LQGs.

N. Extending Time Limit for Accumulation Under Alternative Requirements for Laboratories Owned by Eligible Academic Facilities (40 CFR Part 262 Subpart K)

The Agency is proposing to extend the accumulation time for unwanted material by eligible academic entities with laboratories operating under 40 CFR part 262 subpart K from six months to one year.

Under 40 CFR part 262 subpart K eligible academic entities have the choice of operating their laboratories under the alternative subpart K standards instead of the satellite accumulation area regulations at 40 CFR 262.34(c). Currently, if the eligible academic entity chooses to operate its laboratories under subpart K, the entity must remove the unwanted material from each laboratory under the following two circumstances: (1) Every 6 months; or (2) within 10 days, if the laboratory accumulates more than 55 gallons of unwanted material or 1 quart of reactive acutely hazardous unwanted material.

Operating under the SAA regulations, an eligible academic entity has no time limit for accumulation. Therefore, for smaller eligible academic entities that do not accumulate 55 gallons in a laboratory, subpart K’s six month accumulation time limit can mean a shorter, more stringent, accumulation time than they have under the satellite accumulation area regulations. Eligible academic entities have cited this shorter accumulation time as a disincentive for opting into the alternative standards in subpart K. The Agency therefore requests comment regarding its proposal to increase the accumulation time limit in an eligible academic entity’s laboratory to 12 months.

Lengthening the time would yield a cost savings for those operating under subpart K compared to the costs they have now. The longer accumulation time would come with no increased risk because the volume limits—which are the same as the SAA volume limits—would continue to be in place for the rare cases where labs do accumulate 55 gallons of unwanted material or 1 quart of reactive acutely hazardous unwanted material.

The Agency requests comment on extending the accumulation time for

unwanted material by eligible academic entities with laboratories operating under 40 CFR part 262 subpart K, from six months to one year.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

IX. Proposed Addition to 40 CFR Part 262 for Generators that Temporarily Change Generator Category as a Result of an Episodic Event

EPA is proposing to allow a CESQG or an SQG to maintain its existing generator category if, as a result of a planned or unplanned episodic event, the generator would generate a quantity of hazardous waste in a calendar month sufficient to bump the facility into a more stringent generator category (*i.e.*, CESQG to either an SQG or an LQG; or an SQG to an LQG). This proposed change would allow a CESQG or SQG to generate additional quantities of hazardous waste—exceeding its normal generator category limits temporarily—and still maintain its existing regulatory category provided it complies with specified conditions discussed below. Because these events are considered to be temporary and episodic in nature, the hazardous waste generator would only be allowed to take advantage of this provision once every calendar year. Also as explained below, a CESQG or SQG could petition EPA to manage one additional episodic event per calendar year.

A. Background

Under the current RCRA regulatory framework for hazardous waste generators, a generator's category is determined by the quantity of hazardous waste it generates in a calendar month. For example, if a generator generates less than or equal to 100 kilograms of non-acute hazardous waste and 1 kilogram of acute hazardous waste in a calendar month, then it can comply with the regulations applicable to a CESQG.¹¹⁰ However, if that same generator generates more than 100 kilograms but less than 1,000 kilograms of non-acute hazardous waste and less than or equal to 1 kilogram of acute hazardous waste in the following calendar month, then it must comply with all applicable regulations associated with an SQG.

At issue is when the generator generates an additional quantity of hazardous waste in a calendar month as a result of an episodic event—(planned or unplanned)—only to revert back to its

normal waste generation quantities in the following month. For example, a CESQG plans a short-term demolition project that generates an additional 500 kilograms of hazardous waste in the calendar month, resulting in the CESQG becoming an SQG for that calendar month. However, once the demolition project has been completed, the generator's waste generation drops such that it again qualifies as a CESQG. Other examples of planned episodic events include tank cleanouts, short-term construction projects, site remediation, equipment maintenance during plant shut downs, and removal of excess chemical inventories.

Unplanned episodic events, which may be less frequent, include production process upsets, product recalls, excess inventory, accidental spills, or "acts of nature," such as a tornado, hurricane, or flood. For example, an SQG suffers an unplanned disruption in production that results in the generation of 3,000 kilograms of an off-specification product that cannot be sold and must be discarded, therefore bumping the generator from an SQG to an LQG for that calendar month.

Currently, for the one month the hazardous waste generator was subject to more stringent regulations, the generator has two options: (1) Temporarily change its waste management practices to comply with those of the more stringent generator category for the duration of the event or (2) permanently adjust and manage all subsequent quantities it generates in the more stringent generator category (even though it is in a less stringent generator category in subsequent months). Generators that do not comply will be out of compliance with the applicable regulations.

Under the current regulatory framework, a CESQG must comply with minimal conditions for an exemption. For non-acute hazardous waste, these include the following: making a hazardous waste determination; counting the amount of hazardous waste it generates to ensure it is a CESQG (*e.g.*, generates less than or equal to 100 kilograms of non-acute hazardous waste and 1 kilogram of acute hazardous waste in a calendar month); accumulating no more than 1,000 kilograms on site at any one time; and sending its hazardous waste for subsequent off-site waste management to one of several specified designation facilities.¹¹¹ However, if an

episodic event were to occur, such as the generation of an additional 500 kilograms of non-acute hazardous waste resulting from a disruption in production process, the generator would need to comply with the SQG regulations that include both independent requirements and conditions for exemption. Having to obtain a RCRA identification number would be an example of an independent requirement, whereas managing its hazardous wastes in containers or tanks subject to the applicable 40 CFR part 265 subparts I and J regulations, and marking and labeling the containers would be examples of conditions for exemption. EPA believes requiring a CESQG to comply with the additional SQG or LQG regulations or an SQG to comply with the LQG regulations for the month its hazardous waste exceeded the quantity limits based on an episodic event (planned or unplanned) may be unnecessary to protect human health and the environment. Instead, the Agency is proposing a more practical approach to ease compliance for episodic generators and still protect human health and the environment. By complying with the specified conditions, the generator would be able to maintain its current generator category and would not be required to comply with the more stringent site-wide regulations applicable to the higher generator category.

Although EPA does not have specific information regarding the number of generators that may take advantage of its proposed alternative episodic standards, we can make certain estimates using data collected through the biennial report. EPA currently estimates that 1,270–2,550 generators could potentially take advantage of this provision if it is finalized.¹¹² However, EPA believes that the potential universe of generators that may want to take advantage of the episodic event standards may be significantly higher and is seeking comment on what a more reliable estimate might be. For example, there may be certain industrial sectors in which generators have a higher probability of being episodic generators

facility permitted, licensed or registered by a state to manage non-municipal non-hazardous solid waste; (6) a facility which beneficially uses or reuses or legitimacy recycles or reclaims its wastes or treats its waste prior to beneficial use or reuse or legitimacy recycling or reclamation; or (7) universal waste handler or destination facility subject to the requirements in 40 CFR part 273.

¹¹² Assessment of the Potential Costs, Benefits, and Other Impacts of the Improvements to the Hazardous Waste Generator Regulatory Program, As Proposed, prepared by U.S. Environmental Protection Agency by Industrial Economics, Incorporated, May 2015.

¹¹⁰ Note: Besides the generation of non-acute hazardous waste, a generator's category is also determined by the quantities of acute hazardous waste it generates in a calendar month.

¹¹¹ A CESQG may send its hazardous waste to (1) a hazardous waste facility permitted by EPA; (2) an interim status hazardous waste facility; (3) a hazardous waste facility permitted by an authorized state; (4) a facility permitted, licensed or registered by a state to manage municipal solid waste; (5) a

than in others (e.g., retail, oil and gas exploration, utilities, and military bases).

On February 14, 2014, EPA published a Notice of Data Availability for the Retail Sector in which the Agency requested, among other topics, comments from retailers on issues they face in complying with the RCRA regulations. Some commenters mentioned the challenge posed by complying with the hazardous waste regulations when an irregular event causes them to exceed the threshold of their normal generator category for a single month. This provision would provide a way for retailers and others to manage that challenge.

B. Proposed Conditions for Episodic Generators

Under the proposed framework, a CESQG or an SQG generating an increased quantity of hazardous waste because of an episodic event that resulted in a temporary change in a generator's category would be able to maintain its existing generator category provided specified conditions are met as the waste is accumulated. We believe these conditions will be sufficient to ensure these additional hazardous wastes are managed in an environmentally sound manner. Similar to the existing hazardous waste regulatory framework, should a CESQG fail to meet the specified conditions, it would immediately lose the CESQG accumulation exemption and be the operator of a non-exempt storage facility unless it also immediately complied with all of the conditions for exemption for an SQG or LQG. If an SQG failed to meet any specified condition for exemption, it would immediately lose its exemption and be the operator of a non-exempt storage facility unless it had immediately complied with all of the conditions for an exemption for an LQG.

For both CESQGs and SQGs taking advantage of this provision, the following conditions must be met:

(1) Episodic events are limited to one per calendar year;

(2) The generator must notify EPA at least 30 calendar days prior to initiating a planned episodic event or within 24 hours after an unplanned episodic event or as soon as possible; identify the start and end dates, which may be no more than 45 days apart, as well as other information about the event; and identify a facility contact and/or emergency coordinator with 24-hour telephone access to discuss notification submittal or respond to emergency;

(3) The generator must obtain an EPA ID number (CESQGs);

(4) The generator must comply with specified hazardous waste management conditions as the waste is accumulated on-site;

(5) The generator must use a hazardous waste manifest and hazardous waste transporter to ship the waste generated by the episodic event to a RCRA-designated facility within 45 calendar days from the start of the episodic event;

(6) The generator must complete and maintain specified records.

EPA is also proposing a petition process to allow hazardous waste generators to request from EPA one additional episodic event within the same calendar year and/or an extension of up to 30 calendar days to complete an episodic event and still be eligible to maintain its generator category. An example of how the implementation of these provisions would work in practice, particularly the start and end dates in conjunction with normal waste generation and accumulation operations, follows a discussion of these requirements.

The proposed regulations for episodic generators are located at a new part 262 subpart L, §§ 262.230–232.

1. Number of Episodic Events per Calendar Year

The Agency is proposing that a CESQG or a SQG be allowed to exceed its generator category limits only once per calendar year without affecting its generator category.^{113 114} EPA has several reasons for this restriction. First, if a CESQG or SQG exceeds its generator category limits more frequently than once per calendar year, EPA is concerned that these generators are more likely to be routinely generating greater amounts of hazardous waste and thus it may be more appropriate for the generator to comply with the regulations applicable to the higher generator category, at least for the months they exceed the quantity limits for their generator category. Second, EPA believes most hazardous waste generators experience an episodic event infrequently, such as once every few years, and these events are typically planned maintenance projects. Third, the Agency does not consider an episodic event to be limited to one project within the generator's site. In fact, a generator could start and

¹¹³ As discussed later, the length of a generator's episodic event may overlap two calendar years in which case discretion would be provided to EPA or the authorized state as to how it would address a request for another episodic event in the second year by a generator.

¹¹⁴ EPA is proposing a process to petition the Agency for an additional event, if warranted.

complete multiple projects (e.g., a small demolition project, a tank cleanout, and removal of excess chemicals) at different dates within the 45 day time limit so long as it stayed within the 45 day start and end dates identified on the notification form with all hazardous waste generated considered part of the same episodic event.

2. Notification

A SQG or CESQG would have to notify EPA no later than 30 days prior to initiating a planned episodic event using EPA form 8700–12 (Site ID form). Should EPA finalize this provision, EPA will provide instructions in the Site ID form on how to report an episodic event (for example, using the notes section of the form). The hazardous waste generator would be required to identify the dates the episodic event will begin and end—a time frame not to exceed 45 calendar days—as well as describe the reason for the event and the types and estimated quantities of hazardous wastes that would be generated during the event. Should an unplanned event occur, the generator would be required to notify EPA as soon as possible via phone or email, but must submit EPA form 8700–12 (Site ID form) within 24 hours of the unplanned event, or as soon as possible depending upon the circumstances. Unless notified by EPA or an authorized state, a CESQG or SQG would be allowed to begin its episodic event on the date identified on its form 8700–12.

The date identified on the notification form as the start date for the episodic event is assumed to be the date the generator initiates physical action in generating and accumulating the hazardous waste. Whether such action actually occurs on that date or after by the generator will have no impact in changing the end date of the episodic event identified on the notification form.

No matter what, the end date must be no later than 45 calendar days from the date identified on the notification form as the start date of the episodic event. The end date will be the date on which all hazardous waste generated from the episodic event, and possibly other hazardous waste also generated during that time period as part of normal operations, will have had to be removed and sent to a RCRA designation facility as verified by the hazardous waste manifest. The Agency does not see any reason to preclude a generator taking advantage of this provision to also dispose of other hazardous wastes generated during the time of the episodic event.

As part of the notification form, a CESQG would have to notify its local fire department that it was taking advantage of an episodic event. The notice would need to include the start and end dates and identify the types and quantities of hazardous wastes that would be generated.

EPA believes notification is essential to inform regulatory authorities of the facility's activities in order to enable adequate compliance monitoring of the facility with the conditions of the alternative standards.

3. EPA ID Number

A CESQG generating and accumulating quantities of hazardous waste that would otherwise result in a higher generator category because of an episodic event (whether planned or unplanned) would be required, under the proposed regulations, to obtain an EPA ID number using EPA form 8700-12 if one had not previously been assigned. A generator cannot initiate a hazardous waste shipment to a RCRA-designated facility without an EPA ID number. (SQGs are already required to obtain an EPA ID number.)

4. Waste Management Standards

a. Accumulation standards for CESQGs. Under the current regulations, a CESQG must not accumulate more than 1,000 kilograms of non-acute hazardous waste at any one time, but otherwise does not have any on-site waste management standards when accumulating hazardous waste, primarily because the quantities generated every month are so small. EPA is proposing to require a CESQG that generates episodic hazardous waste that would cause the CESQG to exceed its generator category limit for the calendar month to comply with the following accumulation standards for containers and tanks that manage the episodic wastes if it wants to take advantage of the episodic generator provision (CESQGs are prohibited from using a drip pad or a containment building). EPA believes that these standards are necessary because the quantity of hazardous waste that is accumulated during this episodic period requires standards for safe management in order to adequately protect human health and the environment.

When accumulating hazardous waste in containers, the CESQG would be required to mark its containers with the following: (1) The words "Episodic Hazardous Waste"; (2) other words that identify the contents of the containers—examples may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene

dichloride," or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (3) an indication of the hazards of the contents of the container—examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic). In the case of hazardous wastes ultimately treated and disposed of off-site, the generator could use a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling), use a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200, or use a chemical hazard label consistent with the NFPA code 704; or a hazard pictogram consistent with the United Nations' GHS. Generators also may use any other marking or labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

These marking standards are the same as those for LQGs and SQGs accumulating hazardous wastes in containers in the course of normal business operations and are necessary to protect human health and the environment. In addition to these, the CESQG would be required to mark the date that the episodic event began clearly on each container.

For tanks, the CESQG would have to mark or label the tank containing hazardous waste accumulated during the event with the words "Episodic Hazardous Waste" and would be required to use inventory logs, monitoring equipment, or other records to identify the contents of the tank, the quantity accumulated as a result of the episodic event, and the associated hazards and to identify the date that the episodic event began. The records containing this information would have to be immediately accessible by the generator.

In addition, the generator would be required to manage the hazardous waste in a manner that minimizes the possibility of an accident or release. Management standards are critical to ensure the hazardous waste does not pose a risk to human health and the environment. A CESQG may use best management practices to comply with this condition. In practice, this includes managing the hazardous waste in containers that are in good condition and chemically compatible with any hazardous waste accumulated therein

and keeping the containers closed except to add or remove waste. Complying with the standards in part 265 subpart I would satisfy this condition.

With respect to tanks, the following standards are proposed: (1) Having procedures in place to prevent overflow (*e.g.*, the tank is equipped with a means to stop inflow with systems such as a waste feed cutoff system or bypass system to a standby tank when hazardous waste is continuously fed into the tank); (2) inspecting the tank(s) at least once each operating day during the episodic event to ensure all applicable discharge control equipment, such as waste feed cutoff systems, bypass systems, and drainage systems, are in good working order and (3) using appropriate controls and practices to prevent spills and overflows from tank or secondary containment systems including at a minimum spill prevention controls (*e.g.*, check valves, dry disconnect couplings), overfill prevention controls (*e.g.*, level sensing devices, high level alarms, automatic feed cutoff, or bypass to a standby tank), maintenance of sufficient freeboard in uncovered tanks to prevent overtopping by wave or wind action or by precipitation. Such practices are necessary to prevent the release of the hazardous waste or hazardous constituents to air, soil, or water, which could threaten human health and the environment.

As mentioned above, an emergency coordinator (in compliance with proposed § 262.16(b)(9)(i)) must be identified for the duration of the episodic event on the notification form. A CESQG taking advantage of this provision would also need to notify the local fire department of who their emergency coordinator was if they had not done so already for other emergency preparedness and planning reasons. An emergency coordinator is needed because the CESQG will be generating greater amounts of hazardous waste than normal and, should an accident occur, the emergency coordinator would need to be prepared to handle the situation.

EPA believes these management standards are necessary to adequately protect human health and the environment because of the additional quantities of hazardous waste generated and accumulated as a result of an episodic event. The Agency, however, seeks comment on these proposed management standards. In particular, the Agency is aware of concerns expressed by generators in the past that the marking and labeling of tanks with the date the generator first began

accumulating hazardous waste could prove problematic since the tank could have numerous markings on it. (See comments found in RCRA Docket EPA-HQ-RCRA-2008-0678 in response to EPA's Technical Corrections Direct Final rule, 75 FR 12989.) The Agency has responded to this concern by allowing generators to use log books and other means to identify the hazardous waste accumulation start date. However, the Agency is proposing that CESQGs (and SQGs) label their tanks with the words "Episodic Hazardous Waste" so that emergency responders and others are readily aware of the tank's contents and situation. The Agency requests comment on whether this requirement could also prove problematic, and if so, why, and what cost-effective alternatives exist to address those concerns and still allow emergency responders, inspectors, workers, etc. to be readily aware of the tank's hazardous waste contents.

Under the existing regulations, CESQGs may not treat hazardous waste generated on site in a manner equivalent to SQGs and LQGs under § 262.34, except in an on-site elementary neutralization unit. Elementary neutralization units, as defined in § 260.10, are exempt from RCRA treatment, storage, and disposal standards and permitting requirements. The elementary neutralization unit exclusion does not preclude a CESQG from treating waste in the exempt unit as long as the generator meets the criteria outlined in §§ 264.1(g)(6), 265.1(c)(10), and 270.1(c)(2)(v). Specifically, the elementary neutralization unit must meet the definition of a container, tank, tank system, transport vehicle, or vessel, and must be used for neutralizing wastes that are hazardous only because of the corrosivity characteristic.¹¹⁵

Considering that CESQGs will be required to meet additional waste management requirements under this proposed rule for episodic generation, the Agency seeks comment on whether CESQGs taking advantage of this provision should be allowed to treat their episodic hazardous waste on site in a manner equivalent to SQGs and LQGs at § 262.34. In particular, the Agency seeks comment on whether the volume of hazardous waste generated from an episodic event exceeds the capacity and expertise of CESQGs, which are accustomed to managing smaller quantities of hazardous waste, and whether the Agency should identify a select list of allowable types of

treatment that would not pose a risk to human health and the environment.

b. Manifest use by CESQGs and management at a RCRA-designated facility. EPA is proposing to require CESQGs to manifest the hazardous waste generated from an episodic event and send it to a RCRA-designated facility. Under current regulations, CESQGs are not required to manifest their hazardous waste to a RCRA-designated facility, but can ship them without a manifest and to one of seven types of facilities listed in § 261.5(f)(3). Because the CESQG will be generating quantities of hazardous waste that exceed its normal generator category thresholds, the Agency believes the use of a hazardous waste manifest and the shipment of the hazardous waste to a RCRA-designated facility is necessary to protect human health and the environment. However, the condition to manifest the hazardous waste and send it off site to a RCRA-designated facility would only apply to the hazardous waste generated as a result of the episodic event. The condition would not apply, unless if for economic or logistical reasons, the CESQG desired to ship off site to a RCRA-designated facility all hazardous waste generated and accumulated either as a result of the episodic event, independent of the episodic event, or prior to the event.

c. Accumulation standards for SQGs. Under the current regulations, SQGs must comply with the waste accumulation, waste management, employee training, and emergency preparedness and prevention conditions at 40 CFR 262.34 (d)–(f) with references to 40 CFR 265 subparts C, I, and J in order to accumulate hazardous waste without a RCRA storage permit or compliance with interim status standards. SQGs may not take advantage of this proposed episodic generation provision for wastes accumulated on drip pads or in containment buildings although EPA does seek comment on allowing episodic event wastes to be accumulated in these units prior to sending the hazardous waste off-site for treatment and disposal to a RCRA designated facility. Under this proposed rule, EPA is proposing to require an SQG that generates episodic hazardous waste that would cause the SQG to exceed their generator category limits for the calendar month to comply with certain standards for containers and tanks if it desires to take advantage of the episodic generator provision.

When accumulating hazardous waste generated as a result of an episodic event in containers, the SQG would be required to mark its containers with the following: (1) The words "Episodic

Hazardous Waste"; (2) other words that identify the contents of the containers—examples may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene dichloride," or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (3) an indication of the hazards of the contents of the container—examples of hazards include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic). In the case of hazardous wastes ultimately treated and disposed of off-site, the generator could use a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling), a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200, a chemical hazard label consistent with the NFPA code 704, or a hazard pictogram consistent with the United Nations' GHS. Generators also may use any other marking or labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

These standards are the same as those for SQGs accumulating hazardous wastes in containers in the course of normal business operations and are necessary to protect human health and the environment. In addition to these, the SQG would be required to mark the date that the episodic event began clearly on each container.

For tanks, the SQG would be required to mark or label the tank containing hazardous waste accumulated during the event with the words "Episodic Hazardous Waste" and would be required to use inventory logs, monitoring equipment, or other records to identify the contents of the tank and the associated hazards and to identify the date that the episodic event began and ended. The generator would need to have records containing this information immediately accessible.

In addition, the SQG would need to comply with all the conditions of the exemption in § 262.34 (d) through (f) with references to 40 CFR 265 subparts C, I, and J, part 268 land disposal restrictions (§ 262.16 under the proposed reorganization)—that is, the waste accumulation, waste management, employee training, and emergency preparedness and prevention conditions.

¹¹⁵ RCRA Hotline Q & A, February 1996, RCRA Online 13778.

d. Manifest use by SQGs. As under the current regulations, EPA is proposing that SQGs manifest the hazardous waste generated from an episodic event and send it to a RCRA-designated facility, unless the waste is managed on site. The Agency believes the use of a hazardous waste manifest and shipment of the hazardous waste to a RCRA-designated facility is necessary to protect human health and the environment. However, unlike CESQGs, the use of the hazardous waste manifest would apply not only to the wastes generated from the episodic event, but all other hazardous wastes the SQG generates within its generator category.

5. Forty-five (45) Days or Less Would be Allowed to Treat and Dispose of Hazardous Wastes On Site (SQGs) or Manifested and Shipped Off Site (CESQGs or SQGs) to a RCRA-Designated Facility

The Agency is proposing to allow SQGs and CESQGs 45 calendar days to initiate and complete an episodic event, which includes generation, accumulation and management (*e.g.*, recycling, treatment and disposal—either on site, such as waste neutralization in a container, or off site at a RCRA-designated facility) of all hazardous waste resulting from the episodic event. The Agency believes 45 days is sufficient time for a generator to complete management of the hazardous waste from the time that the generator begins generating and accumulating the hazardous waste. However, as discussed below, a CESQG or SQG can petition the Agency for additional time to complete the generation and removal of the hazardous waste during the episodic event, if necessary.

6. Recordkeeping

Finally, generators would need to keep the following information in their records: (1) Beginning and end dates of the episodic event; (2) a description of the episodic event; (3) a description of the types and quantities of hazardous wastes generated during the episodic event; (4) a description of how the hazardous waste was managed as well as the name of the RCRA designated facility that received the hazardous waste; (5) name(s) of hazardous waste transporters, as appropriate; (6) an approval letter from EPA, if the generator successfully petitioned to conduct an additional episodic event during the calendar year; and (7) an approval letter from EPA, if the generator successfully petitioned for an additional 30 calendar day extension. These records would need to be maintained on site by the generator for

three years from the completion date of each episodic event.

EPA believes the recordkeeping condition is critical to enable effective and credible oversight. We also believe that the information to be maintained is the minimum information necessary to determine that any hazardous waste generated during the episodic event is managed properly.

7. Petitions

a. Petition To Request one Additional Episodic Event

While the Agency believes that most generators will experience an episodic event infrequently, we also recognize that there may be situations, often unexpected, where a hazardous waste generator may have more than one episodic event within a calendar year, such as an unexpected product recall, a major spill, or an act of nature.

Therefore, the Agency is proposing to allow CESQGs and SQGs to petition EPA (at least 30 days before initiating a planned episodic event and within 24 hours after an unplanned event) for permission to manage one additional episodic event without impacting the hazardous waste generator category. The petition must include (1) the reason why an additional episodic event is needed and the nature of the episodic event; (2) the estimated amount of hazardous waste to be managed from the event; (3) how the hazardous waste is to be managed; (4) the estimated length of time needed to complete management of the hazardous waste generated from the episodic event—not to exceed 45 days; and (5) information regarding previous episodic event(s) managed by the generator and whether it complied with the proposed conditions. EPA will then evaluate this and other site-specific information to determine whether a generator should be allowed to initiate a second episodic event under the proposed alternative standards. The petition by the generator may be made via fax, email, or letter. The generator may not manage hazardous waste for an additional episodic event until written approval by EPA (or the authorized state) has been received. The generator must retain written approval in its records for three years from the date the episodic event ended.

b. Petition To Request Additional Time To Complete an Episodic Event

Events may arise, particularly unplanned events, such as an “act of nature,” where 45 days is insufficient to complete the event. The Agency is proposing to allow generators to petition EPA for an additional 30 days to

complete the generation and removal of hazardous waste, if needed. The petition must include (1) the nature of the episodic event; (2) the estimated amount of hazardous waste to be managed from the event; and (3) the generator’s rationale for needing an extension for an additional 30 days beyond the 45-day limit to complete the episodic event. EPA will then evaluate the generator’s request to determine whether it should be allowed up to an additional 30 days to complete the episodic event. For example, a situation may exist where a hazardous waste transporter cannot arrive and remove hazardous waste generated until the 46th day because of unforeseen problems with its truck or the generator did not foresee problems with completing a tank cleanout because cleanout equipment failed to operate. These are all site-specific situations that EPA or authorized state would evaluate when making its decision. The generator cannot go beyond the 45-day limit unless written approval by EPA has been received.

The generator would need to petition EPA for approval at least 15 days before the original end date of the episodic event. The petition by the generator may be made via fax, email, or letter. The generator must retain written approval in its records for three years from the date the episodic event ended.

Should the generator request an extension from the Agency or authorized state with less than 15 days remaining and be denied the extension, then the generator would have to remove all hazardous wastes generated as a result of the episodic event as of the specified end date in its notification or be in violation of its exemption.

Unlike rulemaking petitions in part 260 subpart C of the hazardous waste regulations, the Agency is not proposing to have a notice and comment period for granting an episodic event or an extension. The Agency believes a generator’s actions and performance will dictate approval or disapproval of a generator’s request. In addition, in some cases a timely response to these requests is critical, especially with requests for extension. Taking notice and comment would delay that response.

8. Tracking and Accounting for Hazardous Waste Generation and Accumulation as a Result of an Episodic Event Along With Normal Production Operations

In practice, a generator taking advantage of this rule, in particular a CESQG or SQG, must track and monitor the start and end dates of the episodic event in conjunction with the date the

calendar month ends to ensure compliance with all RCRA regulatory provisions associated with waste generation and management. An example may be the best way of explaining how this rule would work.

A CESQG could have a number of facility operations (e.g., tank cleanouts, disposal of off-spec products it cannot sell or reclaim, repair work involving the removal of lead paint chips) that will often result in a temporary change in its regulatory category. The CESQG decides to notify its authorized state two months prior (as well as identifying a point of contact and emergency coordinator) that it will initiate the planned episodic event on July 20 and take advantage of the full 45 days allowed to conduct the event and end on September 2. Beginning on July 20, the generator must comply with all of the regulatory standards of subpart L discussed above to maintain its exemption as a CESQG. Under this example, if the generator complies with subpart L, it need not be concerned about the total amount of hazardous waste it will generate in the calendar months of July and August (e.g. 100 kg or less) or whether it will exceed the hazardous waste accumulation total of less than 1,000 kilograms associated with a CESQG.

However, on or before September 2, the generator must remove and dispose of all the hazardous wastes it generated over the course of the last 45 days that represented the episodic event. Provided the generator meets that deadline, that waste would not count when determining the generator's status. In this example, the generator chooses to also dispose of waste generated from its normal operations by September 2. In this case, it would then not count that waste in determining its generator status for July, August, and September. The CESQG would then estimate the quantity of hazardous waste it generates and accumulates for the remainder of September (starting on September 3 until the end of the month) to determine its regulatory category.

If the generator decides to separate out normal production operations from episodic event operations, then the waste from normal operations is counted each month to determine the generator's status. For example, assume the generator at the beginning of the episodic event had accumulated 950 kg of hazardous waste and proceeds to accumulate another 75 kg over the course of the 45-day episodic event that is associated with normal operations.¹¹⁶

¹¹⁶Note that it would not matter how much the CESQG had generated during a calendar month in

On September 3, if the generator had not disposed of that 1,025 kg of hazardous waste along with all of the episodic event hazardous wastes it generated and accumulated, then it would have violated the accumulation provision of a CESQG at 40 CFR 261.5(g)(2) (e.g., less than 1,000 kg) and would be in violation of the conditions of the CESQG exemption. A similar concern might occur if the generator generated 101 kg of hazardous wastes on September 1 and 2 from normal operations and did not dispose of it by September 2 with the waste from the episodic event. The generator would not be in compliance with the CESQG threshold for the calendar month and would be required to comply with the SQG conditions for exemption or be in violation of the exemption.

There are numerous variations on the above example (e.g., request to extend the length of time for the episodic event, etc.) that a generator would have to be aware of when it ended its episodic event to avoid exceeding waste generation totals for the calendar month or waste accumulation limitation totals.

9. An Episodic Event Involving Two Calendar Years

An episodic event may also involve overlapping two calendar years. The Agency is proposing that the generator count all the waste from the episodic event in the year with the most days involved in the episodic event. In other words, if the episodic event begins on December 16 of year 1 and ends on January 30 of year 2, the waste would count in year 2.

C. Request for Comment

The Agency requests comment on its proposed approach for addressing hazardous waste generated during an episodic event. Specifically, the Agency requests comment on whether the overall approach proposed would assist generators and allow a CESQG or SQG to maintain its generator category and not be bumped up into a more stringent generator category temporarily.

EPA also requests comment on the number of episodic events that would be allowed under these proposed alternative regulations. As stated above, we are proposing to allow CESQGs and SQGs to take advantage of this alternative regulatory framework for one episodic event per calendar year, with the ability to petition EPA for one additional event per calendar year. EPA

which the episodic event begins because all of that hazardous waste is now folded into the hazardous waste generated as a result of the episodic event. Otherwise, the rule would not work from a practical viewpoint.

is interested in ideas on how best to structure this alternative framework in terms of identifying a reasonable number of episodic events allowed per year and identifying an appropriate time period allowed to conduct and manage the hazardous waste from an episodic event in a way that would be effective while still ensuring protection of human health and the environment.

Additionally, the Agency requests comment regarding its proposed conditions for CESQGs and SQGs managing hazardous waste generated from the episodic event, such as the proposed 45-day limit to generate and manage the waste and the ability for CESQGs and SQGs to petition the Agency for one additional episodic event per calendar year or an additional 30 days to complete an episodic event. The Agency also requests comment on whether the proposed conditions for CESQGs and SQGs are reasonable and sufficient to protect human health and the environment.

Finally, the Agency requests comment on whether to allow a CESQG or SQG to accumulate hazardous waste either on a drip pad or in a containment building in compliance with 40 CFR part 265 subparts W and DD, respectively, as a result of an episodic event. As proposed, the Agency has focused on hazardous wastes accumulated in containers or tanks as a result of an episodic event since almost all CESQGs and SQGs accumulate waste in containers with a small percentage accumulated in tanks. However, there may be circumstances that lend themselves to a CESQG or SQG accumulating hazardous wastes on a drip pad or in a containment building.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

X. Proposed Revisions to 40 CFR Part 263—Standards Applicable to Transporters of Hazardous Waste

The current regulations at § 263.12 for transporters handling hazardous waste at a transfer facility for ten days or less state that the transporter is not subject to the storage regulations in 40 CFR parts 264, 265, 267, 268 and 270. In addition, the regulation stipulates that containers that hold hazardous waste must meet the provisions in § 262.30 that reference DOT's packaging regulations at 49 CFR parts 173, 178, and 179.

The Agency is proposing to change the marking and labeling requirements for transporters handling hazardous waste at transfer facilities, found at § 263.12, to be consistent with the proposed changes for marking and

labeling conditions for containers for SQGs, for LQGs, and in SAAs.¹¹⁷ In addition to these proposed changes, EPA is also proposing to require that containers of hazardous waste at transfer facilities be labeled prior to being transported off site to a RCRA-designated facility with the applicable EPA hazardous waste number(s) (EPA hazardous waste codes), which will help the TSDf receiving the hazardous waste comply with the LDR regulations in 40 CFR part 268. The Agency is proposing these modifications to ensure that hazardous wastes are appropriately labeled and marked throughout transportation to a RCRA-permitted or interim status TSDf or to another transfer facility.

Specifically, EPA is proposing that transporters storing hazardous wastes in containers at transfer facilities mark the containers with the following: (1) The words “Hazardous Waste”; (2) the applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261; (3) other words that identify the contents of the containers—examples may include, but are not limited to the name of the chemical(s), such as “acetone” or “methylene dichloride”; or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; and (4) an indication of the hazards of the contents of the container—examples of which include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the DOT requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the OSHA Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the NFPA code 704; or a hazard pictogram consistent with the United Nations’ GHS. Transfer facilities also may use any other marking and labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers.

A transfer facility may choose to use an appropriate DOT proper shipping name found in the 49 CFR 172.101 hazardous materials table to identify the contents of the container. That way, the

¹¹⁷ EPA is proposing to move these provisions as a part of the reorganization of the generator regulations. They can be found in the proposed regulatory text at the following citations: SAAs—§ 262.15(a)(1)(iv); SQGs—§ 262.16(b)(6)(i); and LQGs—§ 262.17(a)(5).

transfer facility will fulfill EPA and DOT requirements simultaneously; however, EPA is not proposing to require the use of the DOT shipping names while the hazardous waste is accumulating on-site. We only suggest that the DOT shipping name may be one way that some generators may choose to identify the contents of the container.

As previously discussed, the Agency believes providing this information on the container will alert workers and other handlers to the contents of the container and the potential hazards of the materials therein. This information increases the awareness of workers and others who might come into contact with the hazardous waste in the containers and reduces potential adverse impacts from container mismanagement. The Agency does not believe this proposed change will adversely impact transfer facility operations since similar marking and labeling standards are proposed for hazardous waste generators. One difference, however, is the inclusion of the EPA hazardous waste number in the list of labeling requirements. Although generators are not required to have the EPA hazardous waste number on the hazardous waste while accumulating it, we are proposing in this rulemaking that generators must include the EPA hazardous waste number on the label before transporting the hazardous waste off site, so when a container arrives at the transfer facility it should already have the EPA hazardous waste number on its label.

Given that containers received by the transfer facility will already be marked and labeled by the generator, the Agency believes the additional burden on the transfer facility will be minimal. However, there may be situations where the transporter would be required to mark and label a container. One example of when a transfer facility would be required to mark and label its containers would be when it consolidates two containers with the same hazardous waste into a new container or when it is able to combine and consolidate two different hazardous wastes that are compatible with each other and are able to be subsequently managed consistently in compliance with the applicable regulations in parts 264, 265, 267, 268 and 270 of this chapter.

The Agency requests comment on this proposed change, particularly the identification of any unintended problems from this requirement.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

XI. Proposed Revisions to 40 CFR Parts 264 and 265—Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities and Interim Status Standards for Owners and Operators of Hazardous Waste Treatment, Storage, and Disposal Facilities

The Agency is proposing to modify the biennial report requirements for facilities subject to 40 CFR 264.75 and 40 CFR 265.75 and the special requirements for ignitable and reactive wastes at 40 CFR 265.176.

A. Proposed Changes to Biennial Reporting Requirements (40 CFR 264.75 and 40 CFR 265.75)

EPA is proposing to modify the regulations at §§ 264.75 and 265.75 to eliminate the list of specific data elements and to require the completion and submission of all data elements in the biennial report form (EPA form 8700–13).

Section 264.75 currently requires that the biennial report include a specific list of data elements, including the name, address, and EPA ID number of the generator and each transporter and TSDf, the EPA hazardous waste number for each hazardous waste shipped off site, and a signed certification, among other things.

Section 265.75 includes the above data elements as well as requiring monitoring data under § 265.94(a)(2)(ii) and (iii), and (b)(2), where required.

Similar to the approach EPA is proposing for the biennial reporting requirements for LQGs in § 262.41, EPA believes removing the specific data elements in the regulations and replacing it with a requirement to complete and submit all the data elements required in the biennial report form will ensure that the regulations and forms remain consistent. For example, the existing regulations require closure cost information and, at § 265.75(f), groundwater monitoring data under § 265.94(a)(2)(ii) and (iii), and (b)(2) to be submitted as part of the biennial report; however, these data elements are not collected on EPA’s current biennial reporting form 8700–13.¹¹⁸ Thus, EPA believes removing this

¹¹⁸ Closure cost estimates must be submitted in accordance with § 264.142 or 265.142 which requires owners or operators using the financial test or corporate guarantee to update closure costs for inflation within 30 days after the close of the firm’s fiscal year and before submission of updated information to the Regional Administrator under § 264.143(f)(3) or 265.143(e)(3), respectively. Additionally, disposal facilities must submit the most recent post-closure cost estimate under § 264.144 or 265.144, which requires owners or operators using the financial test or corporate guarantee to update for inflation within 30 days

list from the regulations will help TSDFs understand what EPA currently requires to be submitted as part of the biennial report. This approach eliminates the need to update the list of specific required data elements through rulemaking and reduces duplication with review and approval processes established under the PRA.

EPA does not believe this change in any way affects the enforceability of the biennial report regulations. Owners and operators must complete and submit EPA form 8700–13.

EPA also notes that some states develop their own state biennial report forms. EPA does not believe this proposed change would impact a state's ability to use their own biennial report forms or to collect more information than is required by the federal forms. Authorized states that use a different form for collecting biennial report information would simply refer to their authorized state form in their state regulations. Additionally, EPA is aware that some states use their state biennial report form as a vehicle for collecting closure cost data, required to be submitted under § 264.142, and groundwater monitoring data, required to be submitted under § 264.97(j). Because the existing federal regulations already specify collection of this information, EPA would not consider states that continue collecting this data using their state authorized biennial report form to be more stringent than the federal program.

Additionally, as discussed in section VIII.L of this preamble, EPA is proposing to modify the phrase “prepare and submit,” which is the existing language in §§ 264.75 and 265.75, to “complete and submit” because the Agency believes that “complete and submit” more accurately reflects that facilities must complete all applicable elements of the biennial report forms.

The Agency requests comment on these proposed changes to §§ 264.75 and 265.75. EPA also specifically requests whether commenters believe the proposed change to eliminate the specific data elements in these regulations will ease compliance and understanding of the current biennial reporting procedures.

after the close of the firm's fiscal year and before the submission of updated information to the Regional Administrator. Groundwater monitoring data must be submitted in accordance with § 265.94(b)(2), which requires the owner or operator to submit annually, until final closure of the facility, to the Regional Administrator a report containing the results of the groundwater quality assessment program no later than March 1 following each calendar year.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

B. Special Requirements for Ignitable and Reactive Wastes

Sections 262.34(a)(1)(i) and 262.34(d)(2) contain conditions for exemptions for LQGs and SQGs that accumulate hazardous waste on site for up to 90 or 180 days without a permit. These regulations both reference part 265 subpart I, which contains regulations for owners and operators of interim status hazardous waste facilities that store hazardous waste in containers.

The LQG conditions in § 262.34(a)(1)(i) reference § 265.176. Section 265.176 states that containers holding ignitable or reactive waste must be located at least 15 meters (50 feet) from the facility's property line. SQGs are not required to comply with this provision.

In some cases, to comply with this standard for ignitable and reactive wastes, LQGs may modify their production feedstocks or production processes to generate a waste that is not an ignitable or reactive hazardous waste or reexamine the site's layout to identify alternative accumulation areas. However, there are some cases where it may not be physically possible to meet this standard, particularly if the width of the site is 100 feet or less or when the generator's operations have expanded such that it no longer has the ability to accumulate ignitable or reactive waste at least 15 meters (50 feet) from the site's property line. Insurance companies and local fire departments often assist hazardous waste generators in minimizing their environmental hazards and liabilities, but site dimensions may sometimes physically prevent a facility from complying with this condition.

Therefore, the Agency is proposing to modify the regulatory text for generators to allow LQGs to apply for a site-specific waiver from their local fire department if they are unable to meet the hazardous waste accumulation property line condition.¹¹⁹ The proposed change would require LQGs to obtain a waiver from this provision, in writing, from local fire departments. LQGs would then be required to keep the written waiver in their records. In addition, as part of the reorganization of the generator regulations, discussed in section XIII of the preamble, we are also

¹¹⁹The Agency is not proposing to modify § 265.176 to allow interim status facilities to apply for a site-specific waiver from their local fire department if they are unable to meet the hazardous waste accumulation property line condition.

including this provision directly in the LQG accumulation regulations.

Because it is the local fire department that has the expertise to address this problem when it arises, EPA is relying on those local fire departments to work with the generators on any waivers that may be requested and on finding the most appropriate place on site to accumulate this hazardous waste.

Section 265.176 contains a comment that references § 265.17(a) and states that there are additional requirements in that section, which also contains provisions for ignitable, reactive, and incompatible wastes. The Agency is also proposing to incorporate the language from existing § 265.17(a) into § 262.17(a)(1)(vi)(B) of the generator regulations. EPA is proposing to replace the words “owner and operator” with “large quantity generator” as part of this revision. By eliminating the cross-references, generators should be able to more easily discern what provisions are applicable and therefore should be better able to properly manage any ignitable or reactive hazardous waste.

The Agency seeks comment on the proposed addition of this language to the generator conditions for exemption, as well as the change to allow LQGs to seek a waiver from the provision that containers holding hazardous waste must be located at least 15 meters (50 feet) from the property line. Specifically, EPA requests comment on whether this waiver option provides a sufficient level of protection for the facility and the surrounding community and whether generators would benefit from the increased flexibility. Additionally, EPA requests comment on whether it is appropriate to delegate the responsibility for issuing waivers in this case to the fire department and whether EPA should promulgate criteria that must be met as a condition of the waiver as part of this provision. For example, conditions may include a limit on the amount of ignitable or reactive hazardous waste that could be accumulated at any time or a requirement that the facility have certain technical controls, such as fire suppression devices or walls that meet a certain fire-resistance rating. Furthermore, EPA requests comment on whether the insertion of the language from § 265.17(a) in this section is helpful.

Finally, EPA requests comment on whether including a waiver to the provision for ignitable and reactive wastes would also be appropriate for interim status facilities or for permitted facilities in §§ 264.176 and 265.176.

Effect of the Proposed Reorganization: This section is affected by the proposed

reorganization. The revised language would appear directly in § 262.17(a)(1)(vi) as a condition for exemption for LQGs, rather than being located in 40 CFR part 265 subpart I and referenced from the generator regulations. The reorganization is discussed in section XIII of this preamble.

XII. Proposed Revisions to 40 CFR Part 268—Land Disposal Restrictions

The Agency is proposing to change the regulations on marking and labeling of containers by the owner/operator of a hazardous waste TSDF in § 268.50 to be consistent with the proposed marking and labeling changes for LQGs, for SQGs, for SAAs, and for transfer facilities.¹²⁰ EPA is also proposing to require that containers be labeled with the applicable EPA hazardous waste number(s) (EPA hazardous waste codes), which help the TSDF comply with the LDR regulations. More specifically, the Agency is proposing to modify § 268.50(a)(2)(i), which states that one of the requirements for storing hazardous wastes restricted from land disposal is that each container is clearly marked to identify its contents and the date each period of accumulation begins.

Consistent with the other proposed changes that clarify the contents and hazards posed by the contents of hazardous waste in containers, the Agency is proposing to modify this language to state that each container must be clearly marked with (1) the words “Hazardous Waste”; (2) the applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261; (3) other words that identify the contents of the containers—examples may include, but are not limited to the name of the chemical(s), such as, “acetone” or “methylene dichloride”; or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with DOT requirements at 49 CFR part 172 subpart D; (4) an indication of the hazards of the contents of the container (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label

consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; or a hazard pictogram consistent with the United Nations’ Globally Harmonized System); or any other marking or labeling commonly used nationwide in commerce that would alert workers and emergency responders to the nature of the hazards associated with the contents of the containers. The Agency will continue to require each container to be clearly marked with the date each period of accumulation begins.

The Agency believes this proposed change will not adversely impact facility operations. In fact, because these are consistent with the requirements for marking and labeling that are proposed elsewhere in the regulations, we believe it will be easier for all those who manage the hazardous waste to know and comply with the consistent system of marking and labeling. In addition, a clear description of what material is in each container makes the facility safer for employees, first responders, and the public. The Agency requests comment on this proposed change.

Effect of the Proposed Reorganization: This section is not affected by the proposed reorganization.

XIII. Proposed Reorganization of Hazardous Waste Generator Regulations

EPA is proposing to reorganize the hazardous waste generator regulations to make them more user-friendly, which should facilitate better generator compliance. As part of the Agency’s 2004 Program Evaluation of the hazardous waste generator program, the most frequent comment by stakeholders was to improve the user-friendliness of the regulations.

Although many existing generators are familiar with the current regulations, every year many generators either enter the hazardous waste generator program or switch their generator category and therefore need to become familiar with their obligations. Similarly, an existing generator may need to examine a particular regulatory citation to ensure it is complying with the regulations correctly. The Agency believes that providing these generators with a user-friendly regulatory framework is an effective way to make the regulations easier to understand for those who need to comply with them.

Therefore, in response to these concerns, EPA is proposing the following organizational changes:

(1) Integrate the generator regulations in § 261.5 into the generator regulations at part 262 by moving § 261.5 (which contains the regulations applicable to CESQGs, counting of hazardous waste, and mixing of hazardous wastes with non-hazardous wastes);

(2) Move the existing regulations at § 262.34 for SQGs and LQGs into three new sections:

(a) Satellite accumulation areas regulations for small and large quantity generators,

(b) Conditions for exemption for an SQG that accumulates hazardous waste; and

(c) Conditions for exemption for an LQG that accumulates hazardous waste;

(3) Use subtitles in these new sections; and

(4) Where reasonable, incorporate regulations that currently cross reference part 265 into these new sections.

A. Moving and Integrating Regulations from 40 CFR 261.5 into 40 CFR Part 262

Currently, certain hazardous waste generator regulations are located in a different part of the regulations (40 CFR 261.5) from the rest of the generator regulations (40 CFR part 262).

Stakeholders have stated that this current organization is confusing and not user friendly and have asked EPA to move the CESQG regulations in § 261.5 into part 262 so that all the generator regulations are in the same place. The Agency believes this reorganization would alleviate much confusion in the regulated community and, in the process, would foster greater compliance with the regulations.

Specifically, EPA is proposing to move the definition of a CESQG that generates non-acute hazardous waste at § 261.5(a) into the CESQG definition at § 260.10, move § 261.5(c) through (e) to a new section at § 262.13 titled “Generator category determination” and move § 261.5(b) and (f) through (j) to a new section at § 262.14 titled “Conditions for exemption for a very small quantity generator.”¹²¹

1. Hazardous Waste Generation Quantity Limits for CESQGs (40 CFR 261.5(a) and (e))

Currently § 261.5(a) sets forth the non-acute hazardous waste quantity limits for a CESQG and § 261.5(e) provides quantity limits for generating acute hazardous waste and any residue or contaminated soil, waste, or other debris resulting from the cleanup of a spill of

¹²⁰ EPA is proposing to move some of these provisions as a part of the reorganization of the generator regulations. They can be found in the proposed regulatory text at the following citations: SAAs—§ 262.15(a)(1)(iv); SQGs—§ 262.16(b)(6)(i); and LQGs—§ 262.17(a)(5)(i).

¹²¹ EPA is proposing to rename CESQGs to VSQGs (very small quantity generators). For a detailed discussion on this proposed change see section VLB of this preamble.

acute hazardous waste. As mentioned previously, EPA is now proposing to define each category of generator at § 260.10, and, thus, under the reorganization, § 261.5(a) and (e) will be incorporated into those definitions.

2. Determining Generator Category (40 CFR 261.5(c) and (d))

Section 261.5(c) and (d) set forth the provisions for a hazardous waste generator to use in making its generator category determination. Every hazardous waste generator must

determine its generator category so it knows what regulations are applicable to it. Since these regulations are applicable to all hazardous waste generators, it makes sense to move them into 40 CFR part 262 along with the other hazardous waste generator regulations. To further aid in making the regulations more user friendly, the Agency is proposing to make a new section for generator category determination at § 262.13, titled “Generator category determination.”

This new section is appropriate because, after a generator of a solid waste determines it has generated a hazardous waste (§ 262.11), the generator must then determine its hazardous waste generator category for the calendar month. Table 3—Crosswalk of Existing Citations to Proposed Citations for Determining Generator Category provides a summary of the crosswalk between the existing and proposed regulatory citations for determining a generator’s category.

TABLE 3—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR DETERMINING GENERATOR CATEGORY

Regulation	Existing citation	Proposed citation	Comment
Definitions of Generator Categories	§§ 260.10, 261.5 and 262.34.	§ 260.10	Current definition of SQG in § 260.10 is outdated. Current usage of generator categories is based on §§ 261.5 and 262.34.
Hazardous Waste Limits for CESQGs	§ 261.5(a) and (e)	§ 260.10	Not moved, but expanded significantly.
Purpose, Scope, and Applicability	§ 262.10	§ 262.10	
Hazardous Waste Determination and Recordkeeping	§§ 262.11 and 262.40(c) ...	§ 262.11	Content in § 262.11 is expanded and § 262.40(c) is incorporated.
Generator Category Determination	§ 261.5(c)–(e)	§ 262.13	

3. CESQG Conditions for Exemption (40 CFR 261.5(b) and (f) through (j))

Sections 261.5(b) and (f) through (j) establish a CESQG’s conditions for exemption from regulation as an SQG or LQG. More specifically, these conditions for exemption establish the regulations for accumulating acute and non-acute hazardous waste, where the acute and non-acute hazardous waste may be managed off-site, and what the implications are when hazardous waste

is mixed with solid waste or used oil. Since these regulations set forth conditions for exemption for CESQGs, just as the regulations found in existing § 262.34 set forth conditions for exemption for SQGs and LQGs, EPA is proposing to move § 261.5(b) and (f) through (j) to the newly created § 262.14 titled, “Conditions for exemption for a very small quantity generator.” All these regulations would then be located parallel to one another in part 262. Section 262.14 would also include the

CESQG landfill ban for liquids. In addition, CESQGs who episodically generate higher amounts of hazardous waste could follow the newly proposed standards for episodic generation in part 262 subpart L in order to maintain their CESQG status while managing these higher amounts of hazardous waste. Table 4—Crosswalk of Existing Citations to Proposed Citations for CESQGs provides a crosswalk between the existing and proposed CESQG conditions for exemption.

TABLE 4—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR CESQGS

Regulation	Existing citation	Proposed citation	Comment
CESQG Definition	§ 261.5(a)	§ 260.10	
Conditions for Exemption for a Very Small Quantity Generator.	§ 261.5(b) and (f) through (j).	§ 262.14	
CESQG Consolidation by LQGs Within the Same Company.	N/A	§ 262.14(a)(3)(viii)	Proposed new provision.
Landfill Ban for Liquids	§ 258.28	§ 262.14(d)	Proposed new provision.
Episodic Generation	N/A	Part 262 subpart L	

B. SQG and LQG Conditions for Exemption (40 CFR 262.34)

SQGs and LQGs may accumulate their hazardous waste on site without a permit or without having interim status provided they follow all of the conditions for exemption established in § 262.34. Section 262.34 can be difficult to navigate because the SQG and LQG conditions for exemption are

intertwined and there are many references to sections in 40 CFR part 265. Therefore the Agency is proposing to break § 262.34 into three new sections at §§ 262.15, 262.16 and 262.17. Section 262.15 would establish the conditions for exemption for SQGs and LQGs who wish to operate an SAA, § 262.16 would establish conditions for exemption for

SQGs, and § 262.17 would establish the conditions for exemption for LQGs.

1. Satellite Accumulation Area Conditions for Exemption for SQGs and LQGs (40 CFR 262.15)

Many generators use an SAA at their sites. These areas allow generators to accumulate hazardous waste near the point of generation, which provides for

efficiencies and greater safety in the handling of hazardous waste. When the generator has accumulated 55 gallons of hazardous waste (or one quart of acutely hazardous waste) in the SAA, the generator must then move the hazardous waste to the 90- or 180-day central accumulation area within three days. Currently the conditions for exemption for operating an SAA are located at § 262.34(c). The location of this provision in the regulations creates

confusion as to whether it applies to LQs only or both SQGs and LQs because it is located between the hazardous waste accumulation conditions for LQs and those for SQGs. Therefore, the Agency is proposing to move 40 CFR 262.34(c) into its own section at § 262.15 titled, “Satellite accumulation area regulations for small and large quantity generators.” Additionally, the Agency is proposing to duplicate §§ 265.171, 265.172 and

265.173(a) (which are currently referenced from § 262.34(c)(1)(i)) into § 262.15 in order to eliminate cross-referencing and improve the user friendliness of the regulations. Table 5—Crosswalk of Existing Citations to Proposed Citations for SAAs provides a summary of the crosswalk between existing and proposed regulations for SAAs.

TABLE 5—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR SAAS

Regulation	Existing citation	Proposed citation
Satellite Accumulation Area Provisions	§ 262.34(c)	§ 262.15.
Selected Part 265 Subpart I Provisions	§ 265.171	§ 262.15(a)(1)(i).
Selected Part 265 Subpart I Provisions	§ 265.172	§ 262.15(a)(1)(ii).
Selected Part 265 Subpart I Provisions	§ 265.173(a)	§ 262.15(a)(1)(iii).

2. Conditions for Exemption for an SQG Accumulating Hazardous Waste (§ 262.16)

As previously mentioned, the Agency is proposing to create 40 CFR 262.16 titled, “Conditions for exemption for a small quantity generator that accumulates hazardous waste.” This reorganization would move § 262.34(d) through (f) and (m) into § 262.16. Specifically, the Agency proposes to move the bulk of § 262.34(d) to § 262.16(b),¹²² move § 262.34(e) to § 262.16(d), move § 262.34(f) to § 262.16(e) and move § 262.34(m) to § 262.16(f). Paragraph (c) of § 262.16, which covers the mixing of hazardous waste, is a new paragraph that EPA is proposing to add in this rulemaking.¹²³ EPA is also proposing to add subtitles and eliminate several cross-references to 40 CFR part 265 in order to make the regulations easier to navigate.

a. *Addition of subtitles.* EPA is proposing to add subtitles to § 262.16 to

highlight to the reader the topic of each section or paragraph. Every subtitle is italicized after the regulatory citation. For example § 262.16(b)(2) addresses “*Accumulation in Containers.*”

b. *Incorporating 40 CFR part 265 subpart I, § 265.201, and part 265 subpart C into 40 CFR 262.16.* EPA is proposing to integrate three sections of 40 CFR part 265—subpart I, § 265.201 and subpart C—into § 262.16. First, at § 262.34(d)(2), the regulations state an SQG must comply with subpart I of part 265 except for §§ 265.176 and 265.178. Therefore, EPA is proposing to incorporate the text of the appropriate subpart I regulations at § 262.16(b)(2). Second, at § 262.34(d)(3) the regulation states that an SQG must comply with § 265.201 in subpart J when using a tank. Thus, EPA is proposing to incorporate the text of all of § 265.201 except for paragraph (a) at § 262.16(b)(3). Paragraph (a) of § 265.201 is not necessary because it describes what is already stated in § 262.16—the

requirements for an SQG accumulating hazardous waste in a tank for less than 180 days and accumulating no more than 6,000 kg on site at any time. Third § 262.34(d)(4) states an SQG must comply with subpart C of part 265. Therefore, EPA is proposing to incorporate the text of subpart C—Preparedness and Prevention—at § 262.16(b)(8).

c. *Other part 262 provisions for SQGs.* In addition, part 262 subpart L would contain the newly proposed standards for SQGs who episodically generate higher amounts of hazardous waste to maintain their designation as SQGs during these episodic events. Also, § 262.35 would include the landfill ban for liquids that applies to SQGs and LQGs.

Table 6—Crosswalk of Existing Citations to Proposed Citations for SQGs provides a summary of changes between the existing and proposed citations for SQGs.

TABLE 6—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR SQGS

Regulation	Existing citation	Proposed citation	Comment
Definition of Small Quantity Generator	§ 262.34(d)	§ 260.10	
Accumulation Time Limit	§ 262.34(d)	§ 262.16(b)	
Accumulation Limit	§ 262.34(d)(1) and (f)	§ 262.16(a) and (e)	
Accumulation in Containers	§ 262.34(d)(2) references part 265 subpart I.	§ 262.16(b)(2)	
Accumulation in Tanks	§ 262.34(d)(3) references part 265 subpart J.	§ 262.16(b)(3)	
Marking of Tanks and Containers	§ 262.34(d)(4) references § 262.34(a)(2) and (3).	§ 262.16(b)(6)	
Preparedness and Prevention	§ 262.34(d)(4) references part 265 subpart C and § 262.34(d)(5).	§ 262.16(b)(8) and (9)	
Land Disposal Restrictions	§ 262.34(d)(4) references part 268.	§ 262.16(b)(7)	

¹²² The portions of § 262.34(d) that state what the generation limits are for this category of generator

would be moved to the definition of “small quantity generator” in § 262.10.

¹²³ For a detailed discussion of this proposed addition please see section VII.B of this preamble.

TABLE 6—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR SQGs—Continued

Regulation	Existing citation	Proposed citation	Comment
Transporting Over 200 Miles	§ 262.34(e)	§ 262.16(d)	Proposed new provision.
Accumulation Time Limit Extension	§ 262.34(f)	§ 262.16(e)	
Episodic Generation	N/A	Part 262 subpart L	
Landfill Ban for Liquids	§ 258.28	§ 262.35	

3. Conditions for Exemption for an LQG Accumulating Hazardous Waste (40 CFR 262.17)

As previously mentioned the Agency is proposing to create 40 CFR 262.17 titled, “Conditions for exemption for a large quantity generator that accumulates hazardous waste.” The Agency is proposing to move § 262.34(a), (b), (g) through (i) and (m) into § 262.17. Specifically, the Agency is proposing to move § 262.34(a) to § 262.17(a), move § 262.34(b) to § 262.17(b), move § 262.34(g) to § 262.17(c), move § 262.34(h) to § 262.17(d), move § 262.34(i) to § 262.17(e), and move § 262.34(m) to § 262.16(g). EPA is additionally proposing to delete paragraphs (j) through (l), which deal with Performance Track, since the program is no longer in operation.¹²⁴ Paragraph (f) of § 262.17, which deals with the mixing of hazardous waste, is a new paragraph being proposed in this rulemaking.¹²⁵ EPA is also proposing to add subtitles and eliminate some cross-references to part 265 in order to make the regulations easier to navigate.

a. Addition of subtitles. EPA is proposing to add subtitles to § 262.17 to highlight to the reader the central concept addressed by each section or paragraph. Every subtitle is italicized after the regulatory citation. For example § 262.17(a)(1) addresses “accumulation in containers.”

b. Incorporating 40 CFR part 265 subpart I into 40 CFR 262.17. EPA is proposing to incorporate the 40 CFR part 265 subpart I regulations, which are currently referenced at § 262.34(a)(1)(i), into the proposed § 262.17(a)(1). EPA also considered incorporating the text of other subparts of part 265 that contain technical standards for LQGs and that are currently referenced in § 262.34 into the new section § 262.17 (*i.e.*, part 265 subparts J, W, AA, BB, and CC), but ultimately decided not to incorporate these due to the length of these subparts.

Section 262.35 would also include the landfill ban for liquids that applies to SQGs and LQGs. EPA requests comment on the proposed changes.

c. Emergency planning and procedures regulations for LQGs in part

265 subpart M. EPA is proposing to remove the reference to part 265 subparts C and D for the preparedness, prevention, and emergency procedure regulations for LQGs and instead incorporate those regulations in part 262 with the other generator regulations. However, due to the length of these subparts, rather than copying the text of these subparts to § 262.17, EPA is proposing to copy these into a new subpart M in part 262. EPA believes that including these provisions in part 262, along with the rest of the generator regulations, will make the regulations easier to navigate. EPA requests comment on this proposed change.

d. Other part 262 provisions for LQGs. In addition, § 262.17(g) would contain the newly proposed standards for LQGs who accept and consolidate hazardous waste from CESQGs. Also, § 262.35 would include the landfill ban for liquids that applies to SQGs and LQGs.

Table 7—Crosswalk of Existing Citations to Proposed Citations for LQGs provides a summary of changes between the existing and proposed citations for LQGs.

TABLE 7—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR LQGs

Regulation	Existing citation	Proposed citation	Comment
Definition of Large Quantity Generator	N/A	§ 260.10	There is still a cross-reference to part 265 subparts AA, BB, and CC because of the length of these regulations.
Accumulation Time Limit	§ 262.34(a)	§ 262.17(a)	
Accumulation in Containers	§ 262.34(a)(1)(i) references part 265 subparts I, AA, BB, and CC.	§ 262.17(a)(1) (§ 262.17(a)(1) also references part 265 subparts AA, BB, CC).	
Accumulation in Tanks	§ 262.34(a)(1)(ii) references part 265 subparts J, AA, BB, and CC.	§ 262.17(a)(2) references part 265 subparts J, AA, BB, CC.	There is still a reference to part 265 because of the length of these regulations.
Accumulation on Drip Pads	§ 262.34(a)(1)(iii) (§ 262.34(a)(1)(iii) also references part 265 subpart W).	§ 262.17(a)(3) (§ 262.17(a)(3) also references part 265 subpart W).	Recordkeeping provisions move to part 262.17 and the extensive technical standards remain in part 265.
Accumulation in Containment Buildings	§ 262.34(a)(1)(iv) (§ 262.34(a)(1)(iv) also references part 265 subpart DD).	§ 262.17(a)(4) (§ 262.17(a)(4) also references part 265 subpart DD).	Recordkeeping provisions move to part 262.17 and the extensive technical standards remain in part 265.
Marking and Labeling	§ 262.34(a)(2) and (3)	§ 262.17(a)(5)	

¹²⁴ For a detailed discussion of this proposed deletion please see section VIII.K of this preamble.

¹²⁵ For a detailed discussion of this proposed addition please see section VII.A.2 of this preamble.

TABLE 7—CROSSWALK OF EXISTING CITATIONS TO PROPOSED CITATIONS FOR LQGs—Continued

Regulation	Existing citation	Proposed citation	Comment
Preparedness, Prevention, and Emergency Procedures	§ 262.34(a)(4) references part 265 subparts C and D.	§ 262.17(a)(6) references part 262 subpart M.	Cross-references remain but to a subpart of the generator regulations.
Personnel Training	§ 262.34(a)(4)	§ 262.17(a)(7)	
Land Disposal Restrictions	§ 262.34(a)(4) references applicable parts of part 268.	§ 262.17(a)(6)(ii)	
Extension of Accumulation Times	§ 262.34(b)	§ 262.17(b)	
Accumulation of F006	§ 262.34(g) through (i)	§ 262.17(c) through (e)	
Accepting waste from CESQGs to consolidate before sending to TSDF.	N/A	§ 262.17(g)	Proposed new provision.
Rejected Loads	§ 262.34(m)	§ 262.17(h)	
Landfill Ban for Liquids	§ 258.28	§ 262.35	

EPA requests comment on the proposed reorganization to the hazardous waste generator regulations and, in particular, on whether the proposed changes would improve the user friendliness and utility of the regulations.

C. EPA Identification Number (40 CFR 262.12)

In the interest in keeping the generator regulations in a logical order, EPA is proposing to move existing § 262.12—EPA identification number—to § 262.18. Section 262.12 would then be reserved. EPA believes this will improve the flow of the hazardous waste generator regulations as it places the section addressing EPA identification number after § 262.13, which addresses how a generator determines its generator category. This proposed sequence is appropriate because a hazardous waste generator must first determine what generator category it belongs to in order to determine which regulations—including the requirement to obtain an EPA ID number—it must comply with. (For example, SQGs and LQGs must obtain an EPA identification number, but a CESQG does not).

EPA is requesting comment on these proposed changes.

XIV. Technical Corrections and Conforming Changes to 40 CFR Parts 260 through 265, 270, 273, and 279

The Agency is also proposing a number of technical corrections and conforming changes to the hazardous waste generator regulations. This proposed rule eliminates the regulatory text for discontinued programs, identifies areas where conforming changes are necessary, updates existing regulatory text to account for new programs, improves the readability of certain paragraphs, and corrects typographical errors. Specifically, the Agency is proposing the following

changes, in order of the existing regulations:

(1) Revise § 260.3, which currently reads, “As used in parts 260 through 265 and 268 of this chapter.” This text fails to account for additional parts of the regulations that were promulgated after 1986, such as parts 266, 267, and 270 through 273. The Agency is proposing to revise this to read, “As used in parts 260 through 273 of this chapter.”

(2) Modify the definitions of “Treatability Study,” “Universal Waste Handler,” “Universal Waste Transporter” in § 260.10 to only capitalize the first word (e.g., “Universal”) in order to match the formatting in the rest of this section.

(3) Remove the closed parenthesis after “(e.g.)” from § 261.1(c)(6).

(4) Improve the readability of § 261.4(a)(7), which currently reads, “Spent sulfuric acid used to produce virgin sulfuric acid, unless it is accumulated speculatively as defined in § 261.1(c) of this chapter.” The Agency is proposing to revise the language to read “Spent sulfuric acid used to produce virgin sulfuric acid provided it is not accumulated speculatively as defined in § 261.1(c) of this chapter.”

(5) Make conforming changes to citations that reference § 261.5 to reflect EPA’s proposal to move these regulations. The citations where references to § 261.5 are to be revised include all the following: §§ 262.10(b), 262.10(l)(2), 262.201(b), 262.204(a), 262.210(b)(3), 262.210(d)(2), 262.211(e)(3), 262.213(a)(2), 262.213(a)(3), 262.213(b)(2), 262.216(b), 264.1(g)(1), 268.1(e)(1), 270.1(c)(2)(iii), and 279.10(b)(3). In § 261.33(e) and (f), EPA is proposing to altogether remove the references to §§ 261.5(e) and 261.5(a) and (g), respectively, because the quantity limits for hazardous wastes are contained in EPA’s proposed definitions for very small quantity

generator, small quantity generator, and large quantity generator.

(6) Replace the word “waste” with “water” in § 261.5(e)(2), which reads, “A total of 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water. . . .” Prior to 1985, the word “waste” was “water” and the Agency is unable to determine why this change occurred. (In the proposed reorganization, this language is moved to § 260.10 and is contained in the definitions of large quantity generator, small quantity generator and very small quantity generator.)

(7) Revise § 261.420 to clarify that the requirement in § 261.411(c) that all employees be familiar with proper waste handling and emergency procedures relevant to their responsibilities applies to facilities that generate or accumulate more than 6,000 kg of hazardous materials as well as to facilities that generate or accumulate less than that amount.

(8) Remove Notes 1 and 2 from § 262.10. Note 1 states that the provisions of § 262.34 are applicable to the on-site accumulation of hazardous waste by generators. Therefore, the provisions of § 262.34 only apply to owners or operators who are shipping hazardous waste which they generated at that facility. Note 2 states that a generator who treats, stores, or disposes of hazardous waste on site must comply with the applicable standards and permit requirements set forth in 40 CFR parts 264, 265, 266, 268, and 270. These notes are no longer necessary should EPA finalize the changes in this proposed rule, which include replacing § 262.34 with a new reorganization of the regulations that address Note 1 and proposing regulations in § 262.10 that address Note 2.

(9) Remove the extra period in the last line of the paragraph at § 262.10(l).

(10) Make conforming changes to sections that reference § 262.34 to reflect EPA's proposal to move these regulations. The citations where references to § 262.34 are to be revised include the following: §§ 262.10(l)(1), 262.201(a), 262.201(a), 262.216(a), 264.1(g)(3), 264.71(c), 264.1030(b)(2), 264.1050(b)(2), 265.1(c)(7), 265.71(c), 265.1030(b)(2) and (b)(3), 268.7(a)(5) and 270.1(c)(2)(i).

(11) Make conforming change to remove and reserve § 262.40(c) because this section (regarding records for waste determinations) is proposed to move to § 262.11.

(12) Correct the statutory citation at § 262.43 that currently refers to sections 2002(a) and 3002(6) of the Act. The reference to 3002(6) should be to 3002(a)(6). Additionally, the word "he" is removed in order to be gender neutral.

(13) Remove references to Project XL programs that have been discontinued. These include the New York State Public Utilities Project XL program at subpart I of 40 CFR part 262 and the University Laboratories Project XL program at subpart J of 40 CFR part 262. We have also removed and reserved the reference at § 262.10(j) to the University Laboratories Project XL.

(14) Make two conforming changes to the definition of "central accumulation area" in § 262.200 in subpart K. We are proposing to move this definition from this location to § 260.10 with the following revisions. First, because of the reorganization of the regulations in 40 CFR part 262, we are proposing to change the references to the applicable regulations for the central accumulation areas that are used in the definition of central accumulation area in § 262.200. For LQGs, we are proposing that the reference to § 262.34(a) be changed to § 262.17 and for SQGs, we are proposing that the reference to § 262.34(d) through (f) be changed to § 262.16. Second, we are proposing to remove the reference to Performance Track in the definition of "central accumulation area" in § 262.200 of subpart K because the Performance Track program has been terminated (74 FR 22741; May 14, 2009). Both of these conforming changes are reflected in the proposed definition of "central accumulation area" being added in § 260.10.

(15) Make conforming changes to citations that use the term "conditionally exempt small quantity generator" to reflect EPA's proposed change to the term "very small quantity generator." The citations where "conditionally exempt small quantity generator" is to be replaced with "very small quantity generator" include:

§§ 262.200, 262.201(b), 262.202(b), 262.203(a), 262.203(b)(2), 262.204(a), 262.209(b), 262.210(d)(2), 262.213(a)(3), 268.1(e)(1), 270.1(c)(2)(iii), 273.8, 273.8(a)(2), 273.81(b), 279.10(b)(3).

(16) Improve the readability of § 264.170, which currently reads, "The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store containers of hazardous waste. . . ." The Agency is proposing to revise this language to read, "The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store hazardous waste in containers. . . ."

(17) Improve the readability of the first sentence in § 264.191(a), which currently reads, "For each existing tank system. . . . the owner or operator must determine that the tank system is not leaking or is unfit for use." The Agency is proposing to revise this language to read, "For each existing tank system . . . the owner or operator must determine that the tank system is not leaking or is fit for use."

(18) Improve the readability of § 265.1(c)(7), which currently reads, "A generator accumulating waste on-site in compliance with § 262.34 of this chapter, except to the extent the requirements are included in § 262.34 of this chapter." The Agency is proposing to revise the sentence to read, "A generator accumulating waste on site except to the extent the requirements are included in §§ 262.16, and 262.17 of this chapter."

(19) Correct the list of **Federal Register** notices in § 265.54 to be consistent with the list of references in § 264.54. The reference to 53 FR 37935, September 28, 1988, is missing from § 265.54.

(20) Add to § 265.111(c) a missing regulatory citation to § 265.445 applicable to drip pads. Section 265.111(c) would then read, "Complies with the closure requirements of this subpart, including, but not limited to, the requirements of §§ 265.197, 265.228, 265.258, 265.280, 265.310, 265.351, 265.381, 265.404, 265.445, and 265.1102."

(21) Add to § 265.114 a missing regulatory citation to § 265.445 applicable to drip pads and § 265.1102 applicable to containment buildings. Section 265.114 would then read, "During the partial and final closure periods, all contaminated equipment, structures and soil must be properly disposed of, or decontaminated unless specified otherwise in § 265.197, 265.228, 265.445, 265.258, 265.280, 265.310 or 265.1102. . . ."

(22) Make a conforming change to remove and reserve § 265.201 (Special

requirements for generators of between 100 and 1,000 kg/mo that accumulate hazardous waste in tanks). EPA is proposing to move this section into proposed § 262.16.

(23) Add a missing reference to 40 CFR part 268 in § 270.1(a)(3), which currently reads, "The RCRA permit program. . . . in 40 CFR parts 264, 266, and 267." Therefore, the Agency is revising this to read, "The RCRA permit program . . . in 40 CFR parts 264, 266, 267, and 268."

XV. Request for Comment on Use of Electronic Tools to Streamline Hazardous Waste Reporting and Recordkeeping Requirements

As part of this proposed rule, the Agency is also exploring the feasibility of using electronic tools to streamline hazardous waste reporting and recordkeeping requirements. Two examples previously discussed include requesting comment on an electronic hazardous waste determination decision tool and development of an electronic application containing information from the executive summaries of contingency plans that emergency responders can use in responding to an emergency.

Information technology can be an important step toward improving RCRA implementation. Many aspects of our lives can currently be managed electronically. We bank from home, send pictures from phones, and track packages across the country from our desks. Yet, much of the information reported to EPA and states by generators is still submitted on paper, which requires government staff or contractors to manually enter the data into federal and state data systems. Delays in data processing can cause important information to go unnoticed. In addition, errors introduced through manual data entry can require aggravating and time-consuming correction processes by both regulated entities and the government.

Use of electronic tools can provide the regulated community, regulators, and the public with more accurate, complete, and timely information on regulated activities, pollution, and compliance. Software that allows for self-correction by flagging potential errors, as is done by EPA's Toxics Release Inventory—Made Easy web tool or the Greenhouse Gas Reporting system, can even help prevent mistakes before they happen, saving both regulated entities and regulators time and money. Electronic reporting also creates greater transparency as greater information accessibility can inspire better compliance by facilities.

Electronic reporting, in this context, is not simply emailing files to the government. Rather, it would be a system that begins with an electronic “smart” form or web tool to guide the regulated entity thru recordkeeping and reporting processes, such as waste determinations. The system would also include data standards, identity proofing, and a government database to receive data. Error prevention and compliance assistance could be integrated into the reporting tool. For example, forms can be configured to self-populate with data from prior forms (e.g., names and addresses), to question entries that appear erroneous (e.g., entries an order of magnitude or more above or below data from prior years or above or below reasonable levels) and to prevent submission before required data fields are completed.

The Agency believes electronic tools have the potential to greatly assist generators in complying with the existing and proposed hazardous waste regulations. For example, EPA believes that electronic tools could help generators make more accurate hazardous waste determinations. As previously discussed, an app could be used as a decision support tool to help guide generators through the hazardous waste determination process for each waste stream they generate. This tool could walk generators through a series of question and answer steps, identify relevant sources in making the determination, electronically generate and store all of the associated data and records that generators may be required to maintain, and provide assistance on proper management of the identified wastes.

Other examples include using electronic tools to file notifications required under the rule, such as notifications for episodic generators, for LQGs that desire to take advantage of consolidating waste from CESQGs that are within the same company, and for generators that close a unit that accumulated hazardous waste. In this case, the electronic tools could be useful in submitting required reports, and in electronically generating, storing, and filing all reports.

Other areas of the RCRA regulations where electronic tools may assist with compliance include the following:

- Determining monthly generator category;
- Maintaining records of shipments;
- Maintaining contingency planning and emergency procedures recordkeeping and reporting requirements;
- Maintaining inventory logs for documenting accumulation time in

tanks, drip pads, and containment buildings; and

- Maintaining personnel training documents and records.

EPA believes the use of electronic tools would help hazardous waste generators improve and maintain compliance with the RCRA regulations, thereby reducing violations and increasing environmental benefits. EPA also believes the costs of receiving and evaluating reports from generators could be greatly reduced for EPA and state/tribal agencies. For example, when the Toxics Release inventory switched from paper reporting to e-reporting, costs of managing the data went down by 99% and accuracy was increased.

EPA is not aware of any existing electronic tools that would specifically assist generators with meeting the RCRA regulatory requirements. However, EPA did identify a variety of state and academic internet-based hazardous waste determination tools and workbooks (as discussed in section VIII.B.8.).

EPA is considering a range of electronic reporting options. The Agency may explore developing certain tools for use by the regulated community or may invite third-party vendors to provide such tools. The latter option could be similar to the Internal Revenue Service (IRS) model for electronic tax preparation. The IRS model uses third-party software providers for tax data collection and transmission (e.g., TurboTax, TaxACT, or others) from private citizens and businesses. Under this option, the Agency would not purchase services from any provider. All financial transactions would be between the providers and members of the regulated community. EPA would specify the required data for collection and the requirements necessary for exchanging data (e.g., data delivery protocols, standards, guidelines, and procedures compliant with EPA’s Cross-Media Electronic Reporting Regulation (CROMERR) (see 40 CFR part 3)).

EPA welcomes public comment on specific reports and data types that could be reported electronically if the Agency were to move forward with exploring electronic reporting, including what the quality assurance and quality control procedures should be with respect to data timeliness, accuracy, completeness, and consistency. EPA also asks for comment on which reports commenters think should be highest priority for electronic reporting. EPA solicits comment on the option of allowing software vendors to offer their clients federal electronic

reporting services compliant with the final rule and on potential methods for determining whether third-party software vendors meet the minimum federal electronic data requirements. EPA would need to certify or approve the methods used by the software to authenticate, encrypt, and possibly send compliance monitoring and other data. EPA would also like to hear from authorized RCRA programs that have experience in implementing electronic reporting, especially their experience with phasing in implementation. EPA also requests comment on whether electronic tools should be provided by EPA and/or states and tribes.

XVI. Enforceability

Persons that generate hazardous waste must comply with all the applicable independent requirements of the RCRA hazardous waste regulations, unless they obtain a conditional exemption from those requirements, provided by § 262.14 (formerly § 261.5), or by § 262.15, 262.16, or 262.17 (formerly all contained in § 262.34), or by § 262.70. If a person violates independent requirements or fails conditions for exemption, EPA may bring an enforcement action under section 3008 of RCRA for violations of the independent requirements. Where a generator does not comply with conditions for an exemption and is therefore no longer exempt, the enforcement action will allege violations of those independent requirements from which the generator was attempting to remain exempt. States may choose to enforce against violations of state hazardous waste requirements under state authorities.

As with any violation, EPA and authorized states have enforcement mechanisms available that range in severity. In addition, EPA and authorized states have flexibility in applying these mechanisms to the various responsible parties as appropriate to the specific circumstances. Some of the enforcement mechanisms include sending a notice of violation, ordering compliance, ordering that the operations cease, or assessing penalties as appropriate. Nothing in this proposal affects any of these enforcement mechanisms EPA or the states may utilize nor the manner in which enforcement cases will be initiated or pursued.

XVII. State Authorization

A. Applicability of Rules in Authorized States

Under section 3006 of RCRA, EPA may authorize states to administer the

RCRA Subtitle C hazardous waste program. Following authorization, the authorized state program operates in lieu of the federal regulations. EPA retains enforcement authority to enforce the authorized state Subtitle C program, although authorized states have primary enforcement authority. EPA also retains its authority under RCRA sections 3007, 3008, 3013, and 7003. The standards and requirements for state authorizations are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a state with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the federal program in that state. EPA did not issue permits for any facilities in that state, since the state was now authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the state was obligated to enact equivalent authorities within specified time frames. However, the new requirements did not take effect in an authorized state until the state adopted the equivalent state requirements.

In contrast, under RCRA section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized states at the same time that they take effect in unauthorized states. While states must still adopt HSWA related provisions as state law to retain authorization, EPA implements the HSWA provisions in authorized states, including the issuance of any permits pertaining to HSWA requirements, until the state is granted authorization to do so.

Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements.¹²⁶ RCRA section 3009 allows the states to impose standards more stringent than those in the federal program (see 40 CFR 271.1). Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization of Proposed Rule

This notice proposes regulations that amend certain sections of the hazardous

waste generator regulations in 40 CFR parts 260 through 265, 268, 270, 273, and 279. These regulations were promulgated under the authority of sections 2002, 3001, 3002, 3003, 3004, 3007, and 3010 of RCRA). This notice proposes changes to the RCRA Subtitle C program under non-HSWA authority.

Thus, the standards, if finalized, would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. Moreover, authorized states are required to modify their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. For those changes that are less stringent, states are not required to modify their programs. This is a result of section 3009 of RCRA, which allows states to impose more stringent regulations than the federal program.

Several of the revisions to the proposed hazardous waste generator regulations are more stringent than those promulgated in various rules that went into effect when the RCRA hazardous waste Regulations were first initiated (e.g., 1980–1986). These include the following: (1) requiring both SQGs and LQGs to document their non-hazardous waste determinations when they have generated a solid waste (section VIII.B of this preamble); (2) requiring SQGs to re-notify every two years if they have not done so otherwise through an alternative process (section VIII.C of this preamble); (3) requiring SQGs and LQGs to better define the contents and associated risks of hazardous wastes accumulated in tanks, containers, drip pads, and containment buildings, as well as when hazardous waste is accumulated in satellite accumulation areas (sections VII.E., VIII.F and VIII.I of this preamble); (4) requiring LQGs to notify EPA or their authorized state when they plan to close either a hazardous waste accumulation unit or their generator site (section VIII.G of this preamble); (5) requiring new LQGs to prepare an executive summary of their contingency plans to assist responders in an emergency (section VIII.H of this preamble); (6) requiring LQGs to submit a biennial report that identifies all of the hazardous wastes generated in the calendar year, not just for the months the facility was an LQG (sections VIII.L of this preamble); (7) requiring transfer facilities to identify the contents and associated risks of containers that have been consolidated with other hazardous wastes (section X of this preamble); and (8) promulgating prohibitions on storage of restricted wastes (section XII of this

preamble). Therefore, states that have adopted the base RCRA program would be required to modify their hazardous waste programs to incorporate equivalent provisions if these standards are finalized.

On the other hand, three of the proposed revisions would be considered less stringent than the current hazardous waste regulations. These revisions include the following: (1) Allowing CESQGs to voluntarily send hazardous waste to LQGs under the control of the same person to facilitate the cost-effective management of hazardous wastes within the same company (section VII.C of this preamble); (2) allowing CESQGs and SQGs to voluntarily maintain their existing regulatory status if they have an episodic event that generates additional amounts of hazardous waste which would have resulted in them moving into a higher generator category for a short period of time, so long as they comply with specified conditions (section IX of this preamble); and (3) allowing LQGs to voluntarily apply for a waiver from their local fire department to accumulate ignitable and reactive wastes within the 50 foot facility boundary provision (section XI.B of this preamble). Thus, authorized states may, but would not be required to, adopt these changes.

This proposed rule also includes several revisions that are neither more nor less stringent, such as (1) mixing a non-hazardous waste with a hazardous waste (section VII.B of this preamble); (2) defining central accumulation area (section VI.C of this preamble); (3) prohibiting generators from sending hazardous liquids to landfills (section VIII.M of this preamble); (4) reorganizing the hazardous waste generator regulations to make them more user-friendly (section XIII of this preamble); (5) deleting the performance track regulations (section VIII.K of this preamble); (6) replacing the list of specific data elements with a requirement to complete and submit all data elements required in the biennial report form (section VIII.L of this preamble); and (7) technical corrections and conforming changes to various parts of the RCRA regulations (section XIV of this preamble). Thus, authorized states may, but would not be required to, adopt these changes.

¹²⁶ EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes state programs.

XVIII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is a “significant regulatory action” in that it may raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action.

In addition, EPA prepared an analysis of the potential costs and benefits associated with this action. This analysis is contained in EPA’s Regulatory Impact Analysis (RIA) document titled “Assessment of the Potential Costs, Benefits, and other Impacts of the Improvements to the Hazardous Waste Generator Regulatory Program, As Proposed.” A copy of the analysis is available in the docket for this action and the analysis is briefly summarized here.

Based on the impact estimates presented in the RIA, EPA does not expect that this action will be “economically significant” because the estimated annualized cost for compliance with the proposed changes to the hazardous waste generator regulatory program is significantly less than the \$100 million annual effect threshold of Section 3(f)(1) of Executive Order 12866. The RIA estimates the affected universe is between 353,000 and 543,000 entities. Of this universe, between 293,000 and 469,000 CESQGs will only be affected if they choose to take advantage of two voluntary programs being proposed.

EPA estimates the future annualized cost to industry to comply with the requirements of this proposed action at between \$6.2 and \$17.4 million (at 7% discount rate). Similarly, the annualized net cost savings or benefits for facilities opting to take advantage of two voluntary programs in the rule (e.g., consolidation of CESQG waste by large quantity generators under the same ownership, and generators who would not be required to change generator status as a result of an episodic event) is between \$6.2 and \$12.2 million (at 7% discount rate) resulting in a net annualized cost of between \$0.1 million and \$5.2 million.

In addition to estimating the cost for this proposed rule, the RIA also provides both quantitative and qualitative (i.e., non-monetized) descriptions of future expected benefits for this action primarily consisting of improved industry environmental compliance.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2513.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

This proposed rule is necessary for EPA and authorized states to oversee the generation and management of hazardous waste. EPA is proposing the establishment of these information collection requirements under the authority of RCRA Subtitle C. There are several provisions to this rule that will require respondents to either submit information to EPA or authorized state, or maintain records at their facility. For example, generators will have to notify EPA or their authorized state they plan to take advantage of two voluntary provisions that will provide greater flexibility in how they manage hazardous waste (i.e., CESQG consolidation of their hazardous waste by a LQG under the same person or company; and episodic generation of hazardous waste resulting in a temporary change in regulatory status).

Similarly, SQGs will have to re-notify EPA or their authorized state every other year that they have not changed their regulatory category to support effective inspections and program management activities. In an effort to improve program compliance, both SQGs and LQGs will be required to maintain records supporting the basis for their non-hazardous waste determinations (i.e., a generator generated a solid waste but not a hazardous waste). Similarly, new LQGs will be required to develop and submit an executive summary of their emergency response plan to their Local Emergency Planning Committee to effectively assist emergency responders responding to an emergency.

EPA and state agencies will use the collected information to ensure that hazardous wastes are managed in a cost-effective manner that minimizes risks to human health and the environment. Local emergency response organizations will also use the collected information to prepare contingency plans to reduce

risks to emergency responders and bystanders. EPA does not expect confidentiality to be an issue in generators either providing information to EPA or an authorized state or in maintaining the necessary records supporting a non-hazardous waste determination. The statutory authority to collect the proposed information is found at RCRA 3002 (42 U.S.C. 6922) and RCRA 3003 (42 U.S.C. 6923).

Respondents/Affected Entities: Private sector.

Respondent’s Obligation to Respond: Mandatory per RCRA 3002 (42 U.S.C. 6922) and RCRA 3003 (42 U.S.C. 6923).

Estimated Number of Respondents: 96,375

Frequency of Response: On occasion.

Total Estimated Burden: 304,318 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total Estimated Cost: \$16.8 million (per year), includes \$3.9 million annualized capital or operation & maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA’s regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency’s need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB’s Office of Information and Regulatory Affairs via email to oria_submissions@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October 26, 2015. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities directly regulated by this proposed rule include entities that generate hazardous waste across various industries, including, but not limited to, printing, petroleum refining, chemical manufacturing, plastics and resin manufacturing, pharmaceutical manufacturing, paint and coating, iron and steel mills, metal and metal product manufacturing, electroplating, printed circuit board manufacturing, semiconductor manufacturing, motor

vehicle parts manufacturing, research and development, hazardous waste treatment and disposal, academic institutions, and hospitals. We have determined that between 25,550 and 33,800 small entities impacted will experience an impact of less than 1% of annual sales for all affected small entities.

Although this proposed rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. Many of the changes in this proposed rulemaking come from outreach efforts to generators of hazardous waste, including small entities, and are designed to make the generator regulations more accessible and user friendly. As part of the proposal, EPA is including several provisions that would provide increased flexibility for small entities in managing hazardous waste, such as the ability for hazardous waste generators to use the episodic generator provisions if they have a distinct event that would otherwise cause them to have to bump up to a higher generator category. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act

This proposed rule does not contain an unfunded mandate of \$100 million as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The RIA estimates that the state government share of future average annualized direct costs for the proposed rule requirements to range between \$1.2 million and \$2.3 million per year. Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. The rulemaking proposes clarifications and modifications to the hazardous waste generator regulations, which impacts only those entities that generate hazardous waste. Small governments would only be subject to the changes in the proposed rule if they generated hazardous waste subject to the RCRA hazardous waste requirements.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national

government and the states, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132. The proposed rule simply proposes clarifications and modifications to the existing hazardous waste generator regulations. Thus, Executive Order 13132 does not apply to this action. Although section 6 of Executive Order 13132 does not apply to this action, EPA did consult with state officials in developing this action.

F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. Under the RCRA statute, the federal government implements hazardous waste regulations directly in Indian Country. Thus, the proposed changes to the hazardous waste regulations would not impose any direct costs on tribal governments.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this action.

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this action.

G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks

This action is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. The Agency does not believe that this action presents risks to the public. In fact, there are several components to this proposed rule that modify the existing hazardous waste generator regulations to enhance environmental protection in the local community. Examples include (1) requiring LQGs and SQGs to document and maintain records of their waste determinations, including determinations that a solid waste is a non-hazardous waste; (2) requiring

LQGs and SQGs to provide more detailed marking and labeling information for containers, tanks, drip pads, and containment buildings accumulating hazardous wastes; (3) requiring LQGs to notify EPA or an authorized state when they plan to close either a hazardous waste accumulation unit or their site; (4) requiring LQGs and SQGs to re-notify EPA or the authorized state on a periodic basis of their hazardous waste generator activities; and (5) improving emergency preparedness and response regulations on the part of SQGs and LQGs.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This proposed rule does not involve the supply, distribution, or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629 (February 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this proposed rule increases the level of environmental protection for all affected populations and thus will not have disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations. Specifically, there are several components to this proposed rule that modify the existing hazardous waste generator regulations to assist generators in understanding and facilitating improved compliance with the hazardous waste regulations. Examples include modifying regulations regarding mixing of non-hazardous waste with a hazardous waste by a

generator, or when a hazardous waste generator generates both acute and non-acute hazardous waste in the same calendar month. Additionally, EPA is proposing to reorganize the hazardous waste generator rules to make them more user-friendly and therefore assist generators in understanding their responsibilities in managing the hazardous waste they generate safely, which support better environmental protection.

Still other components of this proposed rule enhance environmental protection in the local community, and therefore foster improved environmental protection, including for minority populations and low-income populations. They include, for example, (1) requiring LQGs and SQGs to document and maintain records of their waste determinations, including determinations that a solid waste is a non-hazardous waste; (2) requiring LQGs and SQGs to provide more detailed marking and labeling information for containers, tanks, drip pads, and containment buildings accumulating hazardous wastes; (3) requiring LQGs to notify EPA or an authorized state when they plan to close either a hazardous waste unit or their site; (4) requiring LQGs and SQGs to re-notify EPA or the authorized state on a periodic basis of their hazardous waste generator activities; and (5) improving emergency preparedness and response regulations on the part of SQGs and LQGs.

Furthermore, EPA is also proposing to allow CESQGs to ship their hazardous waste to an LQG under the control of the same person. As described in section VII.C of the preamble, this may increase environmental protection in the local community because hazardous waste generated by CESQGs would be subject to more stringent requirements upon receipt by the LQG, including ultimate management by a RCRA permitted TSD (as opposed to being managed possibly in a municipal solid waste landfill). Although this proposed change could result in an increase in traffic for certain communities, EPA believes the increase would not be significant given that CESQGs currently may send their hazardous waste to a number of destinations, including municipal and non-municipal solid waste management facilities.

Lastly, EPA is proposing alternative standards for CESQGs and SQGs that would allow these entities to maintain their generator category if generating hazardous waste from an episodic event. Although these generators would be allowed to temporarily manage a greater amount of hazardous waste than their

normal generator category allows, EPA is proposing conditions under which the hazardous waste generated from an episodic event must be managed in order to maintain protection of human health and the environment. Therefore, EPA does not anticipate disproportionately high and adverse human health or environmental effects on minority, low-income or indigenous populations from these proposed alternative standards.

List of Subjects

40 CFR Part 260

Environmental protection, Administrative practice and procedure, Confidential business information, Incorporation by reference, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 261

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Incorporation by reference, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 263

Environmental protection, Hazardous materials transportation, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 264

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds.

40 CFR Part 265

Environmental protection, Air pollution control, Hazardous waste, Insurance, Packaging and containers, Reporting and recordkeeping requirements, Security measures, Surety bonds, Water supply.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 270

Environmental protection, Administrative practice and procedure, Confidential business information, Hazardous materials transportation, Hazardous waste, Reporting and

recordkeeping requirements, Water pollution control, Water supply.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

40 CFR Part 279

Environmental protection, Petroleum, Recycling, Reporting and recordkeeping requirements.

Dated: August 31, 2015.

Gina McCarthy,
Administrator.

For the reasons set out in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 260—HAZARDOUS WASTE MANAGEMENT SYSTEM: GENERAL

■ 1. The authority citation for part 260 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921–6927, 6930, 6934, 6935, 6937, 6938, 6939, and 6974.

■ 2. Section 260.3 is amended by revising the introductory paragraph to read as follows:

§ 260.3 Use of number and gender.

As used in parts 260 through 273 of this chapter:

* * * * *

■ 3. Amend § 260.10 by:

- a. Adding in alphabetical order the definitions of “Acute hazardous waste”, “Central accumulation area”, “Large quantity generator”, “Non-acute hazardous waste”;
- b. Removing the definition for “Performance Track member facility”;
- c. Revising the definition of “Small quantity generator”;
- d. Revising the heading of the definition “Treatability Study” to read “Treatability study”;
- e. Revising the heading of the definition “Universal Waste Handler” to read “Universal waste handler”; and
- f. Revising the heading of the definition “Universal Waste Transporter” to read “Universal waste transporter”; and
- g. Adding in alphabetical order the definition of “Very small quantity generator”.

The revisions and additions read as follows:

§ 260.10 Definitions.

* * * * *

Acute hazardous waste means hazardous wastes that meet the listing criteria in § 261.11(a)(2) and therefore are either listed in § 261.31 of this chapter with the assigned hazard code

of (H) or are listed in § 261.33(e) of this chapter.

* * * * *

Central accumulation area means any on-site hazardous waste accumulation area with hazardous waste accumulating in units subject to either § 262.16 (for small quantity generators) or § 262.17 (for large quantity generators). A central accumulation area at an eligible academic entity that chooses to be subject to part 262 subpart K must also comply with § 262.211 when accumulating unwanted material and/or hazardous waste.

* * * * *

Large quantity generator is a generator who generates any of the following amounts in a calendar month:

- (1) Greater than or equal to 1000 kilograms (2200 lbs) of non-acute hazardous waste;
- (2) Greater than 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter; or
- (3) Greater than 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

Non-acute hazardous waste means all hazardous wastes that are not acute hazardous waste, as defined in this section.

* * * * *

Small quantity generator is a generator who generates the following amounts in a calendar month:

- (1) Greater than 100 kilograms (220 lbs) but less than 1000 kilograms (2200 lbs) of non-acute hazardous waste;
- (2) Less than or equal to 1 kilogram (2.2 lbs) of acute hazardous waste listed in §§ 261.31 or § 261.33(e) of this chapter; and
- (3) Less than or equal to 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

Very small quantity generator is a generator who generates less than or equal to the following amounts in a calendar month:

- (1) 100 kilograms (220 lbs) of non-acute hazardous waste; and
- (2) 1 kilogram (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter; and
- (3) 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup

of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter.

* * * * *

■ 4. Section 260.11 is amended by revising the section heading and paragraph (d)(1) to read as follows:

§ 260.11 Incorporation by reference.

* * * * *

(d) * * *

(1) “Flammable and Combustible Liquids Code” (1977 or 1981), IBR approved for §§ 262.16, 264.198, 265.198, 267.202(b).

* * * * *

PART 261— IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 5. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y), and 6938.

§ 261.1 [Amended]

■ 6. Section 261.1, paragraph (c)(6) is amended by removing “(e.g.)” and inserting “(e.g.,” in its place.

■ 7. Section 261.4 is amended by revising paragraph (a)(7) to read as follows:

§ 261.4 Exclusions.

(a) * * *

(7) Spent sulfuric acid used to produce virgin sulfuric acid provided it is not accumulated speculatively as defined in § 261.1(c) of this chapter.

* * * * *

§ 261.5 [Removed and reserved]

■ 8. Remove and reserve § 261.5.

■ 9. Section 261.6 is amended by adding paragraph (c)(2)(iv) to read as follows:

§ 261.6 Requirements for recyclable materials.

* * * * *

(c) * * *

(2) * * *

(iv) Section 265.75 of this chapter (biennial reporting requirements).

* * * * *

■ 10. Section 261.33 is amended by revising paragraphs (e) introductory text and (f) introductory text to read as follows:

§ 261.33 Discarded commercial chemical products, off-specification species, container residues, and spill residues thereof.

* * * * *

(e) The commercial chemical products, manufacturing chemical intermediates or off-specification commercial chemical products or manufacturing chemical intermediates referred to in paragraphs (a) through (d)

of this section, are identified as acute hazardous wastes (H).

* * * * *

(f) The commercial chemical products, manufacturing chemical intermediates, or off-specification commercial chemical products referred to in paragraphs (a) through (d) of this section, are identified as toxic wastes (T).

* * * * *

■ 11. Section 261.420 is amended by adding paragraph (g) to read as follows:

§ 261.420 Contingency planning and emergency procedures for facilities generating or accumulating more than 6000 kg of hazardous secondary material.

* * * * *

(g) *Personnel training.* All employees must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 12. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

Subpart A—General

■ 13. Section 262.1 is added to read as follows:

§ 262.1 Terms used in this part.

As used in this part:
Independent requirement means a requirement of part 262 that states an event, action, or standard that must occur or be met; and that applies without relation to, or irrespective of, the purpose of obtaining a conditional exemption from a permit or having interim status under §§ 262.14, 262.15, 262.16, or 262.17.

Condition for exemption means any requirement in §§ 262.14, 262.15, 262.16, or 262.17, that states an event, action, or standard that must occur or be met in order to obtain a conditional exemption from any requirement in parts 124, 262 through 268, or 270, or from any requirement for notification under section 3010 of RCRA.

- 14. Section 262.10 is amended by:
 - a. Revising paragraphs (a) and (b);
 - b. Removing and reserving paragraph (c);
 - c. Revising paragraph (g);
 - d. Removing and reserving paragraphs (j);
 - e. Revising paragraph (l); and
 - f. Removing Notes 1 and 2.

The revisions and additions read as follows:

§ 262.10 Purpose, scope, and applicability.

(a) The regulations in this part establish standards for generators of hazardous waste as defined by 40 CFR 260.10.

(1) A person who generates a hazardous waste as defined by 40 CFR part 261 is subject to all the applicable independent requirements in the subparts and sections listed below, unless the person is a very small quantity generator that meets the conditions for exemption in § 262.14.

(i) *Independent requirements of a small quantity generator.* (A) Section 262.11 Hazardous waste determination and recordkeeping;

(B) Section 262.13 Generator category determination;

(C) Section 262.18 EPA identification numbers and re-notification for large quantity generators and small quantity generators;

(D) Part 262 subpart B—The manifest;

(E) Part 262 subpart C—Pre-transport requirements;

(F) Section 262.40 Recordkeeping;

(G) Section 262.44 Special independent requirements for small quantity generators;

(H) Part 262 subpart E—subpart F—Imports and exports of hazardous waste;

(I) Part 262 subpart G—Farmers; and

(J) Part 262 subpart H—Transfrontier shipments of hazardous waste for recovery within the OECD.

(ii) *Independent requirements of a large quantity generator.* (A) Section 262.11 Hazardous waste determination and recordkeeping;

(B) Section 262.13 Generator category determination;

(C) Section 262.18 EPA identification numbers and re-notification for large quantity generators and small quantity generators;

(D) Part 262 subpart B—The manifest;

(E) Part 262 subpart C—Pre-transport requirements;

(F) Part 262 subpart D—Recordkeeping and reporting, except § 262.44;

(G) Part 262 subpart E—subpart F—Imports and exports of hazardous waste;

(H) Part 262 subpart G—Farmers; and

(I) Part 262 subpart H—Transfrontier shipments of hazardous waste for recovery within the OECD.

(2) A generator that accumulates hazardous waste on site is a facility that stores hazardous waste and is subject to the applicable requirements of parts 124, 263 through 270, and section 3010 of RCRA, unless it is one of the following:

(i) A very small quantity generator that meets the conditions for exemption in § 262.14;

(ii) A small quantity generator that meets the conditions for exemption in §§ 262.15 and 262.16; or

(iii) A large quantity generator that meets the conditions for exemption in §§ 262.15 and 262.17.

(3) A generator shall not transport, offer its waste for transport, or otherwise cause its waste to be sent to a facility that is not a designated facility, as defined in § 260.10, or not otherwise authorized to receive the generator's waste.

(b) *Determining generator category.* A generator must use 40 CFR 262.13 to determine which provisions of this part are applicable to the generator based on the quantity of hazardous waste generated per calendar month.

* * * * *

(g)(1) A generator's violation of an applicable requirement in 40 CFR part 124, 262 through 268, or 270, or of applicable notification requirements of section 3010 of RCRA, is subject to penalty and injunctive relief under section 3008 of RCRA.

(2) A generator's noncompliance with a condition for exemption in this part is not subject to penalty or injunctive relief under section 3008 of RCRA as a violation of a 40 CFR part 262 condition for exemption. Noncompliance with a condition for exemption in this part results in failure to obtain, or to maintain, such exemption. Failure to obtain or maintain the exemption results in a violation of one or more applicable independent requirements in 40 CFR part 124, 262 through 268, or 270, or of the notification requirements of section 3010 of RCRA. A generator's violation of an independent requirement is subject to penalty and injunctive relief under section 3008 of RCRA.

* * * * *

(l) The laboratories owned by an eligible academic entity that chooses to be subject to the requirements of subpart K of this part are not subject to (for purposes of this paragraph, the terms "laboratory" and "eligible academic entity" shall have the meaning as defined in § 262.200 of subpart K of this part):

(1) The independent requirements of § 262.11 or the regulations in § 262.15 for large quantity generators and small quantity generators, except as provided in subpart K, and

(2) The conditions of § 262.14, for very small quantity generators, except as provided in subpart K.

■ 15. Revise § 262.11 and its section heading to read as follows:

§ 262.11 Hazardous waste determination and recordkeeping.

A person who generates a solid waste, as defined in 40 CFR 261.2, must make an accurate determination of whether that waste is a hazardous waste using the following steps:

(a) A hazardous waste determination for each solid waste must be made at the point of waste generation, before any dilution, mixing, or other alteration of the waste occurs, and at any time in the course of its management that it has, or may have, changed its properties as a result of exposure to the environment or other factors that may change the properties of the waste.

(b) A person must determine if the solid waste is excluded from regulation under 40 CFR 261.4.

(c) If the waste is not excluded under 40 CFR 261.4, the person must then use knowledge of the waste to determine if the waste meets any of the listing descriptions under subpart D of 40 CFR part 261. Acceptable knowledge that may be used in making an accurate determination as to whether the waste is listed includes, but is not limited to, waste origin, composition, the process producing the waste, feedstock, and other relevant information. If the waste is listed, the person may file a delisting petition under 40 CFR 260.20 and 260.22 to demonstrate to the Administrator that the waste from this particular site or operation is not a hazardous waste.

(d) If the waste is not listed in subpart D of 40 CFR part 261 or if it is a listed waste, which must meet the land disposal restrictions under 40 CFR part 268, the person then must also determine whether the waste exhibits one or more hazardous characteristics as identified in subpart C of 40 CFR part 261 by following the procedures in either paragraph (d)(1) or (2) of this section.

(1) The person must test the waste according to the methods set forth in subpart C of 40 CFR part 261 or according to an equivalent method approved by the Administrator under 40 CFR 260.21 and in accordance with the following:

(i) Persons testing their waste must obtain a representative sample of the waste for the testing, as defined at 40 CFR 260.10.

(ii) Where a test method is specified in the regulation, the results of the regulatory test, when properly performed, are definitive for determining the regulatory status of the waste.

(2) The person must apply knowledge of the hazard characteristic of the waste in light of the materials or the processes

used. Acceptable knowledge may include process knowledge (e.g., information about chemical feedstocks and other inputs to the production process); knowledge of products, by-products, and intermediates produced by the manufacturing process; chemical or physical characterization of wastes; information on the chemical and physical properties of the chemicals used or produced by the processor or otherwise contained in the waste; testing that illustrates the properties of the waste; or other reliable and relevant information about the properties of the waste or its constituents. A test other than a test method set forth in subpart C of 40 CFR part 261, or according to an equivalent method approved by the Administrator under 40 CFR 260.21, may be used as part of a person's knowledge to determine whether a solid waste exhibits a characteristic of hazardous waste. However, such tests do not, by themselves, provide definitive results.

(e) *Recordkeeping for small and large quantity generators.* A small or large quantity generator must maintain records supporting its solid and hazardous waste determinations, including records that identify a material as a solid waste, as defined by 40 CFR 261.2, and records identifying whether that solid waste is or is not also a hazardous waste, as defined by 40 CFR 261.3. Generators may wish to segregate any of their municipal solid waste from other solid and hazardous wastes to avoid potential co-mingling. Records must be maintained for at least three years from the date that the waste was last generated. These records must comprise the generator's knowledge of the waste and support the generator's determination, as described at 40 CFR

262.11(c) and (d). The records must include, but are not be limited to, the following types of information: The results of any tests, sampling, or waste analyses; records documenting the tests, sampling, and analytical methods used and demonstrating the validity and relevance of such tests; records consulted in order to determine the process by which the waste was generated, the composition of the waste, and the properties of the waste; and records which explain the knowledge basis for the generator's determination, as described at 40 CFR 262.11(d)(2). The periods of record retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity or as requested by the Administrator.

(f) If the waste is determined to be hazardous, all applicable EPA hazardous waste numbers (EPA hazardous waste codes) in subparts C and D of part 261 must be identified.

(g) If the waste is determined to be hazardous, the generator must refer to parts 261, 264, 265, 266, 267, 268, and 273 of this chapter for other possible exclusions or restrictions pertaining to management of the specific waste.

§ 262.12 [Removed and reserved]

- 16. Remove and reserve § 262.12.
- 17. Add §§ 262.13 through 262.18 to subpart A to read as follows:

- * * * * *
- Sec.
- 262.13 Generator category determination.
- 262.14 Conditions for exemption for a very small quantity generator.
- 262.15 Satellite accumulation area regulations for small and large quantity generators.
- 262.16 Conditions for exemption for a small quantity generator that accumulates hazardous waste.

262.17 Conditions for exemption for a large quantity generator that accumulates hazardous waste.

262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators.

§ 262.13 Generator category determination.

(a) *Monthly determination.* A generator's category is determined each month by the amount of hazardous waste it generates and may change from month to month. This section sets forth procedures to determine whether a generator is a very small quantity generator, a small quantity generator, or a large quantity generator for a particular month, as defined in § 260.10 of this chapter.

(b) *Generators of both acute and non-acute hazardous wastes.* A generator who generates both acute hazardous waste and non-acute hazardous waste in the same calendar month shall determine its generator category for that month by doing the following:

- (1) Counting separately the total amount of acute hazardous waste and the total amount of non-acute hazardous waste generated in the calendar month;
- (2) Subtracting from each total any amounts of waste exempt from counting as described in paragraphs (c) and (d) of this section;
- (3) Determining separately the resulting generator categories for the quantities of acute and non-acute hazardous waste generated; and
- (4) Comparing the resulting generator categories from paragraph (b)(3) of this section and applying the more stringent generator category to the accumulation and management of both non-acute hazardous waste and acute hazardous waste generated for that month.

TABLE 1 TO § 262.13—GENERATOR CATEGORIES BASED ON QUANTITY OF WASTE GENERATED IN A CALENDAR MONTH

#	Quantity of acute hazardous waste generated in a calendar month	Quantity of non-acute hazardous waste generated in a calendar month	Quantity of residues from a cleanup of acute hazardous waste generated in a calendar month	Generator category
1	> 1 kg	Any amount	Any amount	Large quantity generator.
2	Any amount	≥ 1,000 kg	Any amount	Large quantity generator.
3	Any amount	Any amount	> 100 kg	Large quantity generator.
4	≤ 1 kg	> 100 kg and < 1,000 kg	≤ 100 kg	Small quantity generator.
5	≤ 1 kg	≤ 100 kg	≤ 100 kg	Very small quantity generator.

(c) When making the monthly quantity-based determinations required by this part, the generator must include all hazardous waste that it generates, except hazardous waste that:

- (1) Is exempt from regulation under 40 CFR 261.4(c) through (f), 261.6(a)(3), 261.7(a)(1), or 261.8;

(2) Is managed immediately upon generation only in on-site elementary neutralization units, wastewater treatment units, or totally enclosed treatment facilities as defined in 40 CFR 260.10;

- (3) Is recycled, without prior storage or accumulation, only in an on-site

process subject to regulation under 40 CFR 261.6(c)(2);

(4) Is used oil managed under the requirements of 40 CFR 261.6(a)(4) and 40 CFR part 279;

- (5) Is spent lead-acid batteries managed under the requirements of 40 CFR part 266 subpart G;

(6) Is universal waste managed under 40 CFR 261.9 and 40 CFR part 273;

(7) Is a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261 subpart D or exhibiting one or more characteristics in 40 CFR part 261 subpart C) that is generated solely as a result of a laboratory clean-out conducted at an eligible academic entity pursuant to § 262.213. For purposes of this provision, the term eligible academic entity shall have the meaning as defined in § 262.200; or

(8) Is managed under an episodic event in compliance with the conditions of subpart L of this part.

(d) In determining the quantity of hazardous waste generated in a calendar month, a generator need not include:

(1) Hazardous waste when it is removed from on-site accumulation; or

(2) Hazardous waste generated by on-site treatment (including reclamation) of the generator's hazardous waste, so long as the hazardous waste that is treated was previously counted once; or

(3) Spent materials that are generated, reclaimed, and subsequently reused on site, so long as such spent materials have been previously counted once.

§ 262.14 Conditions for exemption for a very small quantity generator.

(a) Hazardous waste generated by a very small quantity generator is not subject to the independent requirements of this part, except the paragraphs of § 262.11 specified below or the requirements of parts 124, 264 through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA. A very small quantity generator may accumulate hazardous waste on site without a permit or interim status, and without complying with all the independent requirements of the above-mentioned parts and the notification requirements of section 3010, provided that it meets all the conditions for exemption listed in this section:

(1) In a calendar month the very small quantity generator generates less than or equal to the amounts specified in the definition of "very small quantity generator" in § 260.10 of this chapter;

(2) The very small quantity generator complies with § 262.11(a) through (d) of this chapter;

(3) *Accumulation conditions for exemption*—(i) *Acute hazardous waste.* If the very small quantity generator accumulates at any time greater than 1 kilogram (2.2 lbs) of acute hazardous waste or 100 kilograms (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water,

of any acute hazardous waste listed in §§ 261.31 or 261.33(e) of this chapter, all quantities of that acute hazardous waste are subject to full hazardous waste regulation under parts 124, 262 through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA. The 90-day accumulation time limit of § 262.17 begins on the date when the accumulated wastes exceed the above waste quantity limits;

(ii) *Non-acute hazardous waste.* If the very small quantity generator accumulates at any time 1,000 kilograms (2,200 lbs) or greater of non-acute hazardous waste, all quantities of that hazardous waste are subject to full hazardous waste regulation under parts 124, 262 through 268, and 270 of this chapter, and the notification requirements of section 3010 of RCRA. The 180-day and 270-day accumulation time limits of § 262.16 begin on the date when the accumulated wastes equal or exceed 1000 kilograms (2,200 lbs).

(4) A very small quantity generator that accumulates hazardous waste within the limits in paragraphs (a)(3)(i) and (ii) of this section must either treat or dispose of its hazardous waste in an on-site facility or ensure delivery to an off-site treatment, storage, or disposal facility, either of which, if located in the U.S., is:

(i) Permitted under part 270 of this chapter;

(ii) In interim status under parts 270 and 265 of this chapter;

(iii) Authorized to manage hazardous waste by a State with a hazardous waste management program approved under part 271 of this chapter;

(iv) Permitted, licensed, or registered by a state to manage municipal solid waste and, if managed in a municipal solid waste landfill is subject to part 258 of this chapter;

(v) Permitted, licensed, or registered by a state to manage non-municipal non-hazardous waste and, if managed in a non-municipal non-hazardous waste disposal unit, is subject to the requirements in §§ 257.5 through 257.30 of this chapter;

(vi) A facility which:

(A) Beneficially uses or reuses, or legitimately recycles or reclaims its waste; or

(B) Treats its waste prior to beneficial use or reuse, or legitimate recycling or reclamation;

(vii) For universal waste managed under part 273 of this chapter, a universal waste handler or destination facility subject to the requirements of part 273 of this chapter;

(viii) A large quantity generator under the control of the same person as the

very small quantity generator, provided the following conditions are met:

(A) The very small quantity generator and the large quantity generator are under the control of the same person as defined in § 260.10 of this chapter. "Control," for the purposes of this section, means the power to direct the policies of the generator site, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator sites on behalf of a different person as defined in § 260.10 of this chapter shall not be deemed to "control" such generator sites.

(B) The very small quantity generator marks its container(s) of hazardous waste with:

(1) The words "Very Small Quantity Generator Hazardous Waste";

(2) Other words that identify the contents of the containers (examples may include, but are not limited to, the name of the chemical(s), such as "acetone" or "methylene dichloride" or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D);

(3) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(4) The applicable EPA hazardous waste number(s) (hazardous waste codes) in part 261 subparts C and D.

(b) *Mixing hazardous waste with non-hazardous waste.* A very small quantity generator may mix listed or characteristic hazardous waste with non-hazardous waste and remain eligible for the conditional exemption applicable to a very small quantity generator provided that either paragraph (b)(1) or (2) of this section is met:

(1) The mixture does not exhibit any of the characteristics of hazardous waste

identified in subpart C of part 261 of this chapter; or

(2) If the mixture does exhibit one or more characteristics of a hazardous waste identified in subpart C of part 261 of this chapter, the mixture does not cause the generator to exceed the very small quantity generator calendar month quantity limits identified in the definition of very small quantity generator at § 260.10 of this chapter. If the mixture does exceed the quantity limit for a very small quantity generator, the very small quantity generator, to remain exempt from the permitting and interim status standards, must meet the conditions for exemption applicable to either a small quantity generator or large quantity generator according to the quantity of the hazardous waste it generated in a calendar month, including the resultant mixture and the total quantity the very small quantity generator accumulated on site.

(c) If a very small quantity generator's wastes are mixed with used oil, the mixture is subject to 40 CFR part 279. Any material produced from such a mixture by processing, blending, or other treatment is also regulated under 40 CFR part 279.

(d) The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids (whether or not sorbents have been added) in any landfill is prohibited.

(e) A very small quantity generator experiencing an episodic event may accumulate hazardous waste in accordance with subpart L of this part in lieu of §§ 262.15, 262.16, and 262.17.

§ 262.15 Satellite accumulation area regulations for small and large quantity generators.

(a) A generator may accumulate as much as 55 gallons of non-acute hazardous waste and/or one quart or 1 kg (2.2 lbs) of acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter in containers at or near any point of generation where wastes initially accumulate which is under the control of the operator of the process generating the waste, without a permit or interim status and without complying with § 262.16(b) or § 262.17(a) provided the generator complies with the following conditions for exemption:

(1) If a container holding hazardous waste is not in good condition, or if it begins to leak, the generator must transfer the hazardous waste from this container to a container that is in good condition and does not leak, or transfer and manage the waste in a central accumulation area.

(2) The generator must use a container made of or lined with materials that will

not react with, and are otherwise compatible with, the hazardous waste to be accumulated, so that the ability of the container to contain the waste is not impaired.

(3) Special standards for incompatible wastes.

(i) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(ii) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(iii) A container holding a hazardous waste that is incompatible with any waste or other materials accumulated nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(4) A container holding hazardous waste must be closed at all times during accumulation, except:

(i) When adding, removing, or consolidating waste, or

(ii) When venting of a container is necessary

(A) For the proper operation of equipment, or

(B) To prevent dangerous situations, such as build-up of extreme pressure.

(5) A generator must mark its container with the following:

(i) The words "Hazardous Waste," and

(ii) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene dichloride"; or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D); and

(iii) An indication of the hazards of the contents. (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; or a

hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit).

(6) A generator who accumulates either non-acute hazardous waste or acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter in excess of the amounts listed in paragraph (a) of this section at or near any point of generation must do the following:

(i) Remove the excess from the satellite accumulation area within three calendar days to either

(A) A central accumulation area;

(B) An on-site interim status or permitted treatment, storage, or disposal facility, or

(C) An off-site designated facility.

(ii) During the three-calendar-day period the generator must continue to comply with paragraphs (a)(1) through (5) of this section. The generator must mark the container(s) holding the excess accumulation of hazardous waste with the date the excess amount began accumulating.

§ 262.16 Conditions for exemption for a small quantity generator that accumulates hazardous waste.

A small quantity generator may accumulate hazardous waste on-site without a permit or interim status, and without complying with the independent requirements of parts 124, 264 through 268, and 270 of this chapter, provided that all the conditions for exemption listed in this section are met:

(a) *Generation.* The generator generates in a calendar month no more than the amounts specified in the definition of "small quantity generator" in § 260.10 of this chapter.

(b) *Accumulation.* The generator accumulates hazardous waste on site for no more than 180 days, unless in compliance with the conditions for exemption for longer accumulation in paragraphs (c) and (d) of this section. The following accumulation conditions also apply:

(1) *Accumulation limit.* The quantity of hazardous waste accumulated on site never exceeds 6,000 kilograms (13,200 pounds);

(2) *Accumulation in containers—(i) Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the small quantity generator must transfer the hazardous waste from this container to a container that is in good condition, or manage the waste in some other way that complies with the conditions for exemption of this section.

(ii) *Compatibility of waste with container.* The small quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be accumulated, so that the ability of the container to contain the waste is not impaired.

(iii) *Management of containers.* (A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or accumulated in a manner that may rupture the container or cause it to leak.

(iv) *Inspections.* At least weekly, the small quantity generator must inspect central accumulation areas. The small quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(2)(i) of this section for remedial action required if deterioration or leaks are detected.

(v) *Special conditions for accumulation of incompatible wastes.*

(A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container accumulating hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(3) *Accumulation in tanks.*

(i) [Reserved]

(ii) A small quantity generator of hazardous waste must comply with the following general operating conditions:

(A) Treatment or accumulation of hazardous waste in tanks must comply with § 265.17(b) of this chapter.

(B) Hazardous wastes or treatment reagents must not be placed in a tank if they could cause the tank or its inner liner to rupture, leak, corrode, or otherwise fail before the end of its intended life.

(C) Uncovered tanks must be operated to ensure at least 60 centimeters (2 feet) of freeboard, unless the tank is equipped with a containment structure (e.g., dike or trench), a drainage control system, or a diversion structure (e.g., standby tank)

with a capacity that equals or exceeds the volume of the top 60 centimeters (2 feet) of the tank.

(D) Where hazardous waste is continuously fed into a tank, the tank must be equipped with a means to stop this inflow (e.g., waste feed cutoff system or by-pass system to a stand-by tank).

(iii) Except as noted in paragraph (a)(3)(iv) of this section, a small quantity generator that accumulates hazardous waste in tanks must inspect, where present:

(A) Discharge control equipment (e.g., waste feed cutoff systems, by-pass systems, and drainage systems) at least once each operating day, to ensure that it is in good working order;

(B) Data gathered from monitoring equipment (e.g., pressure and temperature gauges) at least once each operating day to ensure that the tank is being operated according to its design;

(C) The level of waste in the tank at least once each operating day to ensure compliance with paragraph (a)(3)(ii)(C) of this section;

(D) The construction materials of the tank at least weekly to detect corrosion or leaking of fixtures or seams; and

(E) The construction materials of, and the area immediately surrounding, discharge confinement structures (e.g., dikes) at least weekly to detect erosion or obvious signs of leakage (e.g., wet spots or dead vegetation). As required by § 265.15(c) of this chapter, the small quantity generator must remedy any deterioration or malfunction it finds.

(iv) A small quantity generator accumulating hazardous waste in tanks or tank systems that have full secondary containment and that either use leak detection equipment to alert personnel to leaks, or implement established workplace practices to ensure leaks are promptly identified, must inspect at least weekly, where applicable, the areas identified in paragraphs (a)(3)(iii)(A) through (E) of this section. Use of the alternate inspection schedule must be documented in the site's operating record. This documentation must include a description of the established workplace practices at the site.

(v) [Reserved.]

(vi) A small quantity generator accumulating hazardous waste in tanks must, upon closure of the site, remove all hazardous waste from tanks, discharge control equipment, and discharge confinement structures. At closure, as throughout the operating period, unless the small quantity generator can demonstrate, in accordance with § 261.3(c) or (d) of this chapter, that any solid waste removed

from its tank is not a hazardous waste, then it must manage such waste in accordance with all applicable provisions of parts 262, 263, and 265 of this chapter.

(vii) A small quantity generator must comply with the following special conditions for accumulation of ignitable or reactive waste:

(A) Ignitable or reactive waste must not be placed in a tank, unless:

(1) The waste is treated, rendered, or mixed before or immediately after placement in a tank so that the resulting waste, mixture, or dissolution of material no longer meets the definition of ignitable or reactive waste under § 261.21 or 261.23 of this chapter and § 265.17(b) of this chapter is complied with; or

(2) The waste is accumulated or treated in such a way that it is protected from any material or conditions that may cause the waste to ignite or react; or

(3) The tank is used solely for emergencies.

(B) A small quantity generator which treats or accumulates ignitable or reactive waste in covered tanks must comply with the buffer zone requirements for tanks contained in Tables 2–1 through 2–6 of the National Fire Protection Association's "Flammable and Combustible Liquids Code," (1977 or 1981) (incorporated by reference, see § 260.11).

(C) A small quantity generator must comply with the following special conditions for incompatible wastes:

(1) Incompatible wastes, or incompatible wastes and materials, (see part 265 appendix V for examples) must not be placed in the same tank, unless § 265.17(b) of this chapter is complied with.

(2) Hazardous waste must not be placed in an unwashed tank that previously held an incompatible waste or material, unless § 265.17(b) of this chapter is complied with.

(4) *Accumulation of hazardous waste on drip pads.* A small quantity generator may accumulate hazardous waste on drip pads for 90 days or less without a permit or without having interim status provided that it complies with 40 CFR part 265 subpart W. The generator must maintain at the facility the following records by use of inventory logs, monitoring equipment, or any other effective means:

(i) A written description of procedures that will identify the date hazardous waste first entered the drip pad and ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and

(ii) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

(5) *Accumulation of hazardous waste in containment buildings.* A small quantity generator may accumulate hazardous waste in containment buildings for 90 days or less without a permit or without having interim status provided that it complies with 40 CFR part 265 subpart DD. The generator must also maintain the following records by use of inventory logs, monitoring equipment records, or any other effective means:

(i) The professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101. This certification must be in the facility's operating record prior to operation of the unit; and

(ii) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the site showing that they are consistent with maintaining the 90 day limit, and documentation that the procedures are complied with; or

(iii) Documentation that the unit is emptied at least once every 90 days.

(6) *Labeling and marking of containers, tanks, drip pads, and containment buildings.* (i) A small quantity generator must mark its containers with the following:

(A) The words "Hazardous Waste";

(B) Other words that identify the contents of the containers (examples may include, but are not limited to, the name of the chemical(s), such as "acetone" or "methylene dichloride"; or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D);

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized

System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(D) The date upon which each period of accumulation begins clearly visible for inspection on each container.

(ii) A small quantity generator accumulating hazardous waste in tanks, drip pads and containment buildings must do the following:

(A) Mark or label its waste accumulation units with the words "Hazardous Wastes." In the case of hazardous wastes accumulated in drip pads and containment buildings, generators must label their drip pads and containment buildings with the words "Hazardous Wastes" in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, or other persons on site;

(B) Use inventory logs, monitoring equipment, or records to identify the contents of the tank, drip pad or containment building and its associated hazards;

(C) Use inventory logs, monitoring equipment or records to identify the date upon which each period of accumulation begins; and

(D) Keep inventory logs or records with the above information in close proximity to the tank, drip pad, or containment building.

(7) *Land disposal restrictions.* The generator complies with all the applicable requirements under 40 CFR part 268.

(8) *Preparedness and prevention—(i) Maintenance and operation of site.* A small quantity generator must maintain and operate its site to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

(ii) *Required equipment.* All areas where hazardous waste is either generated or accumulated must be equipped with the items in paragraphs (b)(8)(ii)(A) through (D) of this section (*unless* none of the hazards posed by waste handled at the site could require a particular kind of equipment specified below or the actual waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment specified below). A small quantity generator may determine the most appropriate locations within its generator site to locate equipment necessary to prepare for and respond to emergencies.

(A) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to site personnel;

(B) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or State or local emergency response teams;

(C) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment; and

(D) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

(iii) *Testing and maintenance of equipment.* All communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

(iv) *Access to communications or alarm system.* (A) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel involved in the operation must have immediate access (*e.g.*, direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required under paragraph (a)(8)(ii) of this section.

(B) In the event there is just one employee on the premises while the site is operating, the employee must have immediate access (*e.g.*, direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, *unless* such a device is not required under paragraph (a)(8)(ii) of this section.

(v) *Required aisle space.* The small quantity generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of site operation in an emergency, unless aisle space is not needed for any of these purposes.

(vi) *Arrangements with local authorities.* (A) The small quantity generator must make arrangements with the Local Emergency Planning Committee for the types and quantities of hazardous waste handled at the site, as well as the potential need for the

services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, then the small quantity generator must make arrangements with the local fire department and other relevant emergency responders, (e.g., police and hospitals).

(1) A small quantity generator that must make arrangements with its local fire department must determine the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals.

(2) As part of this coordination, the small quantity generator shall make arrangements, as necessary, to familiarize the above organizations with the layout of the site, the properties of hazardous waste handled at the site and associated hazards, places where site personnel would normally be working, entrances to roads inside the site, and possible evacuation routes as well as the types of injuries or illnesses that could result from fires, explosions, or releases at the site.

(3) Where more than one police or fire department might respond to an emergency, the small quantity generator shall enter into agreements designating primary emergency authority to a specific fire or police department, and agreements with any others to provide support to the primary emergency authority.

(B) A small quantity generator shall maintain records documenting the arrangements with the Local Emergency Planning Committee, or if appropriate, with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include a certified letter or any other documentation that confirms such arrangements actively exist.

(9) *Emergency procedures.* The small quantity generator complies with the following conditions for those areas of the generator site where hazardous waste is generated and accumulated:

(i) At all times there must be at least one employee either on the premises or on call (i.e., available to respond to an emergency by reaching the site within a short period of time) with the responsibility for coordinating all emergency response measures specified in paragraph (b)(9)(iv) of this section.

This employee is the emergency coordinator.

(ii) The small quantity generator must post the following information next to telephones or in areas directly involved in the generation and accumulation of hazardous waste:

(A) The name and emergency telephone number of the emergency coordinator;

(B) Location of fire extinguishers and spill control material, and, if present, fire alarm; and

(C) The telephone number of the fire department, unless the site has a direct alarm.

(iii) The small quantity generator must ensure that all employees are thoroughly familiar with proper waste handling and emergency procedures, relevant to their responsibilities during normal site operations and emergencies;

(iv) The emergency coordinator or his designee must respond to any emergencies that arise. The applicable responses are as follows:

(A) In the event of a fire, call the fire department or attempt to extinguish it using a fire extinguisher;

(B) In the event of a spill, the small quantity generator is responsible for containing the flow of hazardous waste to the extent possible, and as soon as is practicable, cleaning up the hazardous waste and any contaminated materials or soil. Such containment and cleanup can be conducted either by the small quantity generator or by a contractor on behalf of the small quantity generator;

(C) In the event of a fire, explosion, or other release that could threaten human health outside the site or when the small quantity generator has knowledge that a spill has reached surface water, the small quantity generator must immediately notify the National Response Center (using their 24-hour toll free number 800/424-8802). The report must include the following information:

(1) The name, address, and U.S. EPA Identification Number of the small quantity generator;

(2) Date, time, and type of incident (e.g., spill or fire);

(3) Quantity and type of hazardous waste involved in the incident;

(4) Extent of injuries, if any; and

(5) Estimated quantity and disposition of recovered materials, if any.

(c) *Mixing hazardous waste with non-hazardous waste.* A small quantity generator may mix its hazardous waste with non-hazardous waste and remain eligible for the conditional exemption provided that either paragraph (c)(1) or (2) of this section is met.

(1) The mixture is not a hazardous waste according to the mixture rules in

§§ 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i); or

(2) If the mixture is a hazardous waste, the mixture does not cause the generator to exceed the small quantity generator quantity limits for a calendar month, as identified in the definition of small quantity generator at § 260.10 of this chapter. If the mixture does exceed the small quantity generator quantity limits, a small quantity generator, to remain exempt from the permitting and interim status standards, must meet the conditions for exemption applicable to a large quantity generator.

(d) *Transporting over 200 miles.* A small quantity generator who must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more for off-site treatment, storage or disposal may accumulate hazardous waste on site for 270 days or less without a permit or without having interim status provided that the generator complies with the conditions of paragraph (a) of this section.

(e) *Accumulation time limit extension.* A small quantity generator who accumulates hazardous waste for more than 180 days (or for more than 270 days if it must transport its waste, or offer its waste for transportation, over a distance of 200 miles or more) is an operator of a storage facility and is subject to the requirements of 40 CFR parts 264, 265, 267, 268, and 270 and the permit requirements of 40 CFR part 270 unless it has been granted an extension to the 180-day (or 270-day if applicable) period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 180 days (or 270 days if applicable) due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(f) *Rejected load.* A small quantity generator who sends a shipment of hazardous waste to a designated facility with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a), (c), and (d) of this section. Upon receipt of the returned shipment, the generator must:

(i) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or

(ii) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

(g) A small quantity generator experiencing an episodic event may accumulate hazardous waste in accordance with subpart L of this part in lieu of § 262.17.

§ 262.17 Conditions for exemption for a large quantity generator that accumulates hazardous waste.

A large quantity generator may accumulate hazardous waste on-site without a permit or interim status, and without complying with the independent requirements of parts 124, 264 through 268, and 270 of this chapter, provided that all of the conditions for exemption listed in this section are met:

(a) *Accumulation.* A large quantity generator accumulates hazardous waste on site for no more than 90 days, unless in compliance with the accumulation time limit extension or F006 accumulation conditions for exemption in § 262.17(b) through (e). The following accumulation conditions also apply:

(1) *Accumulation in containers.* If the hazardous waste is placed in containers, the large quantity generator must comply with the following:

(i) *Air emission standards.* The applicable requirements of subparts AA, BB, and CC of 40 CFR part 265;

(ii) *Condition of containers.* If a container holding hazardous waste is not in good condition, or if it begins to leak, the large quantity generator must transfer the hazardous waste from this container to a container that is in good condition, or manage the waste in some other way that complies with the conditions for exemption of this section;

(iii) *Compatibility of waste with container.* The large quantity generator must use a container made of or lined with materials that will not react with, and are otherwise compatible with, the hazardous waste to be stored, so that the ability of the container to contain the waste is not impaired;

(iv) *Management of containers.* (A) A container holding hazardous waste must always be closed during accumulation, except when it is necessary to add or remove waste.

(B) A container holding hazardous waste must not be opened, handled, or stored in a manner that may rupture the container or cause it to leak.

(v) *Inspections.* At least weekly, the large quantity generator must inspect central accumulation areas. The large quantity generator must look for leaking containers and for deterioration of containers caused by corrosion or other factors. See paragraph (a)(1)(ii) of this section for remedial action required if deterioration or leaks are detected.

(vi) *Special conditions for accumulation of ignitable and reactive wastes.* (A) Containers holding ignitable or reactive waste must be located at least 15 meters (50 feet) from the site's property line unless a written waiver is obtained from the local fire department allowing hazardous waste accumulation to occur within this restricted area. Record of this approval must be maintained as long as ignitable or reactive hazardous waste is accumulated in this area.

(B) The large quantity generator must take precautions to prevent accidental ignition or reaction of ignitable or reactive waste. This waste must be separated and protected from sources of ignition or reaction including but not limited to the following: open flames, smoking, cutting and welding, hot surfaces, frictional heat, sparks (static, electrical, or mechanical), spontaneous ignition (e.g., from heat-producing chemical reactions), and radiant heat. While ignitable or reactive waste is being handled, the large quantity generator must confine smoking and open flame to specially designated locations. "No Smoking" signs must be conspicuously placed wherever there is a hazard from ignitable or reactive waste.

(vii) *Special conditions for accumulation of incompatible wastes.* (A) Incompatible wastes, or incompatible wastes and materials, (see appendix V of part 265 for examples) must not be placed in the same container, unless § 265.17(b) of this chapter is complied with.

(B) Hazardous waste must not be placed in an unwashed container that previously held an incompatible waste or material (see appendix V of part 265 for examples), unless § 265.17(b) of this chapter is complied with.

(C) A container holding a hazardous waste that is incompatible with any waste or other materials accumulated or stored nearby in other containers, piles, open tanks, or surface impoundments must be separated from the other materials or protected from them by means of a dike, berm, wall, or other device.

(2) *Accumulation in tanks.* If the waste is placed in tanks, the large quantity generator must comply with the applicable requirements of subparts J, AA, BB, and CC of 40 CFR part 265 except § 265.197(c) of Closure and post-closure care and § 265.200—Waste analysis and trial tests.

(3) *Accumulation on drip pads.* If the waste is placed on drip pads, the large quantity generator must comply with subpart W of 40 CFR part 265 and maintain at the facility the following

records by use of inventory logs, monitoring equipment records, or any other effective means:

(i) A written description of procedures that will identify the date hazardous waste first entered the drip pad and ensure that all wastes are removed from the drip pad and associated collection system at least once every 90 days; and

(ii) Documentation of each waste removal, including the quantity of waste removed from the drip pad and the sump or collection system and the date and time of removal.

(4) *Accumulation in Containment Buildings.* (i) If the waste is placed in containment buildings, the large quantity generator must comply with subpart DD of 40 CFR part 265 and must place its professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the generator's files prior to operation of the unit.

(ii) The large quantity generator shall maintain the following records by use of inventory logs, monitoring equipment records, or any other effective means:

(A) A written description of procedures to ensure that each waste volume remains in the unit for no more than 90 days, a written description of the waste generation and management practices for the site showing that they are consistent with respecting the 90 day limit, and documentation that the procedures are complied with; or

(B) Documentation that the unit is emptied at least once every 90 days.

(5) *Labeling and marking of containers, tanks, drip pads, and containment buildings—(i) Containers.* A large quantity generator must mark its containers with the following:

(A) The words "Hazardous Waste";

(B) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene dichloride"; or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D)";

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard

Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(D) The date upon which each period of accumulation begins clearly visible for inspection on each container.

(ii) *Tanks, drip pads, and containment buildings.* A large quantity generator accumulating hazardous waste in tanks, drip pads, and containment buildings must do the following:

(A) Mark or label its waste accumulation units with the words "Hazardous Waste." In the case of hazardous wastes accumulated in drip pads and containment buildings, generators must label their drip pads and containment buildings with the words "Hazardous Waste" in a conspicuous place easily visible to employees, visitors, emergency responders, waste handlers, etc.

(B) Use inventory logs, monitoring equipment, or records to identify the contents of the tank, drip pad or containment building and its associated hazards.

(C) Use inventory logs, monitoring equipment or records to identify the date upon which each period of accumulation begins; and

(D) Keep inventory logs or records with the above information in close proximity to the tank, drip pad, or containment building.

(6) *Emergency procedures.* The large quantity generator complies with the standards in subpart M of this part, Preparedness, Prevention and Emergency Procedures for Large Quantity Generators.

(7) *Personnel training.* (i)(A) Site personnel must successfully complete a program of classroom instruction, online training, or on-the-job training that teaches them to perform their duties in a way that ensures compliance with this part. The large quantity generator must ensure that this program includes all the elements described in the document required under paragraph (a)(7)(iv) of this section.

(B) This program must be directed by a person trained in hazardous waste management procedures, and must include instruction which teaches site personnel hazardous waste management procedures (including contingency plan implementation) relevant to the positions in which they are employed.

(C) At a minimum, the training program must be designed to ensure that site personnel are able to respond effectively to emergencies by familiarizing them with emergency procedures, emergency equipment, and emergency systems, including where applicable:

(1) Procedures for using, inspecting, repairing, and replacing site emergency and monitoring equipment;

(2) Key parameters for automatic waste feed cut-off systems;

(3) Communications or alarm systems;

(4) Response to fires or explosions;

(5) Response to ground-water contamination incidents; and

(6) Shutdown of operations.

(D) For site employees that receive emergency response training pursuant to Occupational Safety and Health Administration regulations 29 CFR 1910.120(p)(8) and 1910.120(q), the large quantity generator is not required to provide separate emergency response training pursuant to this section, provided that the overall site training meets all the conditions of exemption in this section.

(ii) Site personnel must successfully complete the program required in paragraph (a)(7)(i) of this section within six months after the effective date of these regulations or six months after the date of their employment or assignment to the site, or to a new position at the site, whichever is later. Employees hired after the effective date of these regulations must not work in unsupervised positions until they have completed the training standards of paragraph (a)(7)(i) of this section.

(iii) Site personnel must take part in an annual review of the initial training required in paragraph (a)(7)(i) of this section.

(iv) The large quantity generator must maintain the following documents and records at the site:

(A) The job title for each position at the site related to hazardous waste management, and the name of the employee filling each job;

(B) A written job description for each position listed under paragraph (a)(7)(iv)(A) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualifications, and duties of site personnel assigned to each position;

(C) A written description of the type and amount of both introductory and continuing training that will be given to each person filling a position listed

under paragraph (a)(7)(iv)(A) of this section;

(D) Records that document that the training or job experience, required under paragraphs (a)(7)(i), (ii), and (iii) of this section, has been given to, and completed by, site personnel.

(v) Training records on current personnel must be kept until closure of the site. Training records on former employees must be kept for at least three years from the date the employee last worked at the site. Personnel training records may accompany personnel transferred within the same company.

(8) *Closure.* A large quantity generator accumulating hazardous wastes in containers, tanks, drip pads, and containment buildings, prior to closing a unit that accumulates hazardous waste at the site or prior to closing the site must meet the following conditions:

(i) *Notification.* (A) Notify EPA no later than 30 days prior to closing a unit that accumulates hazardous waste at the site or prior to closing the site.

(B) Notify EPA within 90 days after closure of a unit that accumulates hazardous waste at the site or prior to closing the site that it has either clean closed (*e.g.*, complied with the applicable closure performance standards of § 262.17(a)(8)(ii)) or, if it cannot clean close, notify as a landfill under § 265.310 of this chapter.

(ii) *Closure performance standards.* (A) At closure, the generator must close the waste accumulation unit or site in a manner that:

(1) Minimizes the need for further maintenance by controlling, minimizing, or eliminating, to the extent necessary to protect human health and the environment, the post-closure escape of hazardous waste, hazardous constituents, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere,

(2) Properly disposes of or decontaminates all contaminated equipment, structures and soil and any remaining hazardous waste residues from waste accumulation units including containment system components (pads, liners, etc.), contaminated soils and subsoils, bases, and structures and equipment contaminated with waste. Any hazardous waste residues remaining in the unit(s) being closed must be removed from the unit(s). Any leakage must also be decontaminated or removed and managed as a hazardous waste unless § 261.3(d) of this chapter applies.

(3) Any hazardous waste generated in the process of closing either the

generator's site or unit(s) accumulating hazardous waste must be managed in accordance with all applicable standards of parts 260 through 270 of this chapter, including removing any hazardous waste contained in these units within 90 days of generating it and managing these wastes in a RCRA Subtitle C hazardous waste permitted treatment, storage and disposal facility or interim status facility.

(4) If the generator demonstrates that any contaminated soils and wastes cannot be practicably removed or decontaminated as required in paragraph (a)(8)(ii)(A)(2) of this section, then the waste accumulation unit is considered to be a landfill and the generator must close the waste accumulation unit and perform post-closure care in accordance with the closure and post-closure care requirements that apply to landfills (§ 265.310 of this chapter). In addition, for the purposes of closure, post-closure, and financial responsibility, such a waste accumulation unit is then considered to be a landfill, and the generator must meet all of the requirements for landfills specified in subparts G and H of part 265 of this chapter.

(9) *Land disposal restrictions.* The large quantity generator complies with all applicable requirements under 40 CFR part 268.

(b) *Accumulation time limit extension.* A large quantity generator who accumulates hazardous waste for more than 90 days is an operator of a storage facility and is subject to the requirements of 40 CFR parts 264, 265, 267, and 268, and the permit requirements of 40 CFR part 270 unless it has been granted an extension to the 90-day period. Such extension may be granted by EPA if hazardous wastes must remain on site for longer than 90 days due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(c) *Accumulation of F006.* A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, may accumulate F006 waste on site for more than 90 days, but not more than 180 days without a permit or without having interim status provided that it complies with all of the following conditions:

(1) The large quantity generator has implemented pollution prevention practices that reduce the amount of any hazardous substances, pollutants, or contaminants entering F006 or

otherwise released to the environment prior to its recycling;

(2) The F006 waste is legitimately recycled through metals recovery;

(3) No more than 20,000 kilograms of F006 waste is accumulated on site at any one time; and

(4) The F006 waste is managed in accordance with the following:

(i)(A) If the F006 waste is placed in containers, the large quantity generator must comply with the applicable conditions for exemption in § 262.17(a)(1); and/or

(B) If the F006 is placed in tanks, the large quantity generator must comply with the applicable conditions for exemption of § 262.17(a)(2); and/or

(C) If the F006 is placed in containment buildings, the large quantity generator must comply with subpart DD of 40 CFR part 265, and has placed its professional engineer certification that the building complies with the design standards specified in 40 CFR 265.1101 in the site's files prior to operation of the unit. The large quantity generator must maintain the following records:

(1) A written description of procedures to ensure that the F006 waste remains in the unit for no more than 180 days, a written description of the waste generation and management practices for the site showing that they are consistent with the 180-day limit, and documentation that the large quantity generator is complying with the procedures; or

(2) Documentation that the unit is emptied at least once every 180 days.

(ii) The large quantity generator is exempt from all the requirements in subparts G and H of 40 CFR part 265, except for those referenced in § 262.17(a)(8).

(iii) The date upon which each period of accumulation begins is clearly marked and must be clearly visible for inspection on each container;

(iv) While being accumulated on site, each container and tank is labeled or marked clearly with:

(A) The words "Hazardous Waste";

(B) Other words that identify the contents of the container or tank; and

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire

Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(v) The large quantity generator complies with the requirements in §§ 262.17(a)(6) and (7).

(d) *F006 transported over 200 miles.*

A large quantity generator who also generates wastewater treatment sludges from electroplating operations that meet the listing description for the EPA hazardous waste number F006, and who must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more for off-site metals recovery, may accumulate F006 waste on site for more than 90 days, but not more than 270 days without a permit or without having interim status if the large quantity generator complies with all of the conditions for exemption of paragraphs (c)(1) through (4) of this section.

(e) *F006 accumulation time extension.*

A large quantity generator accumulating F006 in accordance with paragraphs (c) and (d) of this section who accumulates F006 waste on site for more than 180 days (or for more than 270 days if the generator must transport this waste, or offer this waste for transportation, over a distance of 200 miles or more), or who accumulates more than 20,000 kilograms of F006 waste on site is an operator of a storage facility and is subject to the requirements of 40 CFR parts 264, 265, and 267, and the permit requirements of 40 CFR part 270 unless the generator has been granted an extension to the 180-day (or 270-day if applicable) period or an exception to the 20,000 kilogram accumulation limit. Such extensions and exceptions may be granted by EPA if F006 waste must remain on site for longer than 180 days (or 270 days if applicable) or if more than 20,000 kilograms of F006 waste must remain on site due to unforeseen, temporary, and uncontrollable circumstances. An extension of up to 30 days or an exception to the accumulation limit may be granted at the discretion of the Regional Administrator on a case-by-case basis.

(f) *Mixing hazardous waste with non-hazardous waste.* Mixtures of hazardous waste with non-hazardous waste are subject to the mixture rule in §§ 261.3(a)(2)(iv), (b)(2) and (3), and (g)(2)(i).

(g) *Consolidation of hazardous waste received from very small quantity generators.* Large quantity generators may receive hazardous waste from very

small quantity generators under control of the same person (as defined in § 260.10), provided that they comply with the following conditions.

“Control,” for the purposes of this section, means the power to direct the policies of the generator site, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate generator sites on behalf of a different person shall not be deemed to “control” such generator sites.

(1) The large quantity generator notifies EPA thirty (30) days prior to receiving the first shipment from a very small quantity generator(s) using EPA form 8700–12; and

(i) Identifies on the form the name(s) and site address(es) for the very small quantity generator(s) as well as the name and business telephone number for a contact person for the very small quantity generator(s); and

(ii) Submits an updated Site ID form (EPA form 8700–12) within 30 days after a change in the name, site address, or contact information for the very small quantity generator.

(2) The large quantity generator maintains records of shipments for three years from the date the hazardous waste was received from the very small quantity generator. These records must identify the name, site address, and contact information for the very small quantity generator and include a description of the hazardous waste received, including the quantity, all applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261 for the hazardous waste, and the date the waste was received.

(3) The large quantity generator manages all hazardous waste received from a very small quantity generator in compliance with the independent requirements in § 262.10(a)(1)(ii) and conditions for exemption in § 262.17 applicable to a large quantity generator. For purposes of the labeling and marking regulations in § 262.17(a)(5), the large quantity generator must label the container or unit with the date accumulation started (*i.e.*, the date the hazardous waste was received from the very small quantity generator). If the large quantity generator is consolidating incoming hazardous waste from a very small quantity generator with either its own hazardous waste or with hazardous waste from other very small quantity generators, the large quantity generator must label each container or unit with the earliest date any hazardous waste in the container was accumulated on site.

(h) *Rejected load.* A large quantity generator who sends a shipment of hazardous waste to a designated facility

with the understanding that the designated facility can accept and manage the waste and later receives that shipment back as a rejected load or residue in accordance with the manifest discrepancy provisions of § 264.72 or 265.72 of this chapter may accumulate the returned waste on site in accordance with paragraphs (a) and (b) of this section. Upon receipt of the returned shipment, the generator must:

(1) Sign Item 18c of the manifest, if the transporter returned the shipment using the original manifest; or

(2) Sign Item 20 of the manifest, if the transporter returned the shipment using a new manifest.

§ 262.18 EPA identification numbers and re-notification for small quantity generators and large quantity generators.

(a) A generator must not treat, store, dispose of, transport, or offer for transportation, hazardous waste without having received an EPA identification number from the Administrator.

(b) A generator who has not received an EPA identification number may obtain one by applying to the Administrator using EPA form 8700–12. Upon receiving the request the Administrator will assign an EPA identification number to the generator.

(c) A generator must not offer its hazardous waste to transporters or to treatment, storage, or disposal facilities that have not received an EPA identification number.

(d) *Re-notification.* (i) A small quantity generator must notify EPA by February 1 of each even-numbered year thereafter using EPA Form 8700–12.

(ii) A large quantity generator must notify EPA by March 1 of each even-numbered year thereafter using EPA Form 8700–12. A large quantity generator may submit this re-notification as part of its biennial report required under § 262.41.

■ 18. Revise the heading for subpart B to read as follows:

Subpart B—Manifest Requirements Applicable to Small and Large Quantity Generators

■ 19. Revise the heading for subpart C to read as follows:

Subpart C—Pre-Transport Requirements Applicable to Small and Large Quantity Generators

■ 20. Amend § 262.32 by adding paragraph (c) to read as follows:

§ 262.32 Marking.

* * * * *

(c) Before transporting or offering hazardous waste for transportation off

site, a generator must mark each container with the applicable EPA hazardous waste numbers (EPA hazardous waste codes) in subparts C and D of part 261 of this chapter.

§ 262.34 [Removed and reserved]

■ 21. Remove and reserve § 262.34.

■ 22. Add § 262.35 to subpart C read as follows:

§ 262.35 Liquids in landfills prohibition.

The placement of bulk or non-containerized liquid hazardous waste or hazardous waste containing free liquids (whether or not sorbents have been added) in any landfill is prohibited.

■ 23. Revise the heading for subpart D to read as follows:

Subpart D—Recordkeeping and Reporting Applicable to Small and Large Quantity Generators

§ 262.40 [Amended]

■ 24. Amend § 262.40 by removing and reserving paragraph (c).

■ 25. Section 262.41 and its section heading are revised to read as follows:

§ 262.41 Biennial report for large quantity generators.

(a) A generator who is a large quantity generator for at least one month of the reporting year must complete and submit EPA form 8700–13 to the Regional Administrator by March 1 of each even numbered year for all hazardous wastes generated during the previous calendar year. This requirement also applies to generators who treat, store, or dispose of hazardous waste on site in accordance with the provisions of 40 CFR parts 264, 265, 266, 267, and 270 and to large quantity generators that receive hazardous waste from very small quantity generators pursuant to § 262.17(g).

(b) Exports of hazardous waste to foreign countries are not required to be reported on the Biennial Report form. A separate annual report requirement is set forth at 40 CFR 262.56 for hazardous waste exporters.

■ 26. Section 262.43 is revised to read as follows:

§ 262.43 Additional reporting.

The Administrator, as deemed necessary under sections 2002(a) and 3002(a)(6) of the Act, may require generators to furnish additional reports concerning the quantities and disposition of wastes identified or listed in 40 CFR part 261.

■ 27. Section 262.44 is amended by revising the introductory paragraph and section heading to read as follows:

§ 262.44 Recordkeeping for small quantity generators.

A small quantity generator is subject only to the following independent requirements in this subpart:

* * * * *

Subparts I and J [Removed and Reserved]

- 28. Remove and reserve subparts I and J.

Subpart K—Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

- 29. Section 262.200 is amended by removing the definition of “Central accumulation area” and revising the definition of “Trained professional” to read as follows:

§ 262.200 Definitions for this subpart.

* * * * *

Trained professional means a person who has completed the applicable RCRA training requirements of § 262.17 for large quantity generators, or is knowledgeable about normal operations and emergencies in accordance with § 262.16 for small quantity generators and very small quantity generators. A trained professional may be an employee of the eligible academic entity or may be a contractor or vendor who meets the requisite training requirements.

* * * * *

- 30. Section 262.201 is revised to read as follows:

§ 262.201 Applicability of this subpart.

(a) *Large quantity generators and small quantity generators.* This subpart provides alternative requirements to the requirements in §§ 262.11 and 262.15 for the hazardous waste determination and accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

(b) *Very small quantity generators.* This subpart provides alternative requirements to the conditional exemption in § 262.14 for the accumulation of hazardous waste in laboratories owned by eligible academic entities that choose to be subject to this subpart, provided that they complete the notification requirements of § 262.203.

- 31. Section 262.202 is revised to read as follows:

§ 262.202 This subpart is optional.

(a) *Large quantity generators and small quantity generators.* Eligible academic entities have the option of complying with this subpart with respect to its laboratories, as an alternative to complying with the requirements of §§ 262.11 and 262.15.

(b) *Very small quantity generators.* Eligible academic entities have the option of complying with this subpart with respect to laboratories, as an alternative to complying with the conditional exemption of § 262.14.

- 32. Section 262.203 is amended by revising paragraphs (a) and (b)(2) to read as follows:

§ 262.203 How an eligible academic entity indicates it will be subject to the requirements of this subpart.

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA Identification Number. An eligible academic entity that is a very small quantity generator and does not have an EPA Identification Number must notify that it is electing to be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on site, as defined by § 260.10. An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA Identification Number (or site, for very small quantity generators) that is electing to be subject to the requirements of this subpart, and must submit the Site Identification Form before it begins operating under this subpart.

(b) * * *
(2) Site EPA Identification Number (except for very small quantity generators).

* * * * *

- 33. Section 262.204 is amended by revising paragraph (a) to read as follows:

§ 262.204 How an eligible academic entity indicates it will withdraw from the requirements of this subpart.

(a) An eligible academic entity must notify the appropriate EPA Regional Administrator in writing, using the RCRA Subtitle C Site Identification Form (EPA Form 8700–12), that it is electing to no longer be subject to the requirements of this subpart for all the laboratories owned by the eligible academic entity under the same EPA Identification Number and that it will

comply with the requirements of §§ 262.11 and 262.15 for small quantity generators and large quantity generators. An eligible academic entity that is a very small quantity generator and does not have an EPA Identification Number must notify that it is withdrawing from the requirements of this subpart for all the laboratories owned by the eligible academic entity that are on site and that it will comply with the conditional exemption in § 262.14. An eligible academic entity must submit a separate notification (Site Identification Form) for each EPA Identification Number (or site, for very small quantity generators) that is withdrawing from the requirements of this subpart and must submit the Site Identification Form before it begins operating under the standards in §§ 262.11 and 262.15 for small quantity generators and large quantity generators or § 262.14 for very small quantity generators.

* * * * *

§ 262.206 [Amended]

- 34. Amend § 262.206 in paragraph (b)(3)(iii) by removing the period at the end of the sentence and inserting “:” in its place.

- 35. Section 262.207 is amended by revising paragraph (d)(2) to read as follows:

§ 262.207 Training.

* * * * *

(d) * * *
(2) Make the hazardous waste determination, pursuant to § 262.11(a) through (d), for unwanted material.

- 36. Section 262.208 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 262.208 Removing containers of unwanted material from the laboratory.

(a) * * *

(1) Remove all containers of unwanted material from each laboratory on a regular interval, not to exceed 12 months; or

(2) Remove containers of unwanted material from each laboratory within 12 months of each container’s accumulation start date.

* * * * *

- 37. Section 262.209 is amended by revising paragraph (b) to read as follows:

§ 262.209 Where and when to make the hazardous waste determination and where to send containers of unwanted material upon removal from the laboratory.

* * * * *

(b) *Very small quantity generators.* An eligible academic entity must ensure that a trained professional makes a hazardous waste determination,

pursuant to § 262.11(a) through (d), for unwanted material in the laboratory before the unwanted material is removed from the laboratory, in accordance with § 262.210.

■ 38. Section 262.210 is amended by revising paragraphs (a), (b)(3), and (d)(2) to read as follows:

§ 262.210 Making the hazardous waste determination in the laboratory before the unwanted material is removed from the laboratory.

* * * * *

(a) A trained professional must make the hazardous waste determination, pursuant to § 262.11(a) through (d), before the unwanted material is removed from the laboratory.

(b) * * *

(3) Count the hazardous waste toward the eligible academic entity's generator category, pursuant to § 262.13, in the calendar month that the hazardous waste determination was made.

* * * * *

(d) * * *

(2) Very small quantity generators must ensure it is taken directly from the laboratory(ies) to any of the types of facilities listed in § 262.14.

* * * * *

■ 39. Section 262.211 is amended by revising paragraphs (c), (d), and (e)(3) to read as follows:

§ 262.211 Making the hazardous waste determination at an on-site central accumulation area.

* * * * *

(c) The unwanted material becomes subject to the generator accumulation regulations of § 262.16 for small quantity generators or § 262.17 for large quantity generators as soon as it arrives in the central accumulation area, except for the "hazardous waste" labeling conditions of § 262.16(b)(6) and § 262.17(a)(5).

(d) A trained professional must determine, pursuant to § 262.11(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials' arrival at the on-site central accumulation area.

(e) * * *

(3) Count the hazardous waste toward the eligible academic entity's generator category, pursuant to § 262.13 in the calendar month that the hazardous waste determination was made, and

* * * * *

■ 40. Section 262.212 is amended by revising paragraph (d) to read as follows:

§ 262.212 Making the hazardous waste determination at an on-site interim status or permitted treatment, storage, or disposal facility.

* * * * *

(d) A trained professional must determine, pursuant to § 262.11(a) through (d), if the unwanted material is a hazardous waste within 4 calendar days of the unwanted materials' arrival at an on-site interim status or permitted treatment, storage, or disposal facility.

* * * * *

■ 41. Section 262.213 is amended by revising paragraphs (a)(2) and (3) and (b)(2) to read as follows:

§ 262.213 Laboratory clean-outs.

(a) * * *

(2) For the purposes of on-site accumulation, an eligible academic entity is not required to count a hazardous waste that is an unused commercial chemical product (listed in 40 CFR part 261, subpart D or exhibiting one or more characteristics in 40 CFR part 261, subpart C) generated solely during the laboratory clean-out toward its hazardous waste generator category, pursuant to § 262.13. An unwanted material that is generated prior to the beginning of the laboratory clean-out and is still in the laboratory at the time the laboratory clean-out commences must be counted toward hazardous waste generator category, pursuant to § 262.13, if it is determined to be hazardous waste; and

(3) For the purposes of off-site management, an eligible academic entity must count all its hazardous waste, regardless of whether the hazardous waste was counted toward generator category under paragraph (a)(2) of this section, and if it generates more than 1 kg/month of acute hazardous waste or more than 100 kg/month of non-acute hazardous waste (i.e., the very small quantity generator limits as defined in § 260.10), the hazardous waste is subject to all applicable hazardous waste regulations when it is transported off site; and

* * * * *

(b) * * *

(2) The requirement to count all hazardous waste, including unused hazardous waste, generated during the laboratory clean-out toward its hazardous waste generator category, pursuant to § 262.13.

■ 42. Section 262.214 is amended by revising paragraph (b)(5) to read as follows:

§ 262.214 Laboratory management plan.

* * * * *

(b) * * *

(5) Describe its intended best practices for making hazardous waste determinations, including specifying the duties of the individuals involved in the process (see the required standards at § 262.11(a) through (d) and §§ 262.209 through 262.212).

* * * * *

■ 43. Section 262.216 is amended by revising paragraphs (a) and (b) to read as follows:

§ 262.216 Non-laboratory hazardous waste generated at an eligible academic entity.

* * * * *

(a) Remains subject to the generator requirements of §§ 262.11 and 262.15 for large quantity generators and small quantity generators (if the hazardous waste is managed in a satellite accumulation area), and all other applicable generator requirements of 40 CFR part 262, with respect to that hazardous waste; or

(b) Remains subject to the conditional exemption of § 262.14 for very small quantity generators, with respect to that hazardous waste.

■ 44. Subpart L is added to read as follows:

Subpart L—Alternative Standards for Episodic Generation

Sec.

- 262.230 Applicability.
- 262.231 Definition of an episodic event.
- 262.232 Conditions for a generator managing hazardous waste from an episodic event.
- 262.233 Petition to manage one additional episodic event per calendar year.
- 262.234 Petition for a 30-day extension to an episodic event.

Subpart L—Alternative Standards for Episodic Generation

§ 262.230 Applicability.

This subpart is applicable to very small quantity generators and small quantity generators as defined in § 260.10.

§ 262.231 Definition of an episodic event.

An episodic event is an activity or activities, either planned or unplanned, that does not normally occur during generator operations, resulting in an increase in the generation of hazardous wastes that exceeds the calendar month quantity limits for the generator's usual category.

§ 262.232 Conditions for a generator managing hazardous waste from an episodic event.

(a) *Very small quantity generator.* A very small quantity generator may maintain its existing generator category during an episodic event provided that

the generator complies with the following conditions:

(1) The very small quantity generator is limited to one episodic event per calendar year unless a petition is granted under § 262.233;

(2) The very small quantity generator must notify EPA no later than thirty (30) calendar days prior to initiating a planned episodic event using EPA form 8700-12. In the event of an unplanned episodic event, the generator must notify EPA within 24 hours of the unplanned event or as soon as possible via phone or email and subsequently submit EPA form 8700-12. The generator shall include the start date of the episodic event, the reason(s) for the event, types and estimated quantities of hazardous waste expected to be generated as a result of the episodic event, and shall identify a facility contact and emergency coordinator with 24-hour telephone access to discuss the notification submittal or respond to an emergency;

(3) The very small quantity generator must have an EPA identification number or obtain an EPA identification number using EPA form 8700-12;

(4) *Accumulation.* A very small quantity generator is prohibited from accumulating hazardous waste generated from an episodic event on drip pads and in containment buildings. When accumulating hazardous waste in containers and tanks the following conditions apply:

(i) *Containers.* A very small quantity generator accumulating in containers must mark its containers with the following:

(A) The words "Episodic Hazardous Waste;"

(B) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as "acetone" or "methylene dichloride"; or the type or class of chemical, such as "organic solvents" or "halogenated organic solvents" or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D);

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label

consistent with the National Fire Protection Association code 704; or a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(D) The date upon which the episodic event began, clearly visible for inspection on each container.

(ii) *Tanks.* A very small quantity generator accumulating episodic hazardous waste in tanks must do the following:

(A) Mark or label the tank with the words "Episodic Hazardous Waste;"

(B) Use inventory logs, monitoring equipment, or records to identify the contents of the tank and its associated hazards;

(C) Use inventory logs, monitoring equipment or records to identify the date upon which each episodic event begins; and

(D) Keep inventory logs or records with the above information in close proximity to the tank.

(iii) Hazardous waste must be managed in a manner that minimizes the possibility of a fire, explosion, or release of hazardous waste or hazardous waste constituents to the air, soil, or water;

(A) Containers must be in good condition and compatible with the hazardous waste being accumulated therein. Containers must be kept closed except to add or remove waste.

(B) Tanks must be in good condition and compatible with the hazardous waste accumulated therein. Tanks must have procedures in place to prevent the overflow (*e.g.*, be equipped with a means to stop inflow with systems such as a waste feed cutoff system or bypass system to a standby tank when hazardous waste is continuously fed into the tank). Tanks must be inspected at least once each operating day to ensure all applicable discharge control equipment, such as waste feed cutoff systems, bypass systems, and drainage systems are in good working order and to ensure the tank is operated according to its design by reviewing the data gathered from monitoring equipment such as pressure and temperature gauges from the inspection.

(5) The very small quantity generator must comply with the hazardous waste manifest provisions of 40 CFR part 262 subpart B when it sends its episodic event hazardous waste off site to a RCRA-designated facility.

(6) The very small quantity generator has up to forty-five (45) calendar days from the start of the episodic event to

manifest and send its hazardous waste generated from the episodic event to a RCRA-designated facility unless an extension is granted pursuant to § 262.233.

(7) Very small quantity generators must maintain the following records for three (3) years from the end date of the episodic event:

(i) Beginning and end dates of the episodic event;

(ii) A description of the episodic event;

(iii) A description of the types and quantities of hazardous wastes generated during the event;

(iv) A description of how the hazardous waste was managed as well as the name of the RCRA designated facility that received the hazardous waste;

(v) Name(s) of hazardous waste transporters;

(vi) An approval letter from EPA if the generator petitioned to conduct one additional episodic event per calendar year; and

(vii) An approval letter from EPA if the generator petitioned for an additional thirty (30) calendar day extension.

(b) *Small quantity generators.* A small quantity generator may maintain its existing generator category during an episodic event provided that the generator complies with the following conditions:

(1) The small generator is limited to one episodic event per calendar year unless a petition is granted under § 262.233;

(2) The small quantity generator must notify EPA no later than thirty (30) calendar days prior to initiating a planned episodic event using EPA form 8700-12. In the event of an unplanned episodic event, the small quantity generator must notify EPA within 24 hours of the unplanned event or as soon as possible via phone or email and subsequently submit EPA form 8700-12. The small quantity generator shall include the start date of the episodic event and the reason(s) for the event, types and estimated quantities of hazardous wastes expected to be generated as a result of the episodic event, and identify a facility contact and emergency coordinator with 24-hour telephone access to discuss the notification submittal or respond to emergency;

(3) The small quantity generator must have an EPA identification number or obtain an EPA identification number using EPA form 8700-12.

(4) *Accumulation by small quantity generators.* A small quantity generator is prohibited from accumulating

hazardous wastes generated from an episodic event waste on drip pads and in containment buildings. When accumulating hazardous waste generated from an episodic event in containers and tanks, the following conditions apply:

(i) *Containers*. A small quantity generator accumulating episodic hazardous waste in containers that meet the standards at part 265 subpart I of this chapter, except §§ 265.176 and 265.178 of this chapter, must mark its containers with the following:

(A) The words “Episodic Hazardous Waste”;

(B) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as “acetone” or “methylene dichloride”; or the type or class of chemical, such as “organic solvents” or halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D);

(C) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; or a hazard pictogram consistent with the United Nations’ Globally Harmonized System; or any other marking or labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(D) The date upon which the episodic event began, clearly visible for inspection on each container.

(ii) *Tanks*. A small quantity generator accumulating episodic hazardous waste in tanks that meet the standards at § 265.201 in subpart J must do the following:

(A) Mark or label its tank with the words “Episodic Hazardous Waste;”

(B) Use inventory logs, monitoring equipment, or records to identify the contents of the tank and its associated hazards;

(C) Use inventory logs, monitoring equipment or records to identify the date upon which each period of accumulation begins and ends; and

(D) Keep inventory logs or records with the above information immediately accessible.

(iii) Comply with the applicable conditions listed in § 262.16.

(5) The small quantity generator must treat hazardous waste generated from an episodic event on site or manifest and ship such hazardous waste off site to a RCRA-designated facility within forty-five (45) calendar days from the start of the episodic event, unless an extension is granted pursuant to § 262.233.

(6) The small quantity generator must maintain the following records for three (3) years from the end date of the episodic event:

(i) Beginning and end dates of the episodic event;

(ii) A description of the episodic event;

(iii) A description of the types and quantities of hazardous wastes generated during the event;

(iv) A description of how the hazardous waste was managed as well as the name of the RCRA designated facility that received the hazardous waste;

(v) Name(s) of hazardous waste transporters;

(vi) An approval letter from EPA if the generator petitioned to conduct one additional episodic event per calendar year; and

(vii) An approval letter from EPA if the generator petitioned for an additional thirty (30) calendar day extension.

§ 262.233 Petition to manage one additional episodic event per calendar year.

(a) A very small quantity generator or a small quantity generator may petition EPA for one additional episodic event per calendar year without it impacting its generator category. The petition must include the following:

(1) The reason(s) why an additional episodic event is needed and the nature of the episodic event;

(2) The estimated amount of hazardous waste to be managed from the event;

(3) How the hazardous waste is to be managed;

(4) The estimated length of time needed to complete management of the hazardous waste generated from the episodic event—not to exceed 45 days; and

(5) Information regarding the previous episodic event managed by the generator, including the nature of the event and whether it was a planned or unplanned event.

(b) The petition must be made via fax, email, or letter.

(c) The generator cannot manage the hazardous waste generated from an

additional episodic event under subpart L until written approval by EPA, including email, has been received.

(d) The generator must retain written approval in its records for three years from the date the episodic event ended.

§ 262.234 Petition for a 30-day extension to an episodic event.

(a) The very small quantity generator or a small quantity generator may petition EPA for a thirty (30) calendar day extension to complete the management of hazardous waste generated by an episodic event. The petition must include the following:

(1) The nature of the episodic event;

(2) The estimated amount of additional hazardous waste to be managed from the episodic event if the extension is granted; and

(3) The generator’s rationale for needing an extension of an additional 30 days beyond the 45-day limit to complete management of the hazardous waste generated from the episodic event.

(b) The generator must petition EPA via fax, email, or letter within fifteen (15) calendar days of the event ending.

(c) The generator cannot go beyond the 45-day limit unless written approval from EPA has been received.

(d) The generator must retain written approval in its records for three years from the date the episodic event ended.

■ 45. Subpart M is added to read as follows:

Subpart M—Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

Sec.

262.250 Applicability.

262.251 Maintenance and operation of facility.

262.252 Required equipment.

262.253 Testing and maintenance of equipment.

262.254 Access to communications or alarm system.

262.255 Required aisle space.

262.256 Arrangements with local authorities.

262.260 Purpose and implementation of contingency plan.

262.261 Content of contingency plan.

262.262 Copies of contingency plan.

262.263 Amendment of contingency plan.

262.264 Emergency coordinator.

262.265 Emergency procedures.

Subpart M—Preparedness, Prevention, and Emergency Procedures for Large Quantity Generators

§ 262.250 Applicability.

The regulations of this subpart apply to those areas of a large quantity generator where hazardous waste is generated or accumulated on site in

accordance with the conditions in § 262.17.

§ 262.251 Maintenance and operation of facility.

A large quantity generator must maintain and operate its site to minimize the possibility of a fire, explosion, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water which could threaten human health or the environment.

§ 262.252 Required equipment.

All areas where hazardous waste is being either generated or accumulated must be equipped with the items in paragraphs (a) through (d) of this section (unless none of the hazards posed by waste handled at the site could require a particular kind of equipment specified below or the actual waste generation or accumulation area does not lend itself for safety reasons to have a particular kind of equipment specified below). A large quantity generator may determine the most appropriate locations within its generator site to locate equipment necessary to prepare for and respond to emergencies:

(a) An internal communications or alarm system capable of providing immediate emergency instruction (voice or signal) to site personnel;

(b) A device, such as a telephone (immediately available at the scene of operations) or a hand-held two-way radio, capable of summoning emergency assistance from local police departments, fire departments, or state or local emergency response teams;

(c) Portable fire extinguishers, fire control equipment (including special extinguishing equipment, such as that using foam, inert gas, or dry chemicals), spill control equipment, and decontamination equipment; and

(d) Water at adequate volume and pressure to supply water hose streams, or foam producing equipment, or automatic sprinklers, or water spray systems.

§ 262.253 Testing and maintenance of equipment.

All communications or alarm systems, fire protection equipment, spill control equipment, and decontamination equipment, where required, must be tested and maintained as necessary to assure its proper operation in time of emergency.

§ 262.254 Access to communications or alarm system.

(a) Whenever hazardous waste is being poured, mixed, spread, or otherwise handled, all personnel

involved in the operation must have immediate access (*e.g.*, direct or unimpeded access) to an internal alarm or emergency communication device, either directly or through visual or voice contact with another employee, *unless* such a device is not required under § 265.252 of this chapter.

(b) In the event there is just one employee on the premises while the site is operating, the employee must have immediate access (*e.g.*, direct or unimpeded access) to a device, such as a telephone (immediately available at the scene of operation) or a hand-held two-way radio, capable of summoning external emergency assistance, *unless* such a device is not required under § 265.252 of this chapter.

§ 262.255 Required aisle space.

The large quantity generator must maintain aisle space to allow the unobstructed movement of personnel, fire protection equipment, spill control equipment, and decontamination equipment to any area of site operation in an emergency, unless aisle space is not needed for any of these purposes.

§ 262.256 Arrangements with local authorities.

(a) The large quantity generator must make arrangements with the Local Emergency Planning Committee for the types and quantities of hazardous waste handled at the site, as well as the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers, and local hospitals. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, then the large quantity generator must make arrangements with the local fire department and other relevant emergency responders (*e.g.*, police and hospitals).

(1) A large quantity generator that must make arrangements with its local fire department must determine the potential need for the services of the local police department, other emergency response teams, emergency response contractors, equipment suppliers and local hospitals.

(2) As part of this coordination, the large quantity generator shall make arrangements, as necessary, to familiarize the above organizations with the layout of the site, the properties of the hazardous waste handled at the site and associated hazards, places where personnel would normally be working,

entrances to roads inside the site, and possible evacuation routes as well as the types of injuries or illnesses which could result from fires, explosions, or releases at the site.

(3) Where more than one police or fire department might respond to an emergency, the large quantity generator shall enter into agreements designating primary emergency authority to a specific fire or police department, and agreements with any others to provide support to the primary emergency authority.

(b) The large quantity generator shall maintain records documenting the arrangements with the Local Emergency Planning Committee, or if appropriate, with the local fire department as well as any other organization necessary to respond to an emergency. This documentation must include a certified letter or any other documentation that confirms such arrangements actively exist.

§ 262.260 Purpose and implementation of contingency plan.

(a) A large quantity generator must have a contingency plan for the site. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water.

(b) The provisions of the plan must be carried out immediately whenever there is a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.

§ 262.261 Content of contingency plan.

(a) The contingency plan must describe the actions site personnel must take to comply with §§ 262.260 and 262.265 in response to fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water at the site.

(b) If the generator has already prepared a Spill Prevention, Control, and Countermeasures (SPCC) Plan in accordance with part 112 of this chapter, or some other emergency or contingency plan, it need only amend that plan to incorporate hazardous waste management provisions that are sufficient to comply with the standards of this part. The generator may develop one contingency plan that meets all regulatory standards. EPA recommends that the plan be based on the National Response Team's Integrated Contingency Plan Guidance ("One Plan").

(c) The plan must describe arrangements agreed to with the Local Emergency Planning Committee. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, then the plan must describe arrangements agreed to by local fire departments and other relevant emergency responders (e.g., police and hospitals) to coordinate emergency services, pursuant to § 262.256.

(d) The plan must list names and emergency telephone numbers of all persons qualified to act as emergency coordinator (see § 262.264), and this list must be kept up to date. Where more than one person is listed, one must be named as primary emergency coordinator and others must be listed in the order in which they will assume responsibility as alternates. In situations where the generator site has an emergency coordinator continuously on duty because it operates 24 hours per day, every day of the year, the plan may list the staffed position (e.g., operations manager, shift coordinator, shift operations supervisor) as well as an emergency telephone number that can be guaranteed to be answered at all times.

(e) The plan must include a list of all emergency equipment at the site (such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment), where this equipment is required. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list, and a brief outline of its capabilities.

(f) The plan must include an evacuation plan for generator personnel where there is a possibility that evacuation could be necessary. This plan must describe signal(s) to be used to begin evacuation, evacuation routes, and alternate evacuation routes (in cases where the primary routes could be blocked by releases of hazardous waste or fires).

§ 262.262 Copies of contingency plan.

A copy of the contingency plan and all revisions to the plan must be maintained at the large quantity generator's site and—

(a) The large quantity generator must submit a copy of the contingency plan to the Local Emergency Planning Committee. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee

determine that it is not the appropriate organization to make arrangements with, the large quantity generator must submit the copy to the local emergency responders.

(b) A generator that first becomes subject to these provisions after [date 6 months after the date of publication of the final rule in the **Federal Register**] must submit an executive summary of the contingency plan to the Local Emergency Planning Committee. Should there be no Local Emergency Planning Committee, should it not respond, or should the Local Emergency Planning Committee determine that it is not the appropriate organization to make arrangements with, the generator must submit the copy to the local emergency responders. The executive summary must include the following elements:

(1) The types/names of hazardous wastes in layman's terms and the associated hazard associated with each waste present at any one time (e.g., toxic paint wastes, spent ignitable solvent, corrosive acid);

(2) The estimated maximum amount of each hazardous waste that may be present at any one time;

(3) The identification of any hazardous wastes where exposure would require unique or special treatment by medical or hospital staff;

(4) A map of the site showing where hazardous wastes are generated and accumulated and routes for accessing these wastes;

(5) A street map of the site in relation to surrounding businesses, schools and residential areas to understand how best to get to the facility and also evacuate citizens and workers;

(6) The locations of water supply (e.g., fire hydrant and its flow rate);

(7) The identification of on-site notification systems (e.g., a fire alarm that rings off site, smoke alarms); and

(8) The name of the emergency coordinator and 7/24-hour emergency telephone number.

§ 262.263 Amendment of contingency plan.

The contingency plan must be reviewed, and immediately amended, if necessary, whenever:

(a) Applicable regulations are revised;

(b) The plan fails in an emergency;

(c) The generator site changes—in its design, construction, operation, maintenance, or other circumstances—in a way that materially increases the potential for fires, explosions, or releases of hazardous waste or hazardous waste constituents, or changes the response necessary in an emergency;

(d) The list of emergency coordinators changes; or

(e) The list of emergency equipment changes.

§ 262.264 Emergency coordinator.

At all times, there must be at least one employee either on the generator's premises or on call (i.e., available to respond to an emergency by reaching the site within a short period of time) with the responsibility for coordinating all emergency response measures and implementing the necessary emergency procedures outlined in § 262.265. This emergency coordinator must be thoroughly familiar with all aspects of the generator's contingency plan, all operations and activities at the site, the location and characteristics of waste handled, the location of all records within the site, and the site's layout. In addition, this person must have the authority to commit the resources needed to carry out the contingency plan.

§ 262.265 Emergency procedures.

(a) Whenever there is an imminent or actual emergency situation, the emergency coordinator (or his designee when the emergency coordinator is on call) must immediately:

(1) Activate internal site alarms or communication systems, where applicable, to notify all site personnel; and

(2) Notify appropriate state or local agencies with designated response roles if their help is needed.

(b) Whenever there is a release, fire, or explosion, the emergency coordinator must immediately identify the character, exact source, amount, and areal extent of any released materials. The emergency coordinator may do this by observation or review of the site records or manifests and, if necessary, by chemical analysis.

(c) Concurrently, the emergency coordinator must assess possible hazards to human health or the environment that may result from the release, fire, or explosion. This assessment must consider both direct and indirect effects of the release, fire, or explosion (e.g., the effects of any toxic, irritating, or asphyxiating gases that are generated, or the effects of any hazardous surface water run-offs from water or chemical agents used to control fire and heat-induced explosions).

(d) If the emergency coordinator determines that the site has had a release, fire, or explosion which could threaten human health, or the environment, outside the facility, the emergency coordinator must report the findings as follows:

(1) If the assessment indicates that evacuation of local areas may be

advisable, the emergency coordinator must immediately notify appropriate local authorities. The emergency coordinator must be available to help appropriate officials decide whether local areas should be evacuated; and

(2) The emergency coordinator must immediately notify either the government official designated as the on-scene coordinator for that geographical area, or the National Response Center (using their 24-hour toll free number 800/424-8802). The report must include:

(i) Name and telephone number of reporter;

(ii) Name and address of the generator;

(iii) Time and type of incident (e.g., release, fire);

(iv) Name and quantity of material(s) involved, to the extent known;

(v) The extent of injuries, if any; and

(vi) The possible hazards to human health, or the environment, outside the site.

(e) During an emergency, the emergency coordinator must take all reasonable measures necessary to ensure that fires, explosions, and releases do not occur, recur, or spread to other hazardous waste at the generator's site. These measures must include, where applicable, stopping processes and operations, collecting and containing released waste, and removing or isolating containers.

(f) If the generator's site stops operations in response to a fire, explosion or release, the emergency coordinator must monitor for leaks, pressure buildup, gas generation, or ruptures in valves, pipes, or other equipment, wherever this is appropriate.

(g) Immediately after an emergency, the emergency coordinator must provide for treating, storing, or disposing of recovered waste, contaminated soil or surface water, or any other material that results from a release, fire, or explosion at the facility. Unless the generator can demonstrate, in accordance with § 261.3(c) or (d) of this chapter, that the recovered material is not a hazardous waste, then it is a newly generated hazardous waste that must be managed in accordance with all the applicable independent requirements and conditions for exemption in parts 262, 263, and 265 of this chapter.

(h) The emergency coordinator must ensure that, in the affected area(s) of the site:

(1) No waste that may be incompatible with the released material is treated, stored, or disposed of until cleanup procedures are completed; and

(2) All emergency equipment listed in the contingency plan is cleaned and fit for its intended use before operations are resumed.

(i) The generator must note in the operating record the time, date, and details of any incident that requires implementing the contingency plan. Within 15 days after the incident, the generator must submit a written report on the incident to the Regional Administrator. The report must include:

(1) Name, address, and telephone number of the generator;

(2) Date, time, and type of incident (e.g., fire, explosion);

(3) Name and quantity of material(s) involved;

(4) The extent of injuries, if any;

(5) An assessment of actual or potential hazards to human health or the environment, where this is applicable; and

(6) Estimated quantity and disposition of recovered material that resulted from the incident.

PART 263—STANDARDS APPLICABLE TO TRANSPORTERS OF HAZARDOUS WASTE

■ 46. The authority citation for part 263 continues to read as follows:

Authority: 42 U.S.C. 6906, 6912, 6922–6925, 6937, and 6938.

■ 47. Section 263.12 is revised to read as follows:

§ 263.12 Transfer facility requirements.

(a) A transporter who stores manifested shipments of hazardous waste in containers meeting the independent requirements of § 262.30 of this chapter at a transfer facility for a period of ten days or less is not subject to regulation under parts 264, 265, 267, 268, and 270 of this chapter with respect to the storage of those wastes.

(b) The transporter must hold hazardous wastes that are stored at transfer facilities in containers marked with the following information:

(1) The words “Hazardous Waste;”

(2) The applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261 of this chapter;

(3) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as “acetone” or “methylene dichloride”; or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D); and

(4) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (i.e., ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking and labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit).

PART 264—STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 48. The authority citation for part 264 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6924, and 6925.

■ 49. Section 264.1 is amended by revising paragraphs (g)(1) and (3) to read as follows:

§ 264.1 Purpose, scope and applicability.

* * * * *

(g) * * *

(1) The owner or operator of a facility permitted, licensed, or registered by a state to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under this part by § 262.14 of this chapter;

* * * * *

(3) A generator accumulating waste on site in compliance with § 262.14, 262.15, 262.16, or 262.17 of this chapter.

* * * * *

■ 50. Section 264.15 is amended by revising paragraph (b)(4) and removing the comment to paragraph (b)(4) and paragraph (b)(5).

The revision reads as follows:

§ 264.15 General inspection requirements.

* * * * *

(b) * * *

(4) The frequency of inspection may vary for the items on the schedule. However, the frequency should be based on the rate of deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or operator error goes undetected between inspections. Areas

subject to spills, such as loading and unloading areas, must be inspected daily when in use. At a minimum, the inspection schedule must include the items and frequencies called for in §§ 264.174, 264.193, 264.195, 264.226, 264.254, 264.278, 264.303, 264.347, 264.602, 264.1033, 264.1052, 264.1053, 264.1058, and 264.1083 through 264.1089, where applicable. Part 270 of this chapter requires the inspection schedule to be submitted with part B of the permit application. EPA will evaluate the schedule along with the rest of the application to ensure that it adequately protects human health and the environment. As part of this review, EPA may modify or amend the schedule as may be necessary.

* * * * *

■ 51. Section 264.71 is amended by revising paragraph (c) and removing the comment following paragraph (c).

The revision reads as follows:

§ 264.71 Use of manifest system.

* * * * *

(c) Whenever a shipment of hazardous waste is initiated from a facility, the owner or operator of that facility must comply with the requirements of part 262 of this chapter. The provisions of §§ 262.15, 262.16, and 262.17 of this chapter are applicable to the on-site accumulation of hazardous wastes by generators. Therefore, the provisions of §§ 262.15, 262.16, and 262.17 of this chapter only apply to owners or operators who are shipping hazardous waste which they generated at that facility.

* * * * *

■ 52. Section 264.75 is revised to read as follows:

§ 264.75 Biennial report.

The owner or operator must complete and submit EPA form 8700-13 to the Regional Administrator by March 1 of each even numbered year for facility activities during the previous calendar year.

■ 53. Section 264.170 is revised to read as follows:

§ 264.170 Applicability.

The regulations in this subpart apply to owners and operators of all hazardous waste facilities that store hazardous waste in containers, except as § 264.1 provides otherwise.

■ 54. Section 264.174 is revised to read as follows:

§ 264.174 Inspections.

At least weekly, the owner or operator must inspect areas where containers are stored. The owner or operator must look for leaking containers and for

deterioration of containers and the containment system cause by corrosion or other factors. See §§ 264.15(c) and 264.171 for remedial action required if deterioration or leaks are detected.

■ 55. Section 264.191 is amended by revising paragraph (a) to read as follows:

§ 264.191 Assessment of existing tank system's integrity.

(a) For each existing tank system that does not have secondary containment meeting the requirements of § 264.193, the owner or operator must determine that the tank system is not leaking or is fit for use. Except as provided in paragraph (c) of this section, the owner or operator must obtain and keep on file at the facility a written assessment reviewed and certified by a qualified Professional Engineer, in accordance with § 270.11(d) of this chapter, that attests to the tank system's integrity by January 12, 1988.

* * * * *

§ 264.195 [Amended]

■ 56. Section 264.195 is amended by removing and reserving paragraph (e).

■ 57. Section 264.1030 is amended by revising paragraph (b)(2) to read as follows:

§ 264.1030 Applicability.

* * * * *

(b) * * *

(2) A unit (including a hazardous waste recycling unit) that is not exempt from permitting under the provisions of 40 CFR 262.17 (i.e., a hazardous waste recycling unit that is not a 90-day tank or container) and that is located at a hazardous waste management facility otherwise subject to the permitting requirements of 40 CFR part 270; or

* * * * *

■ 58. Section 264.1050 is amended by revising paragraph (b)(3) to read as follows:

§ 264.1050 Applicability.

* * * * *

(b) * * *

(3) A unit that is exempt from permitting under the provisions of 40 CFR 262.17 (i.e., a "90-day" tank or container) and is not a recycling unit under the provisions of 40 CFR 261.6.

* * * * *

■ 59. Section 264.1101 is amended by revising paragraph (c)(4) to read as follows:

§ 264.1101 Design and operating standards.

* * * * *

(c) * * *

(4) Inspect and record in the facility operating record, at least once every

seven days, data gathered from monitoring and leak detection equipment as well as the containment building and the area immediately surrounding the containment building to detect signs of releases of hazardous waste.

* * * * *

PART 265—INTERIM STATUS STANDARDS FOR OWNERS AND OPERATORS OF HAZARDOUS WASTE TREATMENT, STORAGE, AND DISPOSAL FACILITIES

■ 60. The authority citation for part 265 continues to read as follows:

Authority: 42 U.S.C. 6905, 6906, 6912, 6922, 6923, 6924, 6925, 6935, 6936, and 6937.

■ 61. Section 265.1 is amended by revising paragraphs (c)(5) and (7) to read as follows:

§ 265.1 Purpose, scope, and applicability.

* * * * *

(c) * * *

(5) The owner or operator of a facility permitted, licensed, or registered by a State to manage municipal or industrial solid waste, if the only hazardous waste the facility treats, stores, or disposes of is excluded from regulation under this part by § 262.14 of this chapter;

* * * * *

(7) * * *

(7) A generator accumulating waste on site in compliance with §§ 262.15, 262.16, and 262.17 of this chapter, except to the extent the provisions are included in § 262.15, 262.16, or 262.17 of this chapter;

* * * * *

■ 62. Section 265.15 is amended by revising paragraph (b)(4) and removing paragraph (b)(5).

The revision reads as follows:

§ 265.15 General inspection requirements.

* * * * *

(b) * * *

(4) The frequency of inspection may vary for the items on the schedule. However, the frequency should be based on the rate of deterioration of the equipment and the probability of an environmental or human health incident if the deterioration, malfunction, or operator error goes undetected between inspections. Areas subject to spills, such as loading and unloading areas, must be inspected daily when in use. At a minimum, the inspection schedule must include the items and frequencies called for in §§ 265.174, 265.193, 265.195, 265.226, 265.260, 265.278, 265.304, 265.347, 265.377, 265.403, 265.1033, 265.1052,

265.1053, 265.1058, and 265.1084 through 265.1090, where applicable.

* * * * *

■ 63. Section 265.71 is amended by revising paragraph (c) to read as follows:

§ 265.71 Use of manifest system.

* * * * *

(c) Whenever a shipment of hazardous waste is initiated from a facility, the owner or operator of that facility must comply with the requirements of part 262 of this chapter. The provisions of §§ 262.15, 262.16, and 262.17 of this chapter are applicable to the on-site accumulation of hazardous wastes by generators. Therefore, the provisions of §§ 262.15, 262.16, and 262.17 only apply to owners or operators who are shipping hazardous waste which they generated at that facility.

* * * * *

■ 64. Section 265.75 is revised to read as follows:

§ 265.75 Biennial report.

The owner or operator must complete and submit EPA form 8700–13 to the Regional Administrator by March 1 of each even numbered year for facility activities during the previous calendar year.

■ 65. Section 265.111 is amended by revising paragraph (c) to read as follows:

§ 265.111 Closure performance standard.

* * * * *

(c) Complies with the closure requirements of this subpart, including, but not limited to, the requirements of §§ 265.197, 265.228, 265.258, 265.280, 265.310, 265.351, 265.381, 265.404, 265.445, and 265.1102.

■ 66. Section 265.114 is revised to read as follows:

§ 265.114 Disposal or decontamination of equipment, structures and soils.

During the partial and final closure periods, all contaminated equipment, structures and soil must be properly disposed of, or decontaminated unless specified otherwise in § 265.197, 265.228, 265.445, 265.258, 265.280, 265.310, or 265.1102. By removing all hazardous wastes or hazardous constituents during partial and final closure, the owner or operator may become a generator of hazardous waste and must handle that hazardous waste in accordance with all applicable requirements of part 262 of this chapter.

■ 67. Section 265.174 is revised to read as follows:

§ 265.174 Inspections.

At least weekly, the owner or operator must inspect areas where containers are stored. The owner or operator must look

for leaking containers and for deterioration of containers caused by corrosion or other factors. See § 265.171 for remedial action required if deterioration or leaks are detected.

§ 265.195 [Amended]

■ 68. Section 265.195 is amended by removing and reserving paragraph (d).

§ 265.201 [Removed and reserved]

■ 69. Remove and reserve § 265.201.

■ 70. Section 265.1030 is amended by revising paragraphs (b)(2) and (3) and removing the Note to (b)(3).

The revisions read as follows:

§ 265.1030 Applicability.

* * * * *

(b) * * *

(2) A unit (including a hazardous waste recycling unit) that is not exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.*, a hazardous waste recycling unit that is not a 90-day tank or container) and that is located at a hazardous waste management facility otherwise subject to the permitting requirements of 40 CFR part 270, or

(3) A unit that is exempt from permitting under the provisions of 40 CFR 262.17 (*i.e.*, a “90-day” tank or container) and is not a recycling unit under the requirements of 40 CFR 261.6.

* * * * *

■ 71. Section 265.1101 is amended by revising paragraph (c)(4) to read as follows:

§ 265.1101 Design and operating standards.

* * * * *

(c) * * *

(4) Inspect and record in the facility’s operating record at least once every seven days data gathered from monitoring and leak detection equipment as well as the containment building and the area immediately surrounding the containment building to detect signs of releases of hazardous waste.

* * * * *

PART 268—LAND DISPOSAL RESTRICTIONS

■ 72. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 73. Section 268.1 is amended by revising paragraph (e)(1) to read as follows:

§ 268.1 Purpose, scope, and applicability.

* * * * *

(e) * * *

(1) Waste generated by very small quantity generators, as defined in § 260.10 of this chapter;

* * * * *

■ 74. Section 268.7 is amended by revising paragraph (a)(5) introductory paragraph to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, treaters, and disposal facilities.

(a) * * *

(5) If a generator is managing and treating prohibited waste or contaminated soil in tanks, containers, or containment buildings regulated under 40 CFR 262.15, 262.16, and 262.17 to meet applicable LDR treatment standards found at § 268.40, the generator must develop and follow a written waste analysis plan which describes the procedures they will carry out to comply with the treatment standards. (Generators treating hazardous debris under the alternative treatment standards of Table 1 to § 268.45, however, are not subject to these waste analysis requirements.) The plan must be kept on site in the generator’s records, and the following requirements must be met:

* * * * *

■ 75. Section 268.50 is amended by revising paragraph (a)(2)(i) to read as follows:

§ 268.50 Prohibitions on storage of restricted waste.

(a) * * *

(2) * * *

(i) Each container is clearly marked with:

(A) The words “Hazardous Waste;”

(B) The applicable EPA hazardous waste number(s) (EPA hazardous waste codes) in subparts C and D of part 261 of this chapter;

(C) Other words that identify the contents of the containers (examples may include, but are not limited to the name of the chemical(s), such as “acetone” or “methylene dichloride”; or the type or class of chemical, such as “organic solvents” or “halogenated organic solvents” or, as applicable, the proper shipping name and technical name markings used to comply with Department of Transportation requirements at 49 CFR part 172 subpart D); and

(D) An indication of the hazards of the contents (examples include, but are not limited to, the applicable hazardous waste characteristic(s) (*i.e.*, ignitable, corrosive, reactive, toxic); a hazard class label consistent with the Department of Transportation requirements at 49 CFR part 172 subpart E (labeling); a label consistent with the Occupational Safety

and Health Administration Hazard Communication Standard at 29 CFR 1920.1200; a chemical hazard label consistent with the National Fire Protection Association code 704; a hazard pictogram consistent with the United Nations' Globally Harmonized System; or any other marking and labeling commonly used nationwide in commerce that identifies the nature of the hazards associated with the contents of the waste accumulation unit); and

(E) The date each period of accumulation begins.

* * * * *

PART 270—EPA ADMINISTERED PERMIT PROGRAMS: THE HAZARDOUS WASTE PERMIT PROGRAM

■ 76. The authority citation for part 270 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912, 6924, 6925, 6927, 6939, and 6974.

■ 77. Section 270.1 is amended by revising paragraphs (a)(3), (c)(2) introductory text, (c)(2)(i), and (c)(2)(iii) to read as follows:

§ 270.1 Purpose and scope of these regulations.

(a) * * *

(3) *Technical regulations.* The RCRA permit program has separate additional regulations that contain technical requirements. These separate regulations are used by permit issuing authorities to determine what requirements must be placed in permits if they are issued. These separate regulations are located in 40 CFR parts 264, 266, 267, and 268.

* * * * *

(c) * * *

(2) *Specific exclusions and exemptions.* The following persons are among those who are not required to obtain a RCRA permit:

(i) Generators who accumulate hazardous waste on site in compliance with all of the conditions for exemption provided in 40 CFR 262.14, 262.15, 262.16, and 262.17.

* * * * *

(iii) Persons who own or operate facilities solely for the treatment, storage, or disposal of hazardous waste excluded from regulations under this part by 40 CFR 261.4.

* * * * *

§ 270.42 [Amended]

■ 78. Section 270.42 is amended by removing and reserving paragraph (l) and the entries under O.1. in the table of appendix I to § 270.42.

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 79. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 80. Section 273.8 is amended by revising the section heading and paragraph (a)(2) to read as follows:

§ 273.8 Applicability—household and very small quantity generator waste.

(a) * * *

(2) Very small quantity generator wastes that are exempt under § 262.14 of this chapter and are also of the same type as the universal wastes defined at § 273.9.

* * * * *

■ 81. Section 273.81 is amended by revising paragraph (b) to read as follows:

§ 273.81 Factors for petitions to include other wastes under 40 CFR part 273.

* * * * *

(b) The waste or category of waste is not exclusive to a specific industry or group of industries, is commonly generated by a wide variety of types of establishments (including, for example, households, retail and commercial businesses, office complexes, very small quantity generators, small businesses, government organizations, as well as large industrial facilities);

* * * * *

PART 279—STANDARDS FOR MANAGEMENT OF USED OIL

■ 82. The authority citation for part 279 continues to read as follows:

Authority: Sections 1006, 2002(a), 3001 through 3007, 3010, 3014, and 7004 of the Solid Waste Disposal Act, as amended (42 U.S.C. 6905, 6912(a), 6921 through 6927, 6930, 6934, and 6974) ; and sections 101(37) and 144(c) of CERCLA (42 U.S.C. 9601(37) and 9614(c)).

■ 83. Section 279.10 is amended by revising paragraph (b)(3) to read as follows:

§ 279.10 Applicability.

* * * * *

(b) * * *

(3) *Very small quantity generator hazardous waste.* Mixtures of used oil and very small quantity generator hazardous waste regulated under § 262.14 of this chapter are subject to regulation as used oil under this part.

* * * * *

[FR Doc. 2015-23166 Filed 9-24-15; 8:45 am]

BILLING CODE 6560-50-P



FEDERAL REGISTER

Vol. 80

Friday,

No. 186

September 25, 2015

Part III

Environmental Protection Agency

40 CFR Parts 261, 262, 266, *et al.*

Management Standards for Hazardous Waste Pharmaceuticals; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261, 262, 266, 268, and 273

[EPA-HQ-RCRA-2007-0932; FRL-9924-08-OSWER]

RIN 2050-AG39

Management Standards for Hazardous Waste Pharmaceuticals

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Some pharmaceuticals are regulated as hazardous waste under the Resource Conservation and Recovery Act (RCRA) when discarded. Healthcare facilities that generate hazardous waste pharmaceuticals as well as associated facilities have reported difficulties complying with the Subtitle C hazardous waste regulations for a number of reasons. First, healthcare workers, whose primary focus is to provide care for patients, are not knowledgeable about the RCRA hazardous waste regulations, but are often involved in the implementation of the regulations. Second, a healthcare facility can have thousands of items in its formulary, making it difficult to ascertain which ones are hazardous wastes when disposed. Third, some active pharmaceutical ingredients are listed as acute hazardous wastes, which are regulated in small amounts. To facilitate compliance and to respond to

these concerns, the U.S. Environmental Protection Agency (EPA or the Agency) is proposing to revise the regulations to improve the management and disposal of hazardous waste pharmaceuticals and tailor them to address the specific issues that hospitals, pharmacies and other healthcare-related facilities face. The revisions are also intended to clarify the regulation of the reverse distribution mechanism used by healthcare facilities for the management of unused and/or expired pharmaceuticals.

DATES: Comments must be received on or before November 24, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-HQ-RCRA-2007-0932, to the *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full

EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Kristin Fitzgerald, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703-308-8286; email address: fitzgerald.kristin@epa.gov or Josh Smeraldi, Office of Resource Conservation and Recovery (5304P), Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460; telephone number: 703-308-0441; email address: smeraldi.josh@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

Does this action apply to me?

This is a proposed rule. If finalized, this rule would apply to healthcare facilities, pharmaceutical reverse distributors, and owners or operators of treatment, storage, and disposal facilities engaged in the management of hazardous waste pharmaceuticals. The list of NAICS codes for the potentially affected entities, other than RCRA treatment, storage and disposal facilities (TSDFs), are presented in Table 1. More detailed information on the potentially affected entities is presented in Section V.A and Section V.B.1 of this preamble.

TABLE 1—NAICS CODES OF ENTITIES POTENTIALLY AFFECTED BY THIS FINAL RULE—HEALTHCARE FACILITIES AND PHARMACEUTICAL REVERSE DISTRIBUTORS

NAICS codes	Description of NAICS code
44611	Pharmacies.
54194	Veterinary Clinics.
6211	Physicians' Offices.
6212	Dentists' Offices.
6213	Other Health Practitioners (<i>e.g.</i> , chiropractors).
6214	Outpatient Care Centers.
6219	Other Ambulatory Health Care Services.
622	Hospitals.
6231	Nursing Care Facilities (<i>e.g.</i> , assisted living facilities, nursing homes, U.S. veterans domiciliary centers).
623311	Continuing Care Retirement Communities (<i>e.g.</i> , assisted living facilities with on-site nursing facilities).
Subset of 92219	Medical Examiners and Coroners' Offices.
Various NAICS	Pharmaceutical Reverse Distributors.

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities potentially impacted by this action. This table lists examples of the types of entities of which EPA is aware that could potentially be affected by this action. Other types of entities not listed could also be affected. To determine whether

your entity, company, business, organization, etc. is affected by this action, you should examine the applicability criteria in this rule. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the preceding **FOR FURTHER**

INFORMATION CONTACT section of this document.

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- II. List of Abbreviations and Acronyms
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 - B. What is the scope of this proposed rule?
 - C. What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?
 - D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?
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- XI. Summary of the Regulatory Impact Analysis
- XII. Statutory and Executive Order Reviews
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 - D. Unfunded Mandates Reform Act (UMRA)
 - E. Executive Order 13132: Federalism

- F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
- G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
- H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act (NTTAA)
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. Statutory Authority

These regulations are proposed under the authority of §§ 2002, 3001, 3002, and 3004 of the Solid Waste Disposal Act (SWDA) of 1970, as amended by the Resource Conservation and Recovery Act (RCRA) of 1976, as amended by the Hazardous and Solid Waste Amendments of 1984 (HSWA), 42 U.S.C. 6921, 6922, 6923, and 6924.

II. List of Abbreviations and Acronyms

- AARP American Association of Retired Persons
- AEA Atomic Energy Act
- API Active Pharmaceutical Ingredient
- BDAT Best Demonstrated Available Technology
- CERCLA Comprehensive Environmental Response, Compensation and Liability Act
- CESSQG Conditionally Exempt Small Quantity Generator
- CFR Code of Federal Regulations
- CSA Controlled Substances Act
- CWA Clean Water Act
- DEA Drug Enforcement Administration
- DHHS Department of Health and Human Services
- DOE Department of Energy
- DOT Department of Transportation
- EPA Environmental Protection Agency
- EO Executive Order
- FDA U.S. Food and Drug Administration
- FR Federal Register
- HIPAA Health Insurance Portability and Accountability Act
- HSWA Hazardous and Solid Waste Amendments
- LQG Large Quantity Generator
- LQUWH Large Quantity Universal Waste Handler
- LTCF Long-term Care Facility
- LTCP Long-term Care Pharmacy
- MSWLF Municipal Solid Waste Landfill
- NIOSH National Institute for Occupational Safety and Health
- NPRM Notice of Proposed Rulemaking
- NRC Nuclear Regulatory Commission
- OIG Office of Inspector General
- OMB Office of Management and Budget
- ONDCP Office of National Drug Control Policy
- OSHA U.S. Department of Labor's Occupational Safety and Health Administration
- OSWER Office of Solid Waste and Emergency Response
- OSWI Other Solid Waste Incinerators

- OTC Over-the-counter
- POTW Publicly Owned Treatment Works
- RCRA Resource Conservation and Recovery Act
- RQ Reportable Quantity
- SQG Small Quantity Generator
- SQUWH Small Quantity Universal Waste Handler
- SWDA Solid Waste Disposal Act
- TC Toxicity Characteristic
- TCLP Toxicity Characteristic Leaching Procedure
- TSDF Treatment, Storage and Disposal Facility

III. Summary of the Proposed Rule

EPA is proposing to add a subpart P under 40 CFR part 266. Part 266 is entitled, "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities." This new subpart P is a tailored, sector-specific regulatory framework for managing hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. If finalized, healthcare facilities that are currently small quantity generators (SQGs) or large quantity generators (LQGs) and all pharmaceutical reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under subpart P of 40 CFR part 266, instead of 40 CFR part 262. That is, the proposed standards are not an optional alternative to managing hazardous waste pharmaceuticals under 40 CFR part 262; they are mandatory standards.

Briefly, healthcare facilities will have different management standards for their non-creditable and creditable hazardous waste pharmaceuticals. Non-creditable hazardous waste pharmaceuticals (*i.e.*, those that are not expected to be eligible to receive manufacturer's credit) will be managed on-site similar to how they would have been under a previous proposal for managing these wastes: The 2008 Universal Waste proposal for pharmaceutical waste (73 FR 73520; December 2, 2008). When shipped off-site, they must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA interim status or permitted facility. On the other hand, healthcare facilities will continue to be allowed to send potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors for processing manufacturers' credit. In response to comments received on the Universal Waste proposal, EPA is proposing standards to ensure the safe and secure delivery of the creditable

hazardous waste pharmaceuticals to pharmaceutical reverse distributors.

EPA is also proposing standards for the accumulation of the creditable hazardous waste pharmaceuticals at pharmaceutical reverse distributors. Like healthcare facilities, pharmaceutical reverse distributors will not be regulated under 40 CFR part 262 as hazardous waste generators, nor will they be regulated under 40 CFR parts 264, 265 and 270 as treatment, storage, and disposal facilities (TSDFs). Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors. The proposed standards for pharmaceutical reverse distributors are, in many respects, similar to the LQGs standards, with supplementary standards added to respond to commenters' concerns.

For both healthcare facilities and reverse distributors, EPA is proposing to prohibit facilities from disposing of hazardous waste pharmaceuticals down the toilet or drain (*i.e.*, flushed or sewerred). Further, EPA proposes that hazardous waste pharmaceuticals managed under subpart P will not be counted toward calculating the site's generator category. Additionally, EPA is proposing a conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances. Finally, EPA is proposing management standards for hazardous waste pharmaceutical residues remaining in containers.

IV. Background

A. What is the history of hazardous waste pharmaceutical management under RCRA?

1. What Is the Resource Conservation and Recovery Act?

The Resource Conservation and Recovery Act governs the management and disposal of hazardous wastes.¹ Under Subtitle C of RCRA, EPA has established a comprehensive set of regulations for hazardous waste management, generation, transportation, treatment, storage, and disposal. EPA can authorize an individual state hazardous waste program to operate in lieu of the federal program provided the authorized state's program is at least as stringent as, and consistent with, the federal program.² However, EPA maintains oversight of the authorized

¹ RCRA also governs the disposal of non-hazardous solid wastes; however, state and/or local environmental regulatory agencies predominantly administer the regulations pertaining to the management of non-hazardous wastes.

² For more information on RCRA State Authorization, see: <http://www.epa.gov/osw/laws-regs/state/index.htm>.

state's hazardous waste program and the authority to take independent enforcement actions. RCRA regulates pharmaceutical wastes that meet a listing of hazardous waste or exhibit one or more characteristics of hazardous waste. Accordingly, hospitals, pharmacies, reverse distributors and other healthcare-related establishments that generate hazardous wastes, including hazardous waste pharmaceuticals, are required to manage and dispose of their hazardous wastes in accordance with applicable federal, state, and/or local environmental regulations.

2. What are the current standards for generators of hazardous waste?

Currently, there are no RCRA Subtitle C regulations that focus specifically on the management of hazardous wastes from hospitals, pharmacies, reverse distributors and other healthcare-related facilities. Rather, healthcare facilities are currently required to comply with the same RCRA hazardous waste regulations as many other industries that generate hazardous waste. While the RCRA Subtitle C program has requirements for all aspects of hazardous waste management, including those generating (referred to as "generators" by RCRA), transporting, storing, treating, and disposing of hazardous wastes, it is the generator requirements found under 40 CFR part 262 that will typically be most pertinent to healthcare-related facilities.

Under the federal RCRA regulations, the standards for hazardous waste generators are divided into three categories—LQGs, SQGs, and Conditionally Exempt Small Quantity Generators (CESQGs) depending upon the total amount of hazardous waste a facility generates per calendar month. It is the facility's generator category that determines the applicable RCRA hazardous waste management requirements with which the generator must comply.³

A generator that generates a solid waste⁴ is required by § 262.11 to determine whether such waste meets the definition of RCRA hazardous waste.⁵ If the waste meets the RCRA

³ For more information on hazardous waste generators, please see: <http://www.epa.gov/waste/hazard/generation/index.htm>.

⁴ See 40 CFR 261.2 for the definition of solid waste.

⁵ The waste determination process includes determining if the waste is specifically excluded or exempted from the RCRA hazardous waste regulations. If not, then the entity must determine if the waste is listed by EPA under the F-, K-, P- or U-lists of hazardous wastes (§§ 261.31–33). If the waste is not listed, then it must be determined if the waste exhibits a characteristic of a hazardous

definition of a hazardous waste, then the generator must manage the waste in accordance with the regulations that apply to its hazardous waste generator category (see § 261.5 and 40 CFR part 262 for the generator regulations). In particular:

- Facilities qualify as LQGs if in a calendar month they generate 1,000 kg or more of hazardous waste or more than 1 kg of acute hazardous waste (*i.e.*, P-listed waste), or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31 or 261.33(e). Federal regulations for LQGs include, but are not limited to the following: Obtaining an EPA Identification number; a 90-day limit for accumulating hazardous waste on-site (with relevant standards for the accumulation of hazardous waste) without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions for exemption set forth in § 262.34(a) such as management and labeling standards specific to the type of accumulation unit (*e.g.*, container, tank); RCRA training of personnel; contingency planning; manifesting and recordkeeping and reporting (biennial report).

- Facilities qualify as SQGs if in a calendar month they generate more than 100 kg but less than 1,000 kg of hazardous waste. SQGs are subject to fewer requirements than LQGs and are given additional flexibility. For example, SQGs have a longer on-site accumulation time limit (180 or 270 days vs. 90 days for LQGs), with fewer standards for the accumulation of hazardous waste, without having to obtain a RCRA permit or comply with the interim status standards, provided that they comply with the conditions set forth in § 262.34(d) (which have fewer personnel training and contingency planning obligations than in the conditions for exemption for LQGs); and do not need to complete a biennial report (BR).

- Facilities qualify as CESQGs if in a calendar month they generate less than or equal to 100 kg of hazardous waste, and less than or equal to 1 kg of acutely hazardous waste (*i.e.*, P-listed), and less than or equal to 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in

waste: Ignitability, corrosivity, reactivity, or toxicity (§§ 261.21–24).

§§ 261.31, or 261.33(e).⁶ CESQGs are subject to very few of the RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5(f)(3) and (g)(3).

Finally, under the household hazardous waste exemption in § 261.4(b)(1), hazardous wastes generated by households are not subject to the RCRA hazardous waste regulations. This exemption from the Subtitle C requirements extends to any household wastes collected during community-oriented take-back programs or events, as long as these collected household hazardous wastes are managed separately from regulated hazardous wastes.⁷ However, while collected household hazardous wastes are not regulated under the federal standards, more stringent state standards may apply.

3. Are pharmaceuticals considered hazardous wastes under RCRA?

A portion of the pharmaceuticals currently on the market meets RCRA's definition of hazardous waste when discarded. As previously explained, it is the responsibility of the generator of a solid waste to determine if the waste is hazardous; this includes solid wastes that are pharmaceuticals. If the pharmaceutical waste meets RCRA's definition of hazardous waste, then the generator must manage it in accordance with all applicable federal, state, and/or local environmental regulations. A pharmaceutical is considered a hazardous waste under RCRA in one of two ways. First, a discarded pharmaceutical can be a listed hazardous waste if it is a commercial chemical product⁸ that is listed under RCRA's P- or U-list, and the pharmaceutical has not been used for its intended purpose (§ 261.33 (e) and (f),

respectively).⁹ A few examples of pharmaceuticals that are considered P-listed wastes when discarded are arsenic trioxide (P012), smoking cessation products with nicotine as the sole active ingredient (P075), and pharmaceuticals with greater than 0.3% warfarin (and salts) as the sole active ingredient, such as Coumadin (P001). Some examples of pharmaceuticals that are considered U-listed wastes are: Cyclophosphamide (U058), mitomycin C (U010), streptozotocin (U206) and warfarin and salts ($\leq 0.3\%$) as the sole active ingredient (U248).

Second, if the discarded pharmaceutical is not on the P- or U-list, then the pharmaceutical may be a hazardous waste if it exhibits one or more of the hazardous waste characteristics. Under the federal requirements (§ 261.21–24), a waste is a characteristic hazardous waste if it is ignitable (D001), corrosive (D002), reactive (D003) or toxic (D004–D043).¹⁰ A number of pharmaceuticals are prepared in alcohol, which may cause the waste to be hazardous due to ignitability (D001), even if the active pharmaceutical ingredient itself is not considered hazardous waste. The Regulatory Impact Analysis for this proposed rule includes a list of pharmaceuticals that, to our knowledge, are hazardous waste when disposed, although this list should not be considered exhaustive (see the docket for this proposed rule EPA–HQ–RCRA–2007–0932).

Since the hazardous waste rules were initially promulgated, EPA has issued several clarifications regarding the regulatory status of certain commercial chemical products on the P- and U-lists, and these clarifications have affected the regulatory status of some active pharmaceutical ingredients.¹¹ For

example, EPA recently clarified that phentermine hydrochloride and other phentermine salts are not included within the scope of the P046 (phentermine) listing.¹² Similarly, EPA has also clarified that epinephrine salts are not included in the epinephrine listing (P042).¹³ In addition, medicinal nitroglycerin typically is not considered P081 since the medicinal form of this compound generally does not exhibit the characteristic of reactivity for which nitroglycerin was originally listed.¹⁴ Furthermore, in a 1998 memo, EPA clarified that the U034 listing includes both anhydrous chloral and chloral hydrate.¹⁵ And in a 2010 memo, EPA stated that unused nicotine patches, gums and lozenges are finished dosage forms of nicotine and therefore are regulated as P075 when discarded.¹⁶

Finally, EPA has developed a “Hazardous Waste Pharmaceuticals Wiki” as a platform to facilitate the sharing of expertise among the healthcare industry and other stakeholders in order to help make accurate hazardous waste determinations for waste pharmaceuticals and increase compliance with the hazardous waste regulations. The Hazardous Waste Pharmaceuticals Wiki will also help users find guidance documents, state-specific information, and manufacturers' information. The Hazardous Waste Pharmaceuticals Wiki can be viewed at: <http://hwpharms.wikispaces.com>. EPA encourages healthcare stakeholders to use the Wiki to share information regarding federal hazardous waste

⁶ EPA recommends that facilities that qualify as CESQGs under the federal regulations contact their state and/or local environmental regulatory agencies, as authorized states can be more stringent than the federal regulations. As a result, not all authorized states recognize the CESQG category or they may have more stringent regulatory requirements for CESQGs.

⁷ For clarification on household hazardous waste collection issues, please see the November 1, 1988 memo from Win Porter to the Regional Waste Management Division Directors (RCRA Online # 11377) at: [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/\\$file/11377.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf).

⁸ Commercial chemical product refers to a chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed and all formulations in which the chemical is the sole active ingredient (§ 261.33(d)).

⁹ The P- and U-lists deem as hazardous certain commercial chemical products when they are discarded or intended to be discarded. These listings consist of commercial chemical products having the generic names listed, off-specification species, container residues, and spill residues. Chemicals on the P-list are identified as acute hazardous wastes and are regulated at lower amounts than those on the U-list.

¹⁰ The toxicity characteristic (TC) indicates that the waste is likely to leach concentrations of contaminants that may be harmful, and TC waste is identified using the Toxicity Characteristic Leaching Procedure (see § 261.24). Examples of TC constituents that may be present in pharmaceuticals include, but are not limited to: Arsenic, barium, cadmium, selenium, silver, chloroform, lindane and m-cresol.

¹¹ In addition, in December 2008, the Agency proposed to regulate hazardous waste pharmaceuticals under the Universal Waste rule. However, based on the comments received, the Agency decided not to finalize that proposal and to proceed with a sector-based approach. (See section IV.C. of the preamble for further discussion of the Universal Waste proposal.)

¹² Memo from Devlin to RCRA Division Directors, February 17, 2012 (RCRA Online #14831) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A5C07D01188ECA59852579EA0067CDB1/\\$file/14831.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A5C07D01188ECA59852579EA0067CDB1/$file/14831.pdf).

¹³ Memo December 1, 1994 (RCRA Online #13718) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/\\$file/13718.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf).

¹⁴ Memo from Dellinger to Smith, March 18, 2003 (RCRA Online #14654) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/\\$file/14654.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7ACFEC572DE8897F85256D1600748BCB/$file/14654.pdf).

¹⁵ Memo from Brandes to Knauss, April 6, 1998 (RCRA Online #14175) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7417D2556AD322FA852568E300468198/\\$file/14175.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/7417D2556AD322FA852568E300468198/$file/14175.pdf).

¹⁶ Memo from Dellinger to Smith, August 23, 2010 (RCRA Online #14817) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD4ECDC852577ED00624E8F/\\$file/14817.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD4ECDC852577ED00624E8F/$file/14817.pdf).

pharmaceuticals, as well as state-only hazardous waste pharmaceuticals.¹⁷

B. What are the rationale and goals for this proposed rule?

1. Sector-Based Approach

The impetus behind this proposal is to address the various concerns raised by stakeholders regarding the difficulty in implementing the Subtitle C hazardous waste regulations for the management of hazardous waste pharmaceuticals generated at healthcare facilities. EPA has met with various stakeholders to learn about compliance challenges, and it has received input from stakeholders through more formal mechanisms. For instance, when EPA solicited stakeholder input in response to Executive Order 13563 (Improving Regulation and Regulatory Review), retailers submitted comments detailing compliance challenges with hazardous waste pharmaceuticals in their stores.¹⁸ Further, EPA's Office of Inspector General (OIG) published a report citing the need to clarify how hazardous waste pharmaceuticals are regulated (for more information on both of these reports, see the next section). These two reports and input from healthcare (and associated) facilities identified a number of ways in which a healthcare facility differs from a manufacturing facility when it comes to applying the RCRA Subtitle C program for generating and managing hazardous waste.

First, in the healthcare setting, many hazardous waste pharmaceuticals are generated unpredictably and in relatively small quantities by a number of different employees across the facility. This situation differs from a manufacturing facility where fewer employees in a few locations generate comparatively much larger volumes of a smaller range of hazardous wastes.

Second, under the current hazardous waste regulatory scheme, healthcare workers, whose primary focus is to provide care for patients, are typically responsible for making hazardous waste determinations since they are at the point of generation (e.g., a patient's bedside). Yet, healthcare workers, such as nurses and doctors, do not typically

have the expertise to make hazardous waste determinations.

Third, a healthcare facility can have thousands of items in its formulary at any one time and these may vary over time. In addition, pharmaceutical wastes come in many different forms, such as pills, patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare workers to make appropriate hazardous waste determinations when pharmaceuticals are disposed. This situation differs from manufacturing, where fewer, more predictable waste streams are generated.

Fourth, several of the hazardous waste pharmaceuticals that are generated by healthcare facilities are P-listed acute hazardous wastes (see § 261.33(e)), which are regulated at much smaller amounts. If a facility generates more than 1 kg of acute hazardous waste per calendar month or accumulates that amount at any time, it is regulated as an LQG. In addition to the pharmaceuticals, residues within pharmaceutical containers that contained P-listed commercial chemical products must be managed as acute hazardous waste even if the pharmaceutical was fully dispensed,¹⁹ unless the container is RCRA-empty (e.g., by triple-rinsing the container). Triple rinsing can be impractical with certain medical devices, such as syringes and paper cups, so healthcare facilities often end up managing these containers as hazardous waste, which can result in the facilities being subject to the most stringently regulated generator category (i.e., LQG).²⁰

To facilitate compliance among healthcare facilities and to respond to these concerns, EPA is proposing a new set of sector-specific regulations to

improve the management and disposal of hazardous waste pharmaceuticals at healthcare facilities. This proposed rule also intends to clarify the regulatory status of a major practice used by healthcare facilities for management of unused and/or expired pharmaceuticals, known as reverse distribution (see Sections V.D.1 and V.G).

In addition to improving compliance and responding to stakeholder concerns, the Agency has two additional goals for this proposal. The first is to reduce the amount of pharmaceuticals that are disposed of "down the drain." This is presently an allowable and common disposal practice among healthcare facilities (as long as the pharmaceutical waste is not ignitable (see the Clean Water Act regulations of 40 CFR 403.5(b)(1)) and provided certain conditions are met (see the Clean Water Act regulations of 40 CFR 403.12(p)). Studies have found that many healthcare facilities, particularly long term-care facilities, are using drain disposal as a routine disposal method for pharmaceutical wastes. Although pharmaceuticals are also entering the environment through excretion, reducing sewer disposal is one mechanism to help reduce the environmental loading of pharmaceuticals into our Nation's waters. For more information about sewer disposal and pharmaceuticals in water, see Section V.E.1.

The second goal is to address the overlap between EPA's RCRA hazardous waste regulations and the controlled substances regulations of the Drug Enforcement Administration (DEA). Stakeholders have indicated that hazardous waste pharmaceuticals that are also controlled substances are stringently regulated and expensive to dispose of in accordance with both sets of requirements when sent for incineration. In addition, stakeholders have indicated that those regulated hazardous waste pharmaceuticals that are also controlled substances are most likely to be sewer disposed to avoid the costs of compliant incineration. EPA plans to address this overlap in this proposed rule, as this is an unnecessary burden for healthcare facilities and revised requirements will help to reduce sewer disposal.

2. Executive Order 13563 for the Retrospective Review of Existing Regulations

On January 18, 2011, President Obama issued Executive Order 13563, which directed all federal agencies to perform periodic retrospective reviews of existing regulations to determine whether any should be modified,

¹⁷ Anyone may view the Wiki. Those in the healthcare community who wish to contribute content or edit the Wiki can register by sending an email request to HWPharmsWiki@epa.gov.

¹⁸ Executive Order 13563 was signed by President Obama on January 18, 2011 and published in the **Federal Register** on January 21, 2011 (76 FR 3821). In response to the Executive Order, EPA solicited comments on "Improving EPA Regulations," in a **Federal Register** notice published on February 23, 2011 (76 FR 9988). See docket number EPA-HQ-OA-2011-0160 for public comments related to waste.

¹⁹ P-listed hazardous waste residues in containers are themselves considered P-listed hazardous wastes (see § 261.33(c)), unless the container is considered "RCRA empty" either by undergoing triple-rinsing with an appropriate solvent; or cleaning with a method that has been proven in scientific literature or tests conducted by the generator to achieve equivalent removal (see § 261.7(b)(3)).

²⁰ On November 4, 2011, ORCR issued a memo to the Regional RCRA Division Directors highlighting three acceptable approaches, beyond triple-rinsing containers, that healthcare facilities can employ when managing P-listed container residues. Please see: Memo from Suzanne Rudzinski to RCRA Division Directors (RCRA Online #14827) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/\\$file/14827.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/57B21F2FE33735128525795F00610F0F/$file/14827.pdf).

streamlined, expanded, or repealed.²¹ EPA made its preliminary plan available for public review and comment during the spring of 2011 and released the final version of the plan in August 2011.²² During the public comment process, EPA received requests to clarify and make more effective the hazardous waste regulations as they pertain to discarded retail products, including pharmaceutical wastes. In response to this specific issue, EPA agreed to review data and information currently in its possession as part of the development for a rulemaking to address pharmaceutical waste management issues.²³ This Notice of Proposed Rulemaking provides notice that EPA has completed its review and has satisfied this part of its obligation for retail hazardous waste pharmaceutical management issues.

3. Retail Notice of Data Availability

EPA published a Notice of Data Availability (NODA) for the Retail Sector on February 14, 2014 (79 FR 8926), in which the Agency requested, among other things, comment on a series of topics related to retail operations in order to better understand the issues retail stores/establishments face in complying with RCRA regulations. Many retail commenters mentioned that because nicotine is an acute hazardous waste (P075), they are considered LQGs when they discard more than 1 kg per month of unused nicotine-containing products (e.g., e-cigarettes and smoking cessation products such as gums, patches and lozenges). Retailers discard these products mainly because they are either expired or they are returned by customers and the retailer does not restock them due to safety concerns. In comments to the NODA, retailers urged the EPA to provide them some regulatory relief with regard to nicotine-containing products. See Section VIII of this preamble for a discussion of EPA's potential future efforts to amend the acute hazardous waste listing for nicotine and salts (P075).

²¹ For a copy of Executive Order 13563, please see: <http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf>.

²² US EPA. Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations. <http://www.epa.gov/regdart/retrospective/documents/eparetroreviewplan-aug2011.pdf>.

²³ See page 45, item 2.2.17 of EPA's "Improving Our Regulations: Final Plan for Periodic Retrospective Reviews of Existing Regulations" at <http://www.epa.gov/regdart/retrospective/documents/eparetroreviewplan-aug2011.pdf>.

C. What was the 2008 Pharmaceutical Universal Waste proposal?

1. The 2008 Proposal To Add Hazardous Waste Pharmaceuticals to the Federal Universal Waste Program

On December 2, 2008, EPA proposed to add hazardous waste pharmaceuticals to the existing federal universal waste program, which would have provided a streamlined approach to facilitate the proper management and disposal of hazardous waste pharmaceuticals generated at pharmacies, hospitals, reverse distributors, and other healthcare-related facilities. Specifically, under the universal waste program, handlers and transporters who generate or manage items designated as a universal waste²⁴ are subject to the management standards under part 273, rather than the full RCRA subtitle C hazardous waste regulations. Universal waste handlers include universal waste generators and collection facilities. The regulations distinguish between "large quantity handlers of universal waste" (or those who handle more than 5,000 kilograms of total universal waste at any one time) and "small quantity handlers of universal waste" (or those who handle 5,000 kilograms or less of universal waste at any one time).²⁵ The streamlined requirements for all types of universal waste include modified requirements for storage, labeling and marking, preparing the waste for shipment off-site, employee training, response to releases and notification.

Transporters of universal waste are also subject to less stringent requirements than the full RCRA subtitle C hazardous waste transportation regulations. However, the primary difference between the universal waste transportation requirements and full RCRA subtitle C requirements is that no hazardous waste manifest is required for the transport of universal waste.

Destination facilities under the universal waste program are those facilities that treat, store, dispose of, or recycle universal wastes. Universal waste destination facilities are subject to all currently applicable requirements for hazardous waste treatment, storage, and disposal facilities (TSDFs), including the requirement to obtain a RCRA permit for such activities. (See 73 FR 73520, December 2, 2008, for a more detailed discussion of the proposed

²⁴ The current federal universal wastes include hazardous waste batteries, certain hazardous waste pesticides, mercury-containing equipment, and hazardous waste lamps.

²⁵ The 5,000 kilogram accumulation criterion applies to the quantity of all universal wastes accumulated.

universal waste program for pharmaceutical wastes.)

2. What were the public comments to the 2008 Pharmaceutical Universal Waste proposal?

EPA received approximately 100 public comments on the 2008 proposal to add hazardous waste pharmaceuticals to the universal waste program.²⁶ Generally, public commenters supported the Agency's desire to address the issue of hazardous waste pharmaceutical management. However, although there were several aspects of the proposal that were well supported (e.g., training requirements, accumulation times, and hazardous waste pharmaceuticals not being counted towards the generator category), public commenters expressed concern over the lack of notification and tracking requirements for small quantity handlers of universal waste and the reduced notification and tracking requirements for large quantity handlers. As a result, commenters, including state environmental regulatory agencies, expressed concern that they would not be informed of hazardous waste pharmaceutical generation, management, and transportation in their regulatory jurisdictions. Furthermore, public commenters expressed concern that because the universal waste program does not require a hazardous waste manifest or another tracking mechanism, the hazardous waste pharmaceuticals could be vulnerable to diversion. Public commenters argued that hazardous waste pharmaceuticals are different from the other federal universal wastes (batteries, mercury-containing equipment, lamps, and pesticides) in that the pharmaceuticals, as well as their containers, still retain considerable value upon disposal and can be easily diverted for illicit purposes. Therefore, tracking requirements beyond the requirements included in the current universal waste program were considered necessary by the majority of the public commenters.

In addition to the public comments about the strengths and weaknesses of using the universal waste program to address the disposal of hazardous waste pharmaceuticals, EPA received other comments expressing concern with the proposal, including the following: The point of generation of hazardous waste pharmaceuticals as it pertains to reverse distribution; the management of

²⁶ See docket EPA-HQ-RCRA-2007-0932 at www.regulations.gov for public comments: <http://www.regulations.gov/#1docketDetail;D=EPA-HQ-RCRA-2007-0932;ct=FR%252BPR%252BN%252BO%252BSR>.

containers that contain hazardous waste pharmaceutical residues; the variability in the land disposal restriction (LDR) treatment standards for hazardous waste pharmaceuticals; the overlap of EPA and DEA regulations for the management of hazardous waste pharmaceuticals that are also controlled substances; and the lack of activity to add pharmaceutical wastes to the hazardous waste listings. The Agency provides additional discussion on these specific comments within this preamble.

3. Why is EPA not finalizing the 2008 Pharmaceutical Universal Waste proposal?

Based on the adverse comments received on the 2008 Pharmaceutical Universal Waste proposal regarding the lack of notification and tracking requirements for small quantity universal waste handlers, the reduced notification and tracking requirements for large quantity universal waste handlers, as well as the other issues raised in public comments, the Agency has decided to not finalize the proposal to add hazardous waste pharmaceuticals to the Universal Waste program. In fact, EPA has concluded that the universal waste program is not appropriate for managing hazardous waste pharmaceuticals because, among other things, we are unable to adequately address the notification and tracking concerns raised by the public comments within the Universal Waste program.

Under the Universal Waste regulations, there are eight factors to consider when determining whether it is appropriate to add a new hazardous waste or category of hazardous waste to the Universal Waste program (§ 273.81). A hazardous waste does not need to meet every factor in order to be added to the Universal Waste program. Rather, the Agency's decision is "based on the weight of evidence showing that regulation under part 273 is appropriate for the waste or category of waste, will improve management practices for the waste or category of waste, and will improve implementation of the hazardous waste program" (§ 273.80(c)).

The Agency has concluded based on the comments received that the weight of evidence does not show that regulation under the Universal Waste program is appropriate for hazardous waste pharmaceuticals. Specifically, we find the Universal Waste program to be lacking with regard to the factor in § 273.81(e), which states that the risk posed by the waste being considered for universal waste be relatively low compared to other hazardous wastes and that the management standards

would be protective of human health and the environment during accumulation and transport. Although we continue to believe that potentially creditable pharmaceuticals en route to reverse distributors pose a low risk for leaks and other releases to the environment, commenters urged us to consider the unique risk posed by the accumulation and transport of hazardous waste pharmaceuticals: the risk of diversion. Although it is rare that a hazardous waste is so valuable that it is sought for abuse or sale on the black market, EPA believes that the diversion of hazardous waste pharmaceuticals for illicit use is a risk to human health.

The Universal Waste program does not include sufficient tracking requirements to address the potential for diversion. Under part 273, tracking is not required for shipments by small quantity handlers of universal waste; certain tracking of shipments is required only for large quantity handlers of universal waste and destination facilities. More importantly, these basic tracking requirements consist only of recordkeeping of shipments sent and received and no tracking is required to ensure delivery. Commenters noted that these tracking requirements are not sufficient given the high value of many of the unused pharmaceuticals en route to reverse distribution and the potential for diversion.

Accordingly, the Agency is proposing to amend § 273.80 to state that hazardous waste pharmaceuticals may not be added as a category of hazardous waste for management under the Universal Waste program. See Section IX State Authorization of the preamble for a discussion on the effect on the two states that have adopted pharmaceuticals under the Universal Waste program (Michigan and Florida).

By proposing a new set of management standards outside the confines of the Universal Waste program, it allows us greater flexibility in addressing the tracking of such shipments, as well as additional pharmaceutical waste management issues raised by stakeholders, such as drain disposal, container residues, pharmaceutical reverse distribution, and the overlap with DEA regulation. This new action will address the original stakeholder concerns that resulted in the 2008 Pharmaceutical Universal Waste proposal, as well as the comments received on that proposal.

To reiterate, EPA is not adding hazardous waste pharmaceuticals to the federal Universal Waste program. Rather, we are proposing sector-specific regulations for the management of hazardous waste pharmaceuticals by

healthcare facilities and pharmaceutical reverse distributors. If finalized, these regulations will be codified in 40 CFR part 266, separate from both the generator regulations (40 CFR part 262) and the Universal Waste program (40 CFR part 273). This new proposed rulemaking will pertain to those waste pharmaceuticals that meet the current definition of a RCRA hazardous waste *and* are generated by healthcare-related facilities and managed by pharmaceutical reverse distributors, as defined by this proposal. Finally, as this current proposal is a direct result of the comments received on the December 2, 2008, Pharmaceutical Universal Waste proposal, the Agency considers the 2008 Pharmaceutical Universal Waste proposal obsolete. Therefore, EPA is withdrawing the Universal Waste proposal for pharmaceutical waste, and does not seek comment on any provisions of the 2008 Pharmaceutical Universal Waste proposal or the current Universal Waste program. The Agency will only be accepting comments from the public on the provisions of this new proposed rulemaking.

D. EPA's Office of Inspector General Report

On May 25, 2012, the EPA's Office of Inspector General (OIG) issued the report, "EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal" (Report No. 12-P-0508).²⁷ The OIG reviewed EPA's process for identifying and listing pharmaceuticals as hazardous wastes. Because of this review, the OIG provided the following recommendations to the Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER):

(1) Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(2) Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

(3) Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that healthcare facilities, and others as needed, have in complying with RCRA regulations for managing HWP's [hazardous waste pharmaceuticals] (Report No. 12-P-0508).

As detailed in OSWER's response to OIG, this proposal fulfills our obligation

²⁷ For a copy of the report, please see: <http://www.epa.gov/oig/reports/2012/20120525-12-P-0508.pdf> or see the docket for this proposed rule: EPA-HQ-RCRA-2007-0932.

for addressing the third recommendation.²⁸ EPA does not address the OIG's first two recommendations as part of this proposed rulemaking; however, in Section VII of this preamble, we solicit comment on our ongoing efforts to identify additional pharmaceuticals as hazardous wastes.

V. Detailed Discussion of the Proposed Rule

EPA is proposing an entirely new set of regulations (40 CFR part 266, subpart P) for managing hazardous waste pharmaceuticals at both healthcare facilities and pharmaceutical reverse distributors. This section discusses in detail the major features of the proposal. The Agency also presents other options that it is considering or were considered in developing the proposed rule. EPA welcomes comments on all aspects of this proposed rule, and on options under consideration. Throughout this section, EPA requests comments on specific options and on specific issues, but comments are welcome on all provisions of this proposal.

A. What terms are defined in this proposed rule?

All the definitions that appear in this proposal are for the purposes of 40 CFR part 266, subpart P only. Therefore, the definitions are relevant only to healthcare facilities and pharmaceutical reverse distributors that are subject to these proposed standards. For the purposes of this regulation, the Agency is proposing and soliciting public comment on the following terms and their definitions presented below: "evaluated hazardous waste pharmaceutical," "hazardous waste pharmaceutical," "healthcare facility," "household waste pharmaceutical," "long-term care facility," "non-creditable hazardous waste pharmaceutical," "non-hazardous waste pharmaceutical," "non-pharmaceutical hazardous waste," "pharmaceutical," "pharmaceutical reverse distributor," and "potentially creditable hazardous waste pharmaceutical." Although the proposed definitions appear in alphabetical order in the regulations, we have chosen to discuss the proposed definitions in a different order in the preamble.

1. What is the proposed definition of "pharmaceutical"?

This proposed rule defines "pharmaceutical" as any chemical or

biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act (FD&C Act), prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from the spills of pharmaceuticals.

This proposed definition of "pharmaceutical" is intended to include all dose forms, including, but not limited to tablets, capsules, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy pharmaceuticals, vaccines, allergenics, medicinal shampoos, antiseptics, and any delivery device, including medicinal dermal patches, with the primary purpose to deliver or dispense the pharmaceutical. As a rule of thumb, if an over-the-counter product is required by the FDA to include "Drug Facts" on the label, it would be considered a pharmaceutical for the purposes of this rule. EPA asks for comment to identify additional types or forms of pharmaceuticals that are not adequately captured by the definition.

EPA previously proposed to define the term "pharmaceutical" in the December 2008 Pharmaceutical Universal Waste proposal to mean "any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or injury in man or other animals; or any chemical product, vaccine, or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine, or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or biohazard waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated

cleaning materials." This definition was adapted from FD&C Act's definition for "drug" 21 U.S.C. 321(g).

Based on the comments received in response to the Pharmaceutical Universal Waste proposal, the Agency is continuing to rely primarily on the FD&C Act's definition for "drug" for the definition of pharmaceutical in this proposal and has preserved most of the definition proposed in the previous proposal. However, EPA is proposing to expand on its previous proposed definition of pharmaceutical based on stakeholder input. In particular, stakeholders requested that the Agency take a broad view in delineating what items are included in the definition of pharmaceutical so that the proposed standards apply broadly. Stakeholders indicated a preference for managing more items under the new standards than trying to determine how to apply the existing RCRA framework to pharmaceutical related items. Thus, the proposed definition of pharmaceutical no longer excludes pharmaceuticals with a radioactive component and includes items not specifically recognized by the U.S. Food and Drug Administration (FDA) as drugs, such as dietary supplements and pharmaceutical residues in containers (including delivery devices), personal protective equipment contaminated with residues of pharmaceuticals, and clean-up material from spills of pharmaceuticals.

EPA's decision to include dietary supplements under this rulemaking's proposed definition of hazardous waste pharmaceutical reflects our interest in promoting a management scheme for all types of pharmaceuticals, and is based upon our understanding that dietary supplements are commonly found in various healthcare settings because they are recommended or prescribed by healthcare providers to patients.²⁹ Further, retail pharmacies routinely sell vitamins and other medicinal minerals and supplements.

When EPA uses the term "dietary supplements" in our proposed definition of "pharmaceutical," EPA is referencing the definition for dietary supplement used by the FD&C Act, as amended by the Dietary Supplement Health and Education Act of 1994 (21 U.S.C. 321(ff)).³⁰ EPA understands that

²⁹ Including dietary supplements under the definition of pharmaceutical for this regulation does not supersede the requirements of the Dietary Supplement Health and Education Act of 1994, the Federal Food, Drug and Cosmetic Act, or FDA regulations.

³⁰ The substance of the definition is: a product (other than tobacco) intended to supplement the

²⁸ For a copy of OSWER's full response to OIG, please see: http://www.epa.gov/oig/reports/2012/12-P-0508_Agency%20Response.pdf.

the FDA does not recognize dietary ingredients or dietary supplements under its definition of “drug,” but rather categorizes such items under the general umbrella of foods and therefore, does not review them before being marketed.^{31 32} For the purposes of this proposed rule, however, EPA recognizes that healthcare facilities may benefit from managing dietary supplements along with other drugs under the regulatory scheme being proposed, and thus, is including it in the proposed definition of pharmaceutical. Although dietary supplements would be considered pharmaceuticals under this proposed definition, only the dietary supplements that meet the definition of hazardous waste (e.g., exhibits the toxicity characteristic for metal content) would be regulated under part 266, subpart P as hazardous waste pharmaceuticals (see the definition of “hazardous waste pharmaceutical”). We seek public comment on the Agency’s decision to recognize dietary supplements as pharmaceuticals under this regulation.

The Agency also is clarifying that its proposed definition includes any items containing pharmaceutical residuals, such as dispensing bottles, IV bags and tubing, vials, unit dose packages, and delivery devices, such as syringes and patches. In addition, EPA is proposing that items contaminated with or containing residual pharmaceuticals, such as personal protective equipment containing trace amounts of pharmaceuticals or related spill clean-up materials (including loose tablets accumulated during pharmacy floor sweepings) also meet this proposed definition of pharmaceutical. However, this proposed definitions does *not* include sharps (e.g., needles from IV bags or syringes). Used sharps, such as needles or syringes with needles, are not included under the proposed rule because sharps are considered medical

diet that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described in clause (A), (B), (C), (D), or (E); For the complete definition for dietary supplement, please see: <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/pdf/USCODE-2013-title21-chap9-subchapII-sec321.pdf>.

³¹ For more information regarding dietary supplements, please see: <http://www.fda.gov/Food/DietarySupplements/default.htm>.

³² It is the responsibility of the manufacturers to ensure their dietary supplements are safe and that all claims on labels are true and accurate. Nevertheless, FDA has the authority to take action against any unsafe dietary supplements, as well as to take action against any products with false and misleading claims.

wastes, presently regulated at the state and local level. In addition, sharps pose both an unreasonable physical danger and biohazard danger so have not been included in the definition of pharmaceutical under this proposed rule. OSHA’s Technical Manual incorporates a recommendation from the American Society of Hospital Pharmacists that “all syringes and needles used in the course of preparation be placed in “sharps” containers for disposal without being crushed, clipped or capped.”³³ Further, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation. However, EPA is concerned about the possibility that some syringes may be disposed of in sharps containers that may contain significant amounts of undispensed pharmaceutical. EPA seeks comment on the prevalence of this situation.

The Agency solicits public comment on the proposed definition of “pharmaceutical” in its entirety, and particularly on EPA’s decision to incorporate dietary supplements and items containing pharmaceutical residuals as part of the definition of pharmaceutical.

2. What is the proposed definition of a “hazardous waste pharmaceutical”?

This proposed rule defines “hazardous waste pharmaceutical” as a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C. See Section IV.A.3. of this preamble for a discussion of pharmaceuticals that may be listed or characteristic hazardous wastes.³⁴

The Agency is proposing to define the term “hazardous waste pharmaceutical” in order to clarify its intent that only pharmaceuticals (as defined in this proposal) that meet the definition of hazardous waste when disposed or discarded need to be managed under these proposed management standards. This means that any pharmaceutical waste that meets the definition of hazardous waste is a hazardous waste pharmaceutical for the purposes of this rule. For example, the prescription pharmaceutical warfarin (brand name Coumadin) is a listed hazardous waste

³³ See Section VI, Chapter 2 of OSHA’s Technical Manual (paragraph V.C.1.b.) https://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.

³⁴ For additional information about RCRA hazardous waste listings and characteristics, see: <http://www.epa.gov/osw/hazard/wastetypes/index.htm>.

and when discarded meets the definition of a hazardous waste pharmaceutical. EPA requests public comment on the proposed definition for “hazardous waste pharmaceutical.” The Agency also solicits information on whether any dietary supplements currently on the market meet or potentially could meet RCRA’s definition of a hazardous waste.

3. What is the proposed definition of a “potentially creditable hazardous waste pharmaceutical”?

In order to distinguish hazardous waste pharmaceuticals that are transported to RCRA treatment, storage and disposal facilities (TSDFs) from those hazardous waste pharmaceuticals being returned by a healthcare facility to a pharmaceutical reverse distributor for a determination or verification of manufacturer’s credit, the Agency is proposing a definition for “potentially creditable hazardous waste pharmaceutical.”

The proposed rule defines “potentially creditable hazardous waste pharmaceutical” to mean a hazardous waste pharmaceutical that has the potential to receive manufacturer’s credit and is

- (1) unused or un-administered; and
- (2) unexpired or less than one year past expiration date.

The term does not include “evaluated hazardous waste pharmaceuticals,” residues of pharmaceuticals remaining in containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals.

Whether a pharmaceutical is eligible for manufacturer’s credit is determined solely by the manufacturer’s return policy. Based on comments received for the 2008 Universal Waste proposed rule and through discussions with various stakeholders, the Agency understands that the return policies of manufacturers change regularly. As a result, pharmacies are not always aware if a particular pharmaceutical will be creditable at the time that it is pulled from the shelves. However, the Agency also understands that there are instances where it is well known that a pharmaceutical will not be creditable. Examples of these instances include the following: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which

they had already received compensation by a third-party payer; or if the pharmaceutical is more than one year past its expiration date. In these instances, as well as others, the healthcare facility knows that it will not receive manufacturer's credit. It is the Agency's intent for the proposed definition of potentially creditable hazardous waste pharmaceuticals to allow the return of hazardous waste pharmaceuticals to reverse distributors for the determination of credit. It is not the Agency's intent, however, for reverse distributors to serve in the capacity as TSDFs when it is well known that the manufacturer will not give credit for those hazardous waste pharmaceuticals.

Also, based on communication with stakeholders and the public comments received on the 2008 Universal Pharmaceutical Waste proposal, EPA understands that pharmaceutical manufacturers' policies often allow for credit to be received on the return of 'partials.' Partials is a term used in the industry to refer to opened containers that have had some contents removed. Under the proposed definition, the Agency would consider partials to be potentially creditable hazardous waste pharmaceuticals.

The Agency is soliciting comment on the proposed definition of "potentially creditable hazardous waste pharmaceutical" and whether the definition is broad enough to encompass the various types of hazardous waste pharmaceuticals that are shipped to reverse distributors for manufacturer's credit, while also ensuring that non-creditable hazardous waste pharmaceuticals are not inappropriately shipped to reverse distributors solely for waste management purposes. Finally, the Agency is seeking comment on additional situations where it is well known that a returned pharmaceutical will or will not receive manufacturer's credit.

4. What is the proposed definition of "non-creditable hazardous waste pharmaceutical"?

As discussed previously, there are instances when it is well known that credit will not be received for certain hazardous waste pharmaceuticals. In order to distinguish hazardous waste pharmaceuticals that have the potential for credit from those that have no expectation of receiving credit, the Agency is proposing to define the term "non-creditable hazardous waste pharmaceutical." The proposed definition of a "non-creditable hazardous waste pharmaceutical" is a hazardous waste pharmaceutical that is

not expected to be eligible for manufacturer's credit. Examples include, but are not limited to: if the pharmaceutical has been removed from the original container and re-packaged for dispensing purposes; if an attempt was made to administer a pharmaceutical, but the patient refused to take it; if the hazardous waste pharmaceutical was generated during patient care; if the pharmacy receives a return of a dispensed pharmaceutical for which they had already received compensation by a third-party payer (e.g. health insurance company); or if the pharmaceutical is more than one year past its expiration date. EPA requests comment on the proposed definition and seeks additional examples of hazardous waste pharmaceuticals that have no expectation of receiving manufacturer's credit.

5. What is the proposed definition of "evaluated hazardous waste pharmaceutical"?

After potentially creditable hazardous waste pharmaceuticals arrive at a pharmaceutical reverse distributor, they are evaluated to determine whether they are eligible for manufacturer's credit, or whether they need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit. Hazardous waste pharmaceuticals that need to be transferred to another pharmaceutical reverse distributor for additional verification of manufacturer's credit will continue to be considered potentially creditable hazardous waste pharmaceuticals. EPA is proposing that hazardous waste pharmaceuticals for which manufacturer's credit has been issued (and no further verification of credit is required), as well as those that have been deemed non-creditable, be referred to as "evaluated hazardous waste pharmaceuticals." EPA is proposing to define "evaluated hazardous waste pharmaceutical" as a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification. It is important to define this term since the proposed management and shipping standards for potentially creditable hazardous waste pharmaceuticals differ from the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals. For a discussion of the proposed management

and shipping standards for potentially creditable hazardous waste pharmaceuticals, see Section V.F.2. For a discussion of the proposed management and shipping standards for evaluated hazardous waste pharmaceuticals, see Section V.F.1.b.

6. What is the proposed definition of "household waste pharmaceutical"?

We are proposing to define the term "household waste pharmaceutical" as a solid waste, as defined in § 261.2, that also meets the definition of pharmaceutical, as defined in this proposed rule, but is not a hazardous waste because it is exempt from RCRA Subtitle C regulation by the household waste exclusion in § 261.4(b)(1). We are proposing this term to distinguish this type of waste pharmaceutical from the hazardous waste pharmaceuticals that are proposed to be regulated under this new subpart. This proposed rule does not apply to pharmaceutical waste that is exempt due to the household waste exclusion.

7. What is the proposed definition of "non-hazardous waste pharmaceutical"?

We are proposing to define the term "non-hazardous waste pharmaceutical." While hazardous waste pharmaceuticals are proposed to be regulated under this new subpart, non-hazardous waste pharmaceuticals will not be regulated under this new subpart, nor the RCRA subtitle C hazardous waste regulations. The Agency is proposing to include this definition since we believe it important to delineate what is and is not regulated under this new subpart. We propose to define the term "non-hazardous waste pharmaceutical" to mean a pharmaceutical that is a solid waste, as defined in § 261.2, but that is not a listed hazardous waste and does not exhibit any characteristics of hazardous waste (i.e., ignitable, corrosive, reactive, toxic).

8. What is the proposed definition of "non-pharmaceutical hazardous waste"?

Like the previous definition, we are proposing a definition for non-pharmaceutical hazardous waste to help us delineate what is and what is not regulated under this new subpart. We are proposing to define the term "non-pharmaceutical hazardous waste" as a solid waste, as defined in § 261.2, that is either a listed hazardous waste or exhibits one or more characteristics of hazardous waste, but does not meet the definition of a pharmaceutical, as proposed under this new subpart. The management of non-pharmaceutical hazardous wastes is not regulated under this subpart; rather generators of non-

pharmaceutical hazardous wastes, including healthcare facilities and reverse distributors, remain subject to the existing Subtitle C hazardous waste regulations for the management of those hazardous wastes. Examples of non-pharmaceutical hazardous wastes that healthcare facilities may generate include cleaning solutions, solvents, and laboratory wastes. Some hazardous wastes exist in pharmaceutical form and non-pharmaceutical form. For example, warfarin, nicotine, and lindane were all originally listed as hazardous waste because they were pesticides, not medicines. If these products are not intended for human or animal use, they would be considered non-pharmaceutical hazardous wastes and remain subject to the existing RCRA hazardous waste regulations, not part 266, subpart P.

9. What is the proposed definition of a “healthcare facility”?

These proposed regulations differ from those in the Pharmaceutical Universal Waste proposal in that they apply based not only on the type of hazardous waste generated, but also on the sector generating the waste. Accordingly, EPA is proposing a definition for “healthcare facility” so that it is clear to whom these proposed regulations apply. This proposed definition is adapted from the definition of “health care” that the Department of Health and Human Services (DHHS) promulgated as a result of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR part 160.103).³⁵ Thus, for the purposes of these proposed regulations, EPA is proposing that “healthcare facility” means any person that (1) provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) sells or dispenses over-the-counter or prescription pharmaceuticals. This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians’ offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and

hospitals. Thus, these proposed regulations will be applicable to any healthcare facility for human or animal which generates hazardous waste pharmaceuticals on its premises.

EPA proposes to include coroners in the definition of a healthcare facility despite the fact that the services coroners provide occur after life. Coroners will often inventory, and then dispose of, any pharmaceuticals that may be found at the scene of a death. A common method of disposal is sewerage. In order to reduce the sewer disposal practices of coroners, and to provide the same management options that are available to other healthcare facilities, EPA has decided to include “coroners” within the definition of healthcare facility, although the Agency solicits comment on including coroners within the definition of healthcare facility.³⁶

Under the proposed definition, healthcare facilities include locations that sell pharmaceuticals over the internet, through the mail, or through other distribution mechanisms. A pharmacy does not necessarily have to have a “brick and mortar” or “store front” presence to be considered a healthcare facility for the purposes of this proposed rule. The proposed definition of a “healthcare facility” also applies to entities that engage in drug compounding. In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The proposed definition of “healthcare facility” applies to state-licensed pharmacies, Federal facilities, and licensed physicians that compound drugs in accordance with section 503A of the FD&C Act, and to outsourcing facilities that compound drugs in accordance with section 503B of the FD&C Act. The Agency is soliciting comment on the proposed definition of “healthcare facility,” including whether it is appropriate to consider these compounders as healthcare facilities within the scope of this proposed rule.

The proposed definition of “healthcare facility” does not apply to pharmaceutical manufacturers and their representatives, wholesalers, or any

other entity that is involved in the manufacturing, processing or wholesale distribution of over-the-counter or prescription pharmaceuticals, unless they meet the definition of a “reverse distributor” as discussed in this section and in Section V.G. The purpose for these sector-based regulations is to address the various issues that healthcare facilities and reverse distributors face when managing hazardous waste pharmaceuticals. As noted previously, the Agency does not anticipate that manufacturing facilities, which predictably generate a known range of hazardous wastes, face the same issues as healthcare facilities.

10. What is the proposed definition of a “long-term care facility”?

The term “long-term care facility” does not have a standardized, industry definition. EPA is, therefore, proposing the following definition for “long-term care facility” (LTCF): a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

The included facilities are licensed care facilities that are more similar to hospitals than to standard residences. Although group homes may be licensed care facilities, they are typically very small (under 10 beds). Independent living communities are not licensed care facilities, but rather are residences made up of individual units such as townhomes or apartments. Finally, private residences with visiting nurses are not considered long-term care facilities. EPA requests public comment on the proposed definition of long-term care facility, and the inclusion of assisted living facilities, skilled nursing facilities and other LTCFs that administer their residents’ pharmaceuticals as an integral part of their services within the definition of “healthcare facility.”

The DEA’s definition of “long term care facility” is “a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients” (21 CFR 1300.01). EPA’s definition is more descriptive, and includes a list—which is not

³⁶ For more information on the disposal process, please see: Ruhoy, I.S. and Daughton, C.G. “Types and Quantities of Leftover Drugs Entering the Environment via Disposal to Sewage—Revealed by Coroner Records,” *Sci. Total Environ.*, 2007, 388(1–3):137–148. <http://www.epa.gov/nrelsd1/bios/daughton/SOTE2007.pdf>.

³⁵ 45 CFR part 160 <http://aspe.hhs.gov/admsimp/final/pvctxt01.htm>.

exhaustive—of examples of long-term care facilities. We feel this a more flexible way to define the universe. Although the definitions differ, they are not necessarily incompatible.

11. What is the proposed definition of a “pharmaceutical reverse distributor”?

As more fully discussed in Section V.G.1 of this preamble, pharmaceutical manufacturers often offer credit to healthcare facilities on the return of unused and/or expired pharmaceuticals.³⁷ Stakeholders have informed the Agency that manufacturers issue credit for a variety of reasons. For example, it is a marketing incentive tool that helps ensure against illicit diversion³⁸ or improper disposal, and it allows manufacturers to collect data on the returned items, which then can be used to help plan for future pharmaceutical production. Reverse distributors are contracted by both pharmaceutical manufacturers and healthcare facilities to facilitate the crediting process.

Some of the pharmaceuticals returned for credit will meet RCRA’s definition of a hazardous waste. Due to the fact that the vast majority of pharmaceuticals that are returned for manufacturer’s credit are disposed of once credit eligibility is determined, EPA is proposing new standards for shipment of potentially creditable hazardous waste pharmaceuticals (see Section V.F.2.) and the management of potentially creditable hazardous waste pharmaceuticals by reverse distributors (see Section V.G.). Thus, EPA is proposing to define pharmaceutical reverse distributor to clearly delineate which types of facilities are subject to this proposed rule. In keeping with how the term is commonly used in the healthcare sector, EPA is proposing to define a “pharmaceutical reverse distributor” as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer’s credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer’s credit is considered a pharmaceutical reverse distributor.

³⁷ As noted in the definition of “potentially creditable hazardous waste pharmaceutical,” credit is provided for those pharmaceuticals that are less than one year past the expiration date.

³⁸ Through the return of pharmaceuticals by a pharmacy for manufacturer’s credit, manufacturers are able to maintain control of the pharmaceutical up to the point of its disposal, thereby, decreasing the risk of diversion of the pharmaceutical.

The Agency also needs to clarify the difference between what is defined as a pharmaceutical reverse distributor for the purpose of these proposed regulations and how DEA regulations define “reverse distribute.” The recently amended DEA regulatory definition of “reverse distribute” is to “acquire controlled substances from another registrant or law enforcement for the purposes of: (1) Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer’s behalf; or (2) Destruction (21 CFR 1300.01).³⁹

Under DEA’s definition, a reverse distributor does not necessarily process pharmaceuticals for the purpose of determining manufacturer’s credit; rather, their main function under DEA’s definition is to destroy the controlled substances. Under EPA’s proposed definition, however, a pharmaceutical reverse distributor is defined more broadly as a facility that can accept potentially creditable pharmaceuticals for the purposes of determining manufacturer’s credit. These potentially creditable pharmaceuticals may or may not be identified as controlled substances by DEA.⁴⁰ Therefore, a DEA-registered reverse distributor may or may not meet EPA’s definition of a pharmaceutical reverse distributor and vice versa. For example, a pharmaceutical reverse distributor that accepts controlled substances (that are also hazardous wastes) for the sole purpose of destruction (*e.g.*, incineration) would be regulated as a DEA-registered reverse distributor and as a RCRA TSDF, and not as a pharmaceutical reverse distributor under the RCRA hazardous waste regulations. Conversely, a pharmaceutical reverse distributor that processes pharmaceuticals for manufacturer’s credit, but is not a DEA registrant and therefore, cannot accept controlled substances, would meet the RCRA pharmaceutical reverse distributor definition, but not DEA’s reverse distributor definition. However, EPA has heard from stakeholders that many, if not all, entities that facilitate manufacturer’s credit are also DEA-registered reverse distributors. Therefore, such pharmaceutical reverse

³⁹ On September 9, 2014, DEA finalized new definitions for “reverse distribute” and “reverse distributor.” Please see 79 FR 53520. The term “reverse distributor” is defined as “a person registered with the Administration [DEA] as a reverse distributor.”

⁴⁰ In order for a reverse distributor to be able to accept controlled substances, the reverse distributor must be a DEA registrant. See 21 CFR part 1308 for a complete list of controlled substances.

distributors would meet both EPA’s proposed definition of pharmaceutical reverse distributor, as well as the DEA’s definition of reverse distributor. Lastly, we would note that EPA’s definition for reverse distribution does not alter or supersede the requirements of the Controlled Substances Act and DEA regulations.

In addition, the Department of Transportation’s Pipeline and Hazardous Materials Safety Administration (PHMSA) has defined the closely related term, “reverse logistics,” in a recent proposed rulemaking.⁴¹ The EPA has been coordinating with the PHMSA to ensure that our rules are compatible, even if the definitions differ. It is important to note that, when finalized, the PHMSA rule will not supersede EPA’s RCRA Subtitle C regulations for when something is considered a solid or hazardous waste or how a hazardous waste must be managed.

The Agency solicits public comment on its proposed definition of a “pharmaceutical reverse distributor.” Specifically, EPA asks for comment on whether the definition of “pharmaceutical reverse distributor” captures the universe of facilities acting as reverse distributors for pharmaceuticals. In addition, the Agency asks for comment regarding the intersection of DEA and EPA’s definitions.

B. What is the scope of this proposed rule?

1. What facilities are subject to this rulemaking?

a. Healthcare facilities. The Agency is proposing that healthcare facilities that are currently considered either SQGs or LQGs will be required to manage all hazardous waste pharmaceuticals generated at their facilities in accordance with the standards proposed in this document. In other words, these management standards will apply to any healthcare facility that generates (or accumulates) more than 100 kg of hazardous waste per calendar month *or* more than 1 kg of acute hazardous waste per calendar month (*e.g.*, P-listed hazardous waste) *or* more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e) per calendar month. All healthcare facilities

⁴¹ 79 FR 46748; August 11, 2014. The PHMSA’s proposed definition of reverse logistics “is the process of moving goods from their final destination for the purpose of capturing value, recall, replacement, proper disposal, or similar reason.”

that meet these applicability criteria will be subject to the same set of standards for the management of their hazardous waste pharmaceuticals. That is, subpart P is not optional for healthcare facilities that generate above the CESQG monthly quantity limits (see Section V.B.1.c. of the preamble for a discussion of what regulations apply to CESQGs). EPA is proposing to make subpart P mandatory to promote national consistency, a goal championed by stakeholder comments as well as EPA. In addition, having one set of standards applicable to pharmaceutical waste will be less confusing to the regulated community, which should lead to better compliance. The stringency of the subpart P management standards for hazardous waste pharmaceuticals do not change if a healthcare facility generates more hazardous waste pharmaceuticals from one month to another. The generator categories—that is, LQG, SQG, and CESQG—under the part 262 RCRA requirements will only be relevant for the healthcare facilities' non-pharmaceutical hazardous waste because non-pharmaceutical hazardous waste remain subject to the 40 CFR part 262 generator regulations (see Section VI. *Implementation and Enforcement* for further discussion).

b. Long-term care facilities subject to this rule. Long-term care facilities are included within the proposed definition of healthcare facility. Further, EPA is proposing to change its policy regarding the management of hazardous waste and hazardous waste pharmaceuticals generated on the premises of long-term care facilities. Under current federal RCRA interpretation (see 73 FR 73525, December 2, 2008), hazardous wastes (including pharmaceuticals) generated on the premises of a long-term care facility can fall under two categories: (1) RCRA Subtitle C hazardous waste or (2) household hazardous waste that is exempt from RCRA Subtitle C regulation. As explained in the preamble to the proposal to add pharmaceuticals to the Universal Waste program, “the [long-term care] facility itself may generate hazardous wastes as a result of its central management of pharmaceuticals in its pharmacy or pharmacy-like area. These hazardous pharmaceutical wastes would be subject to the RCRA hazardous waste generator regulations since the pharmaceuticals are under the control of the facility, and thus, the resulting wastes are generated by that facility. However, patients and residents in long-term care facilities may generate hazardous wastes. Those pharmaceuticals that are under the

control of the patient or resident of the long-term care facility, when discarded, would be subject to RCRA's household hazardous waste exclusion (§ 261.4(b)(1)). Hazardous pharmaceutical wastes generated by the resident are excluded from regulation because they are considered to be derived from a household” (see December 2, 2008; 73 FR 73525).

The Agency is now providing notice that it intends to revise this interpretation. Specifically, hazardous waste (including pharmaceuticals) generated at long-term care facilities will no longer be considered exempt as household hazardous waste. It will be regulated as hazardous waste, subject to the appropriate RCRA Subtitle C management standards, including the standards being proposed. The Agency is revising its interpretation with regard to hazardous wastes generated at long-term care facilities based on a reevaluation of how such facilities operate. Specifically, in order for hazardous waste to qualify for the household hazardous waste exemption of § 261.4(b)(1), it must meet two criteria: (1) The hazardous waste must be generated by individuals on the premises of a household, and (2) the hazardous waste must be composed primarily of materials found in the wastes generated by consumers in their homes.⁴² EPA now believes that hazardous waste generated at long-term care facilities, even when those pharmaceuticals are under the control of the patient or resident, does not meet either criterion for the household hazardous waste exemption.

First, a long-term care facility is more akin to a hospital than it is a typical residence and EPA does not consider hospitals to be households. Long-term care facilities are licensed, residential care settings that offer their residents a wide range of services, many of which are centered on administering medications and providing healthcare by various professional healthcare providers, such as medical technicians, nurse's aides, nurses, and doctors. Other services provided involve assistance in performing activities of daily living, such as bathing, and eating. A 2012 American Association of Retired Person (AARP) Public Policy Institute report indicates that there is an average of 24 beds per licensed residential care facilities (excluding nursing homes).⁴³

⁴² See November 13, 1984; 49 FR 44978.

⁴³ AARP Public Policy Institute, INSIGHT on the Issues 58, Assisted Living and Residential Care in the States in 2010, April 2012. http://www.aarp.org/content/dam/aarp/research/public_policy_institute/lc/2012/residential-care-insight-on-the-issues-july-

Based on another report prepared as a collaborative project of the American Association of Homes and Services for the Aging (AAHSA), American Seniors Housing Association (ASHA), Assisted Living Federation of America (ALFA), National Center for Assisted Living (NCAL) and National Investment Center for the Seniors Housing and Care Industry (NIC), there is an average of 54 units (e.g., rooms) for all types of assisted living/dementia care properties.⁴⁴ Unlike other multiple dwellings, approximately 81 percent of these facilities store medications in a central location and 89 percent administer medications to their residents.⁴⁵ Given that long-term care facilities are licensed settings for the care of their residents and routinely provide healthcare services, we believe that long-term care facilities more closely resemble hospitals than typical residences.

Second, the hazardous wastes generated by long-term care facilities do not meet the second criteria for the waste to be considered household hazardous waste. This is primarily due to the quantity of pharmaceutical wastes that are often generated on the premises of long-term care facilities when compared to a typical residence. For example, the Colorado Department of Public Health and Environment estimates that a 100-bed nursing home might expect to generate approximately 120 to 336 pounds of pharmaceutical waste per year.⁴⁶ In addition, long-term care facilities, such as assisted living facilities and nursing homes, generate a greater variety of hazardous waste pharmaceuticals and a greater quantity of hazardous waste than a typical household generates. The AARP Public Policy Institute report indicates that “residents take an average of seven or eight different prescriptions and two OTC [over-the-counter] medications daily.” This number is larger than what we would expect a typical household to generate. This distinction about volume of waste is analogous to the distinction that EPA has made in the past about contractor or do-it-yourself waste from

2012-AARP-ppi-ltc.pdf or see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

⁴⁴ 2009 Overview of Assisted Living; a collaborative research project of AAHSA, ASHA, ALFA, NCAL & NIC.

⁴⁵ *Ibid.*

⁴⁶ Net weight (without packaging) of types of pharmaceuticals wastes, including those that are RCRA hazardous, non-RCRA hazardous, DEA controlled, prescription and over-the-counter. Memo from Lillian Gonzalez, Colorado Department of Public Health and Environment to Kristin Fitzgerald, EPA; January 9, 2013, see the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

households: waste from “routine residential maintenance” is exempt as household hazardous waste, while waste from “building construction, renovation, demolition” is not exempt.⁴⁷ Therefore, EPA is providing notice that if this rule is finalized, long-term care facilities may no longer use the household hazardous waste exemption. If this rule is finalized, long-term care facilities would need to manage their hazardous waste pharmaceuticals in accordance with the healthcare facility specific management standards in this proposal and their non-pharmaceutical hazardous wastes in accordance with the applicable RCRA hazardous waste generator requirements in § 261.5 (for CESQGs) or part 262 (for SQGS and LQGs). However, even though long-term care facilities will no longer be considered eligible to use the household hazardous waste exemption, our data show that only 28% of long-term care facilities generate hazardous waste pharmaceuticals, and of those, 85% are small enough to be considered CESQGs of hazardous waste (regulated under § 261.5) and therefore not subject to part 266, subpart P (except the sewer ban).⁴⁸ The Agency seeks comment on whether this proposed change to consider long-term care facilities to be healthcare facilities instead of households is appropriate. We also seeking comment on the extent to which long-term care facilities will pass the cost of compliance onto its customers. Until this rule is finalized, the current interpretation from the Universal Waste preamble will stand regarding hazardous waste from long-term care facilities.

c. Conditionally exempt small quantity generators (CESQGs). As discussed in the Background Section (Section IV.A.2), CESQGs are subject to a limited set of federal RCRA Subtitle C hazardous waste regulations, provided that they comply with the conditions set forth in § 261.5.⁴⁹ This proposed rulemaking will preserve this current regulatory structure for the most part; therefore, healthcare facilities that

generate hazardous waste pharmaceuticals and qualify as CESQGs, will maintain their conditional exemption under § 261.5 and will not be subject to *most* aspects of this proposal. However, as part of this rulemaking, EPA is proposing a ban on sewer disposal of hazardous waste pharmaceuticals by all healthcare facilities and reverse distributors. EPA is proposing that the sewer ban would apply to all healthcare facilities, including CESQG healthcare facilities. Please see Section V.E.1 of this preamble for a more detailed discussion on this proposed sewer prohibition. EPA asks for comment on whether the proposed healthcare facility standards, in addition to the sewer ban, should apply to CESQG healthcare facilities.

EPA is proposing one additional change for CESQGs in order to allow them to continue to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Currently, under § 261.5, CESQGs are limited in where they may send their hazardous waste for treatment and disposal (see § 261.5(f)(3)(i)-(vii) for acute hazardous waste and § 261.5(g)(3)(i)-(vii) for hazardous waste). However, in § 266.504(a) we are proposing to allow CESQGs to send their potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor. Without this change, CESQGs would be required to send all their hazardous waste pharmaceuticals, including those that are potentially creditable, to one of the types of facilities in § 261.5, which does not include a pharmaceutical reverse distributor. Although we are proposing to make this change within part 266, subpart P, we request comment on whether stakeholders would prefer this change to be made within § 261.5 instead. CESQGs will still be required to send their non-pharmaceutical hazardous waste and their non-creditable hazardous waste pharmaceuticals to one of the types of facilities listed in § 261.5.

In addition, it has been suggested that EPA seek comment on providing a rebuttable presumption that LTCFs with fewer than 10-beds are assumed to be CESQGs and thus would not be required to count the amount of hazardous waste generated each month. Under this presumption, they would be subject to all the requirements for CESQGs as described elsewhere in this proposal, including the requirement not to sewer hazardous waste pharmaceuticals. Therefore, EPA asks for comment on this rebuttable presumption and specifically whether the 10-bed cut off

is appropriate or whether there are other criteria EPA should take into account. Further, EPA asks for commenters to submit data to support a 10-bed cut off to show that LTCFs with fewer than 10-beds are generally CESQGs. Alternatively, if comments wish to support a different cut-off for the rebuttable assumption, EPA also asks that the commenters submit information/data to support their suggested cut-off.

d. Pharmaceutical reverse distributors. EPA is proposing that pharmaceutical reverse distributors, including pharmaceutical manufacturers, which accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to this rule. Pharmaceutical reverse distributors are only subject to this proposed rule for the *accumulation* of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals; if a reverse distributor also treats and/or disposes of hazardous waste pharmaceuticals, it is subject to the applicable RCRA Subtitle C TSDF regulations, including the requirement to have a permit or interim status. Stakeholders have indicated a strong preference for EPA to clarify how pharmaceutical reverse distributors are regulated under RCRA, as states have applied varied hazardous waste regulatory approaches to pharmaceutical reverse distributors. EPA is proposing specific standards in 40 CFR part 266, subpart P for pharmaceutical reverse distributors (as defined in this proposed rule) that incorporate various generator standards, as well as some TSDF standards. See Section V.G for more information.

2. To what facilities does this rule not apply?

a. Pharmaceutical manufacturers. EPA does not intend for these proposed regulations to apply to hazardous waste pharmaceuticals that are generated by pharmaceutical manufacturers or wholesalers. Pharmaceutical manufacturers and wholesalers do not face the same challenges that healthcare facilities experience when managing hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals in accordance with the federal RCRA subtitle C requirements (for an explanation of the challenges healthcare facilities face, see discussion in section IV.B.1 of the preamble). These entities (*i.e.*, manufacturers and wholesalers) generate hazardous waste pharmaceuticals that are more predictable and the staff have the

⁴⁷ Memo from Petruska to McNally, February 28, 1995; RCRA Online #11897 that discusses the distinction about what renovation waste is household hazardous waste and what is not.

⁴⁸ See the docket for this rulemaking for data about long-term care facilities which was developed using data in the economic analysis: EPA-HQ-RCRA-2007-0932.

⁴⁹ Not all authorized states recognize the CESQG category and may have more stringent regulatory requirements for CESQGs. Therefore, as noted previously, EPA recommends that facilities that qualify as CESQGs under the federal regulations contact their state and/or local environmental regulatory agencies to determine whether more stringent regulatory requirements apply to CESQGs in their state.

necessary expertise to determine which pharmaceutical waste is hazardous waste. However, as mentioned previously, when any facility, including a pharmaceutical manufacturer, meets the definition found in this proposal for a “pharmaceutical reverse distributor,” it would be subject to the proposed regulations for pharmaceutical reverse distributors with respect to those operations.

b. Households. The Agency would like to emphasize that the regulatory requirements in this proposed rule do not apply to households or to household pharmaceutical collection and take-back events and programs. (For information regarding collection programs, see Section V.E.2.) Pharmaceuticals that are unwanted by consumers (households) are not regulated as hazardous waste and are generally considered municipal solid wastes. While a small percentage of these household waste pharmaceuticals meet the definition of hazardous waste under RCRA, the federal RCRA hazardous waste regulations include an exclusion for all hazardous wastes generated by households (see the “household hazardous waste” exclusion at § 261.4(b)(1)). Thus household waste pharmaceuticals—like other household hazardous wastes—are not subject to the federal RCRA hazardous waste regulations.

“EPA excluded household wastes because the legislative history of RCRA indicated an intent to exclude such wastes, though *not* because they necessarily pose no hazard.”⁵⁰ Some household products, including pharmaceuticals, contain ignitable, corrosive, reactive, or toxic ingredients. As a result, for household hazardous waste collected at a take-back event or program, the Agency has historically recommended that communities operating the collection programs manage the collected household hazardous wastes as hazardous waste, even though it is not required by RCRA.⁵¹ Furthermore, the Agency has recently recommended that collected household waste pharmaceuticals be incinerated—preferably at a permitted hazardous waste incinerator, but when that is not feasible, at a large or small municipal waste combustor.⁵² The

Agency believes that this practice is already common among collection programs since one goal of many collection programs is to divert pharmaceuticals from municipal landfills. Nevertheless, the Agency is proposing to make this recommendation a requirement for collected household waste pharmaceuticals in § 266.506.⁵³ The Agency seeks comment on changing this recommendation to a requirement for pharmaceutical collection programs.

The Agency recommends that, whenever possible, households utilize pharmaceutical collection and take-back events as the disposal option for their unwanted pharmaceuticals. For consumers without access to a pharmaceutical take-back event, FDA provides information on the disposal of unused pharmaceuticals and step-by-step guidance for disposing of pharmaceuticals in the household trash. For more information on the safe disposal of household pharmaceuticals, please see: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm>.

3. Which hazardous wastes are addressed by this proposed rule?

a. Hazardous waste pharmaceuticals. If finalized, these regulations will only pertain to those pharmaceutical wastes that are RCRA hazardous wastes generated by healthcare facilities or managed by pharmaceutical reverse distributors. Under this rulemaking, EPA is not proposing to add additional pharmaceuticals to the hazardous waste listings or to expand the hazardous waste characteristics to include additional pharmaceuticals. See Section VII of the preamble, *Request for Comment on EPA’s Efforts to Identify Additional Pharmaceuticals as Hazardous Waste*, for a discussion of possible future actions by EPA to regulate additional pharmaceuticals as hazardous waste.

b. How does this proposal affect hazardous waste pharmaceuticals that are also regulated by other federal or state regulations? The management, transportation, treatment, storage and disposal of hazardous waste pharmaceuticals are regulated under RCRA Subtitle C. However, hazardous

waste pharmaceuticals may also be subject to a number of other statutes and implementing regulations administered by state or other federal agencies. Examples include pharmaceuticals that are subject to the Controlled Substances Act and DEA regulations; infectious pharmaceutical wastes that are subject to state and local medical waste regulations; and pharmaceuticals with a radioactive component that are subject to the Atomic Energy Act (AEA). These potentially overlapping requirements make the appropriate management of pharmaceutical wastes a complex matter. The following discusses the impact of this proposed rule on various dually regulated hazardous waste pharmaceuticals.

i. Hazardous waste pharmaceuticals that are also controlled substances. Under current regulations, any healthcare facility generating or managing a RCRA hazardous waste pharmaceutical that is also a controlled substance listed in Schedule II–V⁵⁴ must comply with the RCRA hazardous waste requirements, as well as the requirements of the Controlled Substances Act and DEA regulations. Recently revised DEA regulations to implement the Secure and Responsible Drug Disposal Act of 2010 require that controlled substances be destroyed so that they are “non-retrievable.”⁵⁵ In the preamble to both the proposed and final rules, DEA has stated that flushing alone will not meet DEA’s new non-retrievable standard.⁵⁶ Stakeholders have told EPA that it is expensive and difficult to incinerate controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes. As a result, healthcare facilities with hazardous waste pharmaceuticals that are also controlled substances have often sewered on-site in order to avoid the expense of complying with dual regulation that would apply if they were incinerated. Due to difficulties associated with managing these hazardous waste pharmaceuticals that are also controlled substances, the Agency is proposing to conditionally exempt from RCRA regulatory requirements those pharmaceuticals that are both a RCRA hazardous waste and a DEA controlled substance, provided the hazardous waste pharmaceuticals that are also DEA controlled substances are combusted at a permitted or interim

⁵⁰ See 49 FR 44978; November 13, 1984.

⁵¹ See memo November 1, 1988, from Porter to Regions (RCRA Online #11377). [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/\\$file/11377.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/2FD51915214EF63C8525670F006BDC88/$file/11377.pdf).

⁵² See memo September 26, 2012, Rudzinski to the Regional RCRA Division Directors (RCRA Online# 14833). <http://yosemite.epa.gov/osw/>

[rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/\\$file/14833.pdf](http://rcra.nsf/0c994248c239947e85256d090071175f/FCB11DD6F61D4B1685257AFE005EB5CE/$file/14833.pdf).

⁵³ Since pharmaceutical collection programs typically co-mingle DEA controlled substances with non-controlled substances, this requirement is included in a section of the regulations that pertains to controlled substances.

⁵⁴ See 21 CFR 1308 for a complete list of controlled substances.

⁵⁵ Final rule: September 9, 2014; 79 FR 53520.

⁵⁶ Proposed rule: December 21, 2012; 77 FR 75784, see page 75803; and final rule: September 9, 2014; 79 FR 53520, see page 53548).

status hazardous waste incinerator, or a permitted municipal solid waste incinerator. A more detailed discussion of this exemption is found in Section V.E.2 of this proposal, *Conditional Exemption for Hazardous Waste Pharmaceuticals that are also Controlled Substances*.

ii. *Hazardous waste pharmaceuticals that are also medical wastes*. There are instances when a hazardous waste pharmaceutical will also exhibit a biological hazard. The healthcare industry often refers to pharmaceutical wastes that are both RCRA hazardous and a biological hazard as “dual wastes,” and such wastes must be managed in accordance with RCRA and state and/or local medical waste regulations. As a result, the healthcare facility must send these dual wastes to a hazardous waste treatment, storage and disposal facility that is also permitted to accept medical wastes. Some examples of dual wastes include un-administered syringes containing hazardous waste pharmaceuticals (e.g., physostigmine) or IV bags containing residues of a hazardous waste pharmaceutical that are attached to the tubing and needles used to administer the pharmaceutical. The RCRA hazardous waste pharmaceutical portion of these “dual” wastes are included within these proposed management standards so that healthcare facilities can obtain the benefits of this proposal, while ensuring the hazardous waste portion of the waste is managed appropriately and ultimately delivered to RCRA-permitted TSDFs. In addition, healthcare facilities must still manage the biological hazard in accordance with state and/or local medical waste requirements. EPA notes that autoclaving is not an acceptable method of treating hazardous wastes that are also medical waste. In addition, as discussed in Section V.E.3.c of this preamble, EPA is proposing to conditionally exclude the residues of hazardous waste pharmaceuticals remaining in fully dispensed syringes from RCRA regulation.

iii. *Hazardous waste pharmaceuticals that contain a radioactive component*. Hazardous waste pharmaceuticals that also contain a radioactive component subject to the Atomic Energy Act of 1954 (AEA) (i.e., “mixed waste”) are regulated by multiple agencies. The hazardous waste component is regulated under EPA or the authorized state RCRA programs, while either the Nuclear Regulatory Commission (NRC) or the Department of Energy (DOE) regulates the radioactive component of the waste

under the AEA.⁵⁷ Healthcare facilities would be able to use this rule (if finalized) to comply with the hazardous waste component for hazardous waste pharmaceuticals. Although we do not believe that anything in this proposal is inconsistent with the AEA, § 1006(a) of RCRA states that if the RCRA requirements are inconsistent with the AEA requirements, then the RCRA requirements do not apply. Therefore, if a healthcare facility that manages hazardous waste pharmaceuticals encounters specific RCRA requirements that are inconsistent with specific AEA requirements, only the AEA requirements would apply.

As is discussed in the Joint NRC/EPA Guidance on Testing Requirements for Mixed Radioactive and Hazardous Waste (62 FR 62079, 62085; November 20, 1997), an inconsistency occurs when compliance with one statute or set of regulations would necessarily cause non-compliance with the other statute or set of regulations. Relief from the regulatory inconsistency would be provided by the AEA requirement overriding the specific RCRA requirement. It is important to note, however, that the determination of an inconsistency would relieve the healthcare facility only from compliance with the specific RCRA requirement(s) that is deemed inconsistent with the AEA requirement(s); it would still be required to comply with all of the other hazardous waste pharmaceutical management standards.

4. Management of Wastes Generated at Healthcare Facilities That Are Not Included in the Scope of this Proposed Rule

Wastes that are not included in the scope of this proposed rule include non-hazardous wastes or non-pharmaceutical hazardous wastes. Pharmaceutical wastes that are not listed or characteristic hazardous wastes under RCRA Subtitle C may nonetheless pose some risks to public health and the environment. These wastes are discussed further below.

a. *How should non-hazardous waste pharmaceutical be disposed?* A large portion of the pharmaceutical wastes generated at healthcare facilities will not meet the definition of a RCRA hazardous waste under RCRA Subtitle C. This proposal, therefore, does not require that healthcare facilities manage these waste pharmaceuticals under the RCRA subtitle C hazardous waste

⁵⁷ The NRC regulates radioactive wastes generated by commercial or non-DOE facilities, whereas DOE regulates radioactive wastes generated by DOE facilities.

regulations, including this proposed rule. However, a healthcare facility may choose to manage its solid and hazardous waste pharmaceuticals together (as hazardous waste pharmaceuticals) under these new proposed regulations. Because all healthcare facilities operating under this subpart are regulated in the same way regardless of quantity of pharmaceutical hazardous waste generated, managing non-hazardous waste pharmaceuticals as hazardous waste under this subpart would not affect the facility’s hazardous waste generator category. While not regulated by the federal RCRA hazardous waste requirements, non-hazardous waste pharmaceuticals are still considered solid wastes under the federal regulations and must be managed in accordance with applicable federal, state and/or local regulatory requirements.

If a healthcare facility decides to segregate its hazardous and non-hazardous pharmaceuticals, EPA recommends that healthcare facilities follow the best management practices (BMPs) outlined in the “Managing Pharmaceutical Waste: A 10-Step Blueprint for Healthcare Facilities in the United States” (Practice Greenhealth, Revised August 2008)⁵⁸ for the management, treatment, storage and disposal of non-hazardous waste pharmaceuticals. The following summarizes the recommended BMPs found in the Blueprint for various categories of pharmaceutical wastes, including those wastes that possess hazardous waste-like qualities yet are not regulated as hazardous waste under RCRA Subtitle C.

i. *Recommended BMPs for healthcare facilities managing non-hazardous waste pharmaceuticals possessing hazardous waste-like qualities*. Currently, most pharmaceuticals are not regulated as RCRA hazardous wastes when discarded by healthcare facilities. These “non-RCRA-hazardous” pharmaceuticals can be divided into two categories: those that possess hazardous waste-like qualities and those that do not. As outlined in the Blueprint, there are pharmaceuticals that possess hazardous waste-like qualities, but for various reasons, are not regulated by the RCRA Subtitle C hazardous waste regulations. The Agency supports the Blueprint’s

⁵⁸ Published in 2006, the development of the original *Blueprint* was funded by the Office of Solid Waste and Emergency Response and managed by EPA Region 1. The 2008 revision of the *Blueprint* was funded by the Healthcare Environmental Resource Center. <http://practicegreenhealth.org/sites/default/files/upload-files/pharmwasteb Blueprint.pdf>

recommendation of hazardous waste incineration as the BMP for healthcare facilities and pharmaceutical reverse distributors discarding pharmaceuticals that may possess hazardous waste-like qualities, but are not regulated as RCRA hazardous waste. This recommendation would apply to pharmaceuticals with more than one active ingredient listed on the P- or U-lists,⁵⁹ chemotherapeutic agents characterized as bulk wastes,⁶⁰ pharmaceuticals which meet the NIOSH Hazardous Drug Criteria,⁶¹ pharmaceuticals listed in Appendix VI of the OSHA Technical Manual,⁶² pharmaceuticals with LD50s \leq 50 mg/kg, pharmaceuticals that are carcinogenic or endocrine disrupting compounds, and vitamin/mineral preparations containing heavy metals.

ii. *Recommended best management practices for other non-hazardous pharmaceutical wastes (i.e., those not possessing hazardous waste like-qualities).* As far as other non-hazardous waste pharmaceuticals (i.e., those not possessing hazardous waste-like qualities), disposing of non-hazardous waste pharmaceuticals at healthcare facilities via drain disposal is strongly discouraged and not recommended by EPA. Therefore, EPA endorses the Blueprint's recommendation of municipal solid waste or medical waste incineration for any non-hazardous waste pharmaceuticals, even when they do not possess hazardous waste-like qualities. The potential risk remains for active pharmaceutical ingredients (APIs) to be released into the environment if municipal solid waste landfills or medical waste autoclaves are used for the purposes of pharmaceutical waste treatment and disposal. For example, autoclaves are designed to kill pathogens and do not achieve the temperatures required to destroy most APIs during the autoclaving process. As a result, there is the potential for wastewater containing APIs to be generated and discharged into the sewer. In addition, some limited studies have shown APIs present in landfill

⁵⁹ As noted in the comment after § 261.33(d), the phrase "commercial chemical product" includes formulations in which the P- or U-listed chemical is the sole active ingredient. Therefore, formulations with more than one active ingredient do not meet the specifications of the P- and U-listings even if one, two or all of the active ingredients are listed on the P- and/or U-lists.

⁶⁰ The descriptions "bulk" and "trace" when applied to chemotherapeutic wastes are industry terms and are not defined by the federal RCRA regulations.

⁶¹ *NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2012.* <http://www.cdc.gov/niosh/docs/2012-150/>.

⁶² *OSHA Technical Manual, Section VI: Chapter 2, Appendix VI: 2-1.* http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.

leachate collected in municipal solid waste landfill leachate systems.^{63 64} Typically, the collected landfill leachate is subsequently sent to wastewater treatment plants for treatment, but their treatment technologies are not designed to remove all APIs from the wastewater (See Section V.E.1 for more information regarding sewerage and APIs).

b. *Non-pharmaceutical hazardous wastes.* These proposed regulations will only pertain to hazardous waste pharmaceuticals. Therefore, other types of hazardous wastes generated at healthcare facilities that do not meet the definition of a hazardous waste pharmaceutical cannot be managed in accordance with these proposed regulations. For example, hazardous wastes generated in hospital laboratories or during cleaning and maintenance of the facility are not considered hazardous waste pharmaceuticals and are not included within the scope of this proposal. The generation of non-pharmaceutical hazardous wastes is often more routine and does not trigger the same concerns that healthcare facilities experience when managing hazardous waste pharmaceuticals.

After a healthcare facility determines it is subject to this proposed rule and manages its hazardous waste pharmaceuticals under part 266, subpart P, it is no longer required to count the hazardous waste pharmaceuticals that it generates towards its generator category. As a result, the healthcare facility may experience a change in RCRA generator category for its non-pharmaceutical hazardous waste. For example, a healthcare facility may shift from being an LQG to a SQG or even CESQG by not counting its hazardous waste pharmaceuticals toward its generator category, especially when acute hazardous waste pharmaceuticals such as warfarin (brand name: Coumadin) no longer need to be counted. A shift in generator category, should it occur, would allow a healthcare facility to manage its non-pharmaceutical hazardous waste, such as hazardous waste from laboratories, according to the reduced generator requirements. It is important to note that only when a

⁶³ Barnes, K.K., Christenson, S.C., Kolpin, D.W., Focazio, M.J., Furlong, E.T., Zaugg, S.D., Meyer, M.T. and Barber, L.B. (2004), *Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill.* *Groundwater Monitoring & Remediation*, 24: 119–126.

⁶⁴ Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), *Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002.* *Bulletin of Environmental Contamination and Toxicology*, V82.6:635–659.

healthcare facility is managing its hazardous waste pharmaceuticals under the new proposed subpart does it have the benefit of not counting them towards its generator category (see Section VI. *Implementation and Enforcement* for further discussion).

C. *What are the proposed standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals?*

This section discusses the proposed management standards for healthcare facilities (except CESQGs) that manage non-creditable hazardous waste pharmaceuticals, which include the following:

- (1) Notification requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (2) personnel training requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (3) making a hazardous waste determination for non-creditable hazardous waste pharmaceuticals;
- (4) elimination of central accumulation area and satellite accumulation area requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (5) container standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (6) labeling standards on containers for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (7) accumulation time limits for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (8) land disposal restrictions for non-creditable hazardous waste pharmaceuticals;
- (9) procedures for shipping non-creditable hazardous waste pharmaceuticals off-site from healthcare facilities;
- (10) procedures for managing rejected shipments of non-creditable hazardous waste pharmaceuticals from healthcare facilities;
- (11) reporting requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (12) recordkeeping requirements for healthcare facilities managing non-creditable hazardous waste pharmaceuticals;
- (13) procedures for responses to releases by healthcare facilities managing non-creditable hazardous waste pharmaceuticals;

(14) special requirements for long-term care facilities managing non-creditable hazardous waste pharmaceuticals;

(15) conditions for healthcare facilities that accept hazardous waste pharmaceuticals from off-site CESQGs; and

(16) a prohibition of sewerage hazardous waste pharmaceuticals for all healthcare facilities; (see section V.E.1. of the preamble, *Sewer Disposal Prohibition*).

The proposed management standards discussed in this section only apply to hazardous waste pharmaceuticals that are non-creditable hazardous waste pharmaceuticals (*i.e.*, they are destined for a RCRA permitted or interim status TSDF). They do not apply to those hazardous waste pharmaceuticals that meet the definition of a “potentially creditable hazardous waste pharmaceutical.” Please refer to Section V.D for the proposed healthcare facility management standards for potentially creditable hazardous waste pharmaceuticals that are transported to reverse distributors for the processing of manufacturer’s credit.

1. Notification Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

In order to address commenters’ concerns from the 2008 Pharmaceutical Universal Waste proposal that regulatory agencies are unaware of hazardous waste pharmaceutical management activities, EPA is proposing to require that a healthcare facility that does not qualify as a CESQG to submit a one-time notification as a “healthcare facility” to the appropriate EPA Regional Administrator. Healthcare facilities subject to 40 CFR part 266, subpart P will have to submit notification even if the healthcare facility has previously obtained an EPA identification number. The required notification will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals subject to the 40 CFR part 266, subpart P requirements. In addition, having this information allows EPA and state environmental regulatory agencies to track healthcare facilities for enforcement and inspection purposes, ensuring the hazardous waste pharmaceuticals are managed in accordance with the regulations.

At any point a healthcare facility’s hazardous waste pharmaceutical generation may change due to waste minimization efforts or other reasons, causing the facility to legitimately

decrease its total monthly hazardous waste generation enough to qualify as a CESQG. In this case, if the healthcare facility plans to withdraw from the 40 CFR part 266, subpart P requirements due to qualifying as a CESQG, it will be required to re-notify EPA of its choice to withdraw.

Alternatively, if a healthcare facility determines that it is a CESQG,⁶⁵ but does not want to keep track of the amount of hazardous waste generated and whether it is above or below the CESQG threshold limit, it can choose to operate under this proposed rule. By choosing to operate under this proposed rule, the CESQG healthcare facility must comply with *all* of the requirements and must submit the one-time notification that it is operating under 40 CFR part 266, subpart P. Healthcare facilities that are not CESQGs, however, are required to operate under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals.

The Agency is proposing that this notification occur via the RCRA Subtitle C Site Identification Form (EPA Form 8700–12; or Site Identification Form).⁶⁶ EPA believes that notification via the Site Identification Form is the preferred approach for notification purposes for several reasons. First, both state environmental regulatory agencies and hazardous waste generators are familiar with the form, as it is the form currently used by hazardous waste generators to notify regulators of their RCRA Subtitle C activities. Second, as stated previously, the use of the Site Identification Form will allow for EPA and state regulatory agencies to monitor the healthcare facilities utilizing the new regulatory requirements. Lastly, public comments received on previous EPA actions (*e.g.*, Academic Laboratories Rulemaking (73 FR 72912; December 1, 2008)) have indicated that notification via the Site Identification Form is the notification approach typically preferred by the regulated community. We are proposing that healthcare facilities can submit their notification as part of the Biennial Report, if the healthcare facility will be

⁶⁵ A generator is a CESQG if it generates less than or equal to 100 kg of hazardous waste per calendar month, and less than or equal to 1 kg of acute hazardous waste per calendar month and <100 kg of any residue or contaminated soil, waste or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous waste listed in § 261.31 or § 261.33(e) per calendar month, provided it does not accumulate on-site at any time >1 kg of acute hazardous waste or >1000 kg of hazardous waste.

⁶⁶ For information on the current Site Identification Form, please see: <http://www.epa.gov/wastes/inforesources/data/form8700/8700-12.pdf>.

required to submit a Biennial Report due to its non-pharmaceutical hazardous waste. Otherwise, healthcare facilities are required to notify within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart.

If this notification requirement is finalized, the Site Identification Form will be modified by EPA in a separate action.⁶⁷ Specifically, the Agency intends to amend the Site Identification Form by adding a section to the form for a healthcare facility to indicate the type of entity it is (*e.g.*, a hospital, a doctor’s office, a veterinary clinic, a pharmacy, an assisted living facility, etc.) and to indicate that it generates hazardous waste pharmaceuticals. The healthcare facility will no longer be required to identify on the Site Identification Form the specific types of hazardous waste pharmaceuticals it generates. The Agency also intends to add a checkbox to the section in order to allow a healthcare facility to indicate that its generator category is changing to a CESQG and it is no longer managing its hazardous waste pharmaceuticals according to 40 CFR part 266, subpart P.

The Agency does not anticipate that this proposed notification requirement will place any undue economic burden upon healthcare facilities or the environmental regulatory agencies that process these notifications (see the Regulatory Impact Analysis for the proposed rule in the rulemaking docket EPA–HQ–RCRA–2007–0932). In fact, under these proposed regulations, healthcare facilities would no longer need to count the hazardous waste pharmaceuticals managed under 40 CFR part 266, subpart P towards a healthcare facility’s generator category. As a result, EPA anticipates that many healthcare facilities will change their generator category to either a SQG or CESQG for their other, non-pharmaceutical hazardous wastes. So while the notification requirement ensures that the environmental regulatory agencies are informed of all hazardous waste pharmaceutical management activities subject to the 40 CFR part 266, subpart P requirements in their jurisdictions, the fact that some healthcare facilities will no longer qualify as LQGs will reduce the number of healthcare facilities in the LQG universe. Because LQGs are inspected more frequently than SQGs or CESQGs, EPA expects this could result in an overall decrease in burden for both

⁶⁷ The Information Collection Request (ICR) for the Site Identification Form (8700–12) is updated every three years and must be approved by the Office of Management and Budget (OMB). These updates and OMB approvals are published in the **Federal Register** and are subject to public comment.

the healthcare facilities and the environmental regulatory agencies.

The Agency is soliciting comment on the notification requirement for healthcare facilities, the method of notification via the Site Identification Form, and whether this notification requirement will result in any undue burden to either healthcare facilities or state environmental regulatory agencies.

2. Personnel Training Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Under the current RCRA Subtitle C regulations, an LQG healthcare facility must provide RCRA training to its healthcare workers involved in the generation and/or management of hazardous waste. Under § 262.34(a)(4), LQGs are required to comply with the personnel training requirements for interim status TSDFs (which are found in § 265.16). These personnel training requirements include either classroom instruction or on-the-job training in RCRA and state that the facility must maintain training documents and records for each trained staff person. On the other hand, under current regulation, healthcare facilities that are SQGs must meet a performance-based standard when training their healthcare workers. This entails ensuring “that all employees are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies” (§ 262.34(d)(5)(iii)). For comparative purposes, healthcare facilities that are considered CESQGs do not have any personnel training requirements under the current federal regulations. Similarly, generators, including healthcare facilities, are not required to provide RCRA training to personnel that only work in satellite accumulation areas regulated under § 262.34(c). However, healthcare personnel that are involved in the generation of pharmaceutical waste must be familiar enough with the pharmaceuticals with which they are working to know when they have generated a hazardous waste so that it will be managed in accordance with the RCRA regulations.

EPA believes that the LQG RCRA training requirement is excessive for healthcare workers who sporadically generate hazardous waste pharmaceuticals at healthcare facilities, but believe it is necessary to have some familiarity with the dangers that hazardous waste pharmaceuticals can pose. Therefore, the Agency is proposing healthcare facility-specific personnel training requirements that are

akin to the training requirements for SQGs and small quantity universal waste handlers. Specifically, healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the proposed healthcare facility standards must inform all employees that handle or have responsibility for generating and/or managing hazardous waste pharmaceuticals of the proper handling and emergency procedures appropriate to their responsibilities during normal facility operations and emergencies. This training information can be disseminated through verbal communication or through distribution of pamphlets or other documentation. However, a healthcare facility that is an LQG due to its non-pharmaceutical hazardous wastes may choose to continue to use its existing training program as an LQG so as not to have different training programs and that would be acceptable, as well.

The Agency solicits comments on the personnel training requirements proposed in this document for healthcare facilities managing hazardous waste pharmaceuticals. Specifically, the Agency is seeking comment regarding the appropriateness of these personnel training requirements and if these requirements will be sufficient for communicating key procedures to healthcare workers that generate and/or manage hazardous waste pharmaceuticals.

EPA is seeking comment on whether documentation of training is necessary in order to verify compliance with the training requirement. Based on the comments received, we may include a requirement in the final rule for documenting and retaining records of healthcare personnel training. Finally, the Agency wants to reiterate that these proposed personnel training requirements only apply to staff generating and/or managing hazardous waste pharmaceuticals. The training requirements of 40 CFR part 262 will continue to apply to staff generating and/or managing other types of hazardous wastes at the healthcare facility.

3. Making a Hazardous Waste Determination for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities will still be required to make a hazardous waste determination on pharmaceutical wastes prior to managing them under the proposed cradle-to-grave standards. Therefore, when a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the

pharmaceutical waste is listed in 40 CFR part 261, subpart D and if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261, subpart C. However, unlike the existing generator requirements, the healthcare facility does not need to identify the specific waste codes applying to the pharmaceutical wastes. If the pharmaceutical waste is determined to be a hazardous waste, then the healthcare facility must manage the hazardous waste pharmaceuticals in accordance with these proposed requirements instead of 40 CFR part 262. Pharmaceutical wastes not meeting the definition of a hazardous waste (*i.e.*, non-hazardous waste pharmaceuticals) must be managed in compliance with applicable federal, state and local regulations.

EPA understands that healthcare facilities utilize various approaches when making hazardous waste determinations. For example, healthcare facilities may hire contractors to review their formularies and identify those pharmaceuticals that are hazardous wastes when discarded. These facilities may then identify hazardous waste pharmaceuticals at the pharmacy level, marking these pharmaceuticals with a special label so that healthcare personnel know how to properly dispose of the pharmaceutical when it becomes a waste. Other healthcare facilities may instruct personnel to dispose of all pharmaceutical wastes into one RCRA hazardous waste collection container. These facilities may then choose to manage all of the contents of the container as hazardous waste or they may choose to sort the hazardous waste portion from the non-hazardous waste pharmaceutical portion in the central accumulation area. Due to the various ways that healthcare facilities make the hazardous waste determination, the Agency is not proposing that a specific approach be utilized when making the determination, only that the facility performs the waste determination. However, healthcare facilities may choose to manage all of their pharmaceutical wastes as hazardous, and thus, if a healthcare facility chooses this approach, they would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their waste pharmaceuticals are hazardous and manage them as hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

4. No Central Accumulation Area and Satellite Accumulation Area Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Hazardous waste pharmaceuticals are generated at numerous locations across a healthcare facility. Under the current RCRA Subtitle C requirements, each location at the healthcare facility with a RCRA hazardous waste receptacle for the disposal of hazardous waste pharmaceuticals is considered a satellite accumulation area and is subject to volume accumulation limits and other requirements.⁶⁸ Of particular concern regarding the satellite accumulation requirements for healthcare facilities is the one quart accumulation limit for acute hazardous wastes (*i.e.*, P-listed wastes). Under the December 2008 Pharmaceutical Universal Waste proposal, no accumulation areas, central or satellite, were proposed to be established for hazardous waste pharmaceuticals. This proposed approach was consistent with the current federal universal waste program, since facilities are not required to designate a special centralized area for the accumulation of universal wastes nor are they required to have satellite accumulation areas for universal wastes. Nevertheless, EPA understands that facilities that handle universal wastes will often accumulate their universal wastes within their 90- or 180-day hazardous waste accumulation areas.

For the reasons articulated in the Pharmaceutical Universal Waste proposal, the Agency has decided that a healthcare facility accumulating hazardous waste pharmaceuticals will not be subject to the satellite accumulation area regulations or the central accumulation area regulations (also sometimes called less than 90- or 180-day areas), but rather to the proposed accumulation time limits and container standards.

A healthcare facility may choose to accumulate hazardous waste pharmaceuticals within its 90- or 180-day central accumulation area if it has one established for its other hazardous wastes as long as it maintains compliance with the proposed accumulation time limit and container requirements of 40 CFR part 266,

⁶⁸ See § 262.34(c) for the satellite accumulation requirements. For additional information on satellite accumulation areas, please see the memorandum from Robert Springer to the EPA Regional RCRA Directors, "Frequently Asked Questions about Satellite Accumulation Areas" (RCRA Online #14703) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/0AC9E15424B2897D8525770600609793/\\$file/14703.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/0AC9E15424B2897D8525770600609793/$file/14703.pdf).

subpart P. The Agency notes that even if the hazardous waste pharmaceuticals are accumulated in a 90- or 180-day central accumulation area, these hazardous waste pharmaceuticals are not subject to the 90- or 180-day requirements. EPA solicits public comment on its decision to not require hazardous waste pharmaceutical-specific central and satellite accumulation area requirements.

5. Container Standards for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The container standards discussed in this section apply to those containers used by healthcare facilities to accumulate, store and transport non-creditable hazardous waste pharmaceuticals.⁶⁹ First, we would note that due to the relatively small quantities of hazardous waste pharmaceuticals that are typically accumulated and stored at a healthcare facility, the Agency understands that other types of waste management units, such as tanks, are not used for the management of waste pharmaceuticals. Therefore, we are only proposing standards for containers. However, the Agency solicits comment as to whether other types of waste management units are also used by healthcare facilities to accumulate and store hazardous waste pharmaceuticals and whether EPA should establish technical standards for other types of waste management units.

The Agency is proposing to require that healthcare facilities pack hazardous waste pharmaceuticals into containers that are structurally sound and that are compatible with the hazardous waste pharmaceuticals that will be contained within them. EPA intends this requirement to mean that containers used for holding hazardous waste pharmaceuticals must be in good condition, with no severe rusting, apparent structural defects, or deterioration. Containers also must not have any evidence of leakage, spillage or damage that could result in the release of waste under reasonably foreseeable circumstances. Furthermore, the Agency is proposing to require that incompatible wastes not be placed in the same container, unless the commingling of incompatible hazardous wastes is conducted in such a way that it does not have the potential to (1) generate extreme heat or pressure, fire or explosion, or violent reaction; (2) produce uncontrolled toxic mists,

⁶⁹ The container standards proposed do not apply to the various packaging, blister packs, bottles, vials, IV bags, etc., in which pharmaceuticals are stored prior to being dispensed or administered.

fumes, dusts, or gases in sufficient quantities to threaten human health; (3) produce uncontrollable flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (4) damage the structural integrity of the facility or container containing the hazardous waste pharmaceuticals; or (5) through other like means threaten human health or environment. For example, the majority of a healthcare facility's non-creditable hazardous waste pharmaceuticals are likely organic in nature, and thus, compatible with each other and can be accumulated together, especially since they will most likely be incinerated once they are transported to a TSDF. However, some non-creditable hazardous waste pharmaceuticals, such as metal bearing wastes not containing sufficient organics, are prohibited from being incinerated (*e.g.*, P012, arsenic trioxide). The hazardous waste pharmaceuticals that cannot be incinerated must be accumulated separately from organic wastes destined for incineration.

The Agency believes that these technical standards, like similar technical standards that EPA has promulgated in § 265.17 for interim status TSDFs, would ensure that hazardous waste pharmaceuticals are properly managed and would not be released into the environment, while at the same time providing flexibility to the healthcare facility in selecting those containers that are most appropriate for their situation.

In addition to the proposed container standards, the Agency is also proposing that accumulation containers for hazardous waste pharmaceuticals be secured in a manner that prevents unauthorized access to the contents in order to prevent the pilfering of hazardous waste pharmaceuticals or inadvertent exposures to them. As we have noted previously, hazardous waste pharmaceuticals still retain considerable value and can easily be diverted for illicit purposes. To ensure this does not occur, we believe it is important to propose a requirement that would prevent the unauthorized access to the contents of these containers. EPA intends this requirement to be performance-based and does not intend to propose prescriptive regulatory requirements for this standard. The Agency believes that healthcare facilities can choose to utilize containers that have built-in mechanisms to prevent access to their contents or can choose to store containers in locked storage lockers, closets or rooms where the public does not have access to the containers or their contents.

The Agency is seeking comment on the appropriateness of the proposed container management standards. In addition, the EPA is soliciting comment on the proposed requirement for ensuring that the hazardous waste pharmaceuticals contained in collection containers remain secure.

6. Labeling Standards on Containers for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

During the period of accumulation and storage, the Agency is proposing that containers of hazardous waste pharmaceuticals be marked with the words "Hazardous Waste Pharmaceuticals." The Agency is not proposing to require that the hazardous waste numbers (often referred to as hazardous waste codes) of the container's contents be listed on the label. The personnel at healthcare facilities that typically generate the hazardous waste pharmaceuticals will be healthcare workers (*e.g.*, nurses). Healthcare workers are not usually intimately familiar with RCRA and its regulations and are primarily focused on patients and their health. In addition, while a healthcare facility may have an environmental compliance manager or environmental consultant that is knowledgeable about RCRA and its regulations and can make hazardous waste determinations, this individual cannot be present to assign a hazardous waste code and label the collection receptacle each time a pharmaceutical waste is generated. For these reasons, EPA does not believe it is necessary to require individual waste codes on the hazardous waste pharmaceutical collection container at the healthcare facility. The Agency is soliciting comment on the appropriateness of the proposed general labeling requirement. The Agency also requests comment on security concerns regarding having the word "pharmaceutical" marked on the containers.

7. Accumulation Time Limits for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Several hazardous waste pharmaceuticals are P-listed, acute hazardous wastes (*e.g.*, nicotine, warfarin, etc.). Under current regulations, if a generator generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time, the generator is regulated as an LQG. Due to this low generation/accumulation threshold associated with P-listed wastes, healthcare facilities are

often LQGs. However, while healthcare facilities can generate enough P-listed waste to become LQGs, they often do not generate sufficient amounts of hazardous waste pharmaceuticals within the allowed accumulation period of 90 days to make off-site shipments using a hazardous waste transporter cost-effective.

Under the 2008 Pharmaceutical Universal Waste proposal, universal waste handlers would have had one year for accumulation of its hazardous waste pharmaceuticals in order to facilitate proper treatment and disposal. Commenters on the 2008 Universal Waste proposed rule indicated support for the one-year accumulation time limit. Thus, the Agency is proposing to allow healthcare facilities to accumulate hazardous waste pharmaceuticals for up to one year, without having interim status or a RCRA permit. As with Universal Waste, one year is an appropriate timeframe because it strikes a balance between allowing healthcare facilities enough time to accumulate amounts of hazardous waste pharmaceuticals to make it economically viable for transporting their hazardous waste pharmaceuticals off-site while ensuring that the hazardous wastes are not accumulated beyond the one year storage limit under the land disposal restrictions programs (see § 268.50).⁷⁰

Healthcare facilities will have various approaches to demonstrate the length of time that hazardous waste pharmaceuticals are accumulated on-site. For example, a healthcare facility can choose to mark the container label with the date that accumulation first began, maintain an inventory system that identifies dates when the hazardous waste pharmaceuticals were first accumulated, identify in the central accumulation area⁷¹ the earliest date that a hazardous waste pharmaceutical became a waste, or any other method that clearly demonstrates the length of time that the hazardous waste pharmaceutical has been accumulated from the date it became a hazardous waste. The Agency assumes that any accumulation for up to one year is for the purpose of facilitating proper treatment and disposal. EPA proposes to require that any healthcare facility needing a longer accumulation time for any unforeseen circumstances beyond the control of the healthcare facility

(*e.g.*, a recall or litigation) request an extension from the appropriate EPA Regional Administrator. This request must be sent in writing (electronic or paper) explaining the need for the extension, the approximate amount of hazardous waste pharmaceuticals accumulated beyond the one year, and the amount of extra time requested. An extension period will be granted at the discretion of the Regional Administrator on a case-by-case basis.

Finally, the Agency reiterates that the one-year accumulation time limit only applies to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of hazardous waste generated on-site or to potentially creditable hazardous waste pharmaceuticals. EPA solicits comment on the proposed accumulation time limit of one year in order to allow healthcare facilities to generate enough non-creditable hazardous waste pharmaceuticals for cost-effective shipment, and solicits comment on the proposed mechanism to request a time extension.

8. Land Disposal Restrictions for Non-Creditable Hazardous Waste Pharmaceuticals

Similar to the current RCRA Subtitle C generator requirements, healthcare facilities must comply with the land disposal restrictions (LDR) prior to land disposal of the hazardous waste pharmaceuticals they generate. Since healthcare facilities are generators, even though they are not subject to the 40 CFR part 262 requirements for the management of hazardous waste pharmaceuticals, they must comply with the land disposal restrictions found at 40 CFR part 268. The land disposal restrictions are in place to ensure that toxic constituents present in hazardous waste are properly treated to reduce their mobility or toxicity before hazardous waste is placed into or onto the land (*i.e.*, land disposed). With limited exceptions, hazardous waste must be treated by a RCRA permitted or interim status TSDF. Again, EPA notes that autoclaving is not an acceptable method of treating hazardous waste.

In general, generators of hazardous waste assign the appropriate hazardous waste numbers codes to allow TSDFs to determine the specific treatment standard(s) for each prohibited waste. The Agency is proposing that healthcare facilities generating non-creditable hazardous waste pharmaceuticals do not have to assign hazardous waste codes to these wastes, but rather label them as "hazardous waste pharmaceuticals". They do, however, need to be aware that

⁷⁰ See the preamble to the Universal Waste final rule: May 11, 1995; 60 FR 25492 (page 25526).

⁷¹ While the proposed rules do not require healthcare facilities to comply with the central accumulation requirements under 262.34, a healthcare facility may have a central accumulation area for the other hazardous wastes that it generates.

while most of the hazardous waste pharmaceuticals are likely organic in nature and will be incinerated, some of their hazardous waste pharmaceuticals may not be suitable for incineration and therefore must be segregated from the organic wastes. The pharmaceutical hazardous wastes not suitable for incineration include characteristic metal wastes prohibited from being combusted because of the dilution prohibition of

§ 268.3(c), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon. In order to comply with the LDRs, healthcare facilities will need to segregate these wastes from the organic pharmaceutical hazardous wastes so that they can be properly treated by the TSDF. The Agency seeks comment on whether it is necessary to

incorporate into the regulations a requirement to segregate these wastes and whether additional labeling requirements are necessary to identify the hazardous waste pharmaceuticals that are not suitable for incineration.

Tables 2 through 4 list the hazardous waste pharmaceuticals with their hazardous waste codes and their LDR treatment standards.

Table 2: Waste Codes of Characteristic Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
D001	Ignitable	
	Ignitable All D001, except high TOC D001 261.21(a)(1)	DEACT and UTS or RORGS or CMBST
	Ignitable High TOC D001 based on 261.21(a)(1)	RORGS or CMBST or POLYM
D002	Corrosivity	DEACT and UTS
D004 *	Arsenic	5.0 mg/L TCLP and UTS
D005 *	Barium	21 mg/L TCLP and UTS
D006 *	Cadmium	0.11 mg/L TCLP and UTS
D007 *	Chromium	0.60 mg/L TCLP and UTS
D008 *	Lead	0.75 mg/L TCLP and UTS
D009*	Mercury	
	Mercury \geq 260 mg/kg total Hg (high mercury organics)	IMERC or RMERC
	Mercury < 260 mg/kg total Hg & are not residues from RMERC (low mercury)	0.025 mg/L TCLP and UTS
D010 *	Selenium	5.7 mg/L TCLP and UTS
D011 *	Silver	0.14 mg/L TCLP and UTS
D013	Lindane	
	Lindane alpha-BHC	0.066 mg/kg and UTS
	Lindane beta-BHC	0.066 mg/kg and UTS
	Lindane delta-BHC	0.066 mg/kg and UTS
	Lindane gamma-BHC	0.066 mg/kg and UTS
D022	Chloroform	6.0 mg/kg and UTS

Waste Code	Description	Non-Wastewater Treatment Standard
D024	m-Cresol	5.6 mg/kg and UTS

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

BOLD indicates that the waste is an organic waste with a concentration-based treatment standard
UTS = Universal Treatment Standards in § 268.48

Table 3: P-listed Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
P001	Warfarin (concentration > 0.3%)	CMBST
P012 *	Arsenic trioxide	5.0 mg/L TCLP
P042	Epinephrine	CMBST
P046	Phentermine	CMBST
P075	Nicotine	CMBST
P081	Nitroglycerin	CMBST
P188	Physostigmine salicylate	1.4 mg/kg or CMBST
P204	Physostigmine	1.4 mg/kg or CMBST

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

Table 4: U-listed Hazardous Waste Pharmaceuticals

Waste Code	Description	Non-Wastewater Treatment Standard
U010	Mitomycin	CMBST
U015	Azaserine	CMBST
U034	Chloral hydrate	CMBST
U035	Chlorambucil	CMBST
U044	Chloroform	6.0 mg/kg
U058	Cyclophosphamide	CMBST
U059	Daunomycin	CMBST
U075	Dichlorodifluoromethane	7.2 mg/kg

Waste Code	Description	Non-Wastewater Treatment Standard
U089	Diethylstilbestrol	CMBST
U121	Trichloromonofluoromethane	30 mg/kg
U122	Formaldehyde	CMBST
U129	Lindane	
	Lindane alpha-BHC	0.066 mg/kg
	Lindane beta-BHC	0.066 mg/kg
	Lindane delta-BHC	0.066 mg/kg
	Lindane gamma-BHC	0.066 mg/kg
U132	Hexachlorophene	CMBST
U150	Melphalan	CMBST
U151*	Mercury	
	Mercury \geq 260 mg/kg total Hg (high mercury organics)	IMERC or RMERC
	Mercury < 260 mg/kg total Hg & are not residues from RMERC (low mercury)	0.025 mg/L TCLP and UTS
U182	Paraldehyde	CMBST
U187	Phenacetin	16 mg/kg
U188	Phenol	6.2 mg/kg
U200	Reserpine	CMBST
U201	Resorcinol	CMBST
U205 *	Selenium sulfide	5.7 mg/L TCLP
U206	Streptozotocin	CMBST
U237	Uracil mustard	CMBST
U248	Warfarin (Concentration \leq 0.3%)	CMBST

*Waste code may not be treated by combustion unless the waste meets one of the criteria in § 268.3(c) (e.g., has >1% total organic carbon)

BOLD indicates that the waste is an organic waste with a concentration-based treatment standard
 UTS = Universal Treatment Standards in § 268.48

The organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA permitted or interim status hazardous waste combustors. As noted in Tables 2–4, most of the organic wastes have a specified treatment standard of combustion (CMBST). The remaining seven organics (lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane, phenacetin and phenol) have numerical treatment standards, such that no particular treatment technology is specified or required in order to achieve

the numerical treatment standards. While these wastes may be incinerated, the incinerator residue (ash) must be analyzed for these seven organic constituents to demonstrate compliance with the LDR treatment standards before that ash can be disposed.

As mentioned earlier, because this proposed rule does not require that healthcare facilities label their waste with the hazardous waste codes, the TSDf must always analyze the incinerator ash for these seven constituents—lindane, chloroform, m-cresol, dichlorodifluoro methane, trichloromonofluoromethane,

phenacetin, and phenol—according to their waste analysis plan, as they could possibly be present in any shipment of organic hazardous waste pharmaceuticals.

a. Alternative treatment standards considered. In their comments to the 2008 Universal Waste proposal, Environmental Technology Council (ETC) suggested revising the treatment standards for the organic hazardous waste pharmaceuticals that have numerical treatment standards to the specified treatment standard of

combustion.⁷² Specifying combustion would relieve the TSDFs from demonstrating compliance with the numerical treatment standards. EPA explored the feasibility of making combustion an alternative treatment standard for the seven organic hazardous waste pharmaceuticals that currently have numeric treatment standards. In fact, EPA notes that the numerical treatment standards were developed based on levels achieved through combustion. However, in order to allow maximum flexibility, EPA has indicated a preference for numerical treatment standards over specifying treatment standards whenever possible. Furthermore, it is not clear that pharmaceuticals would be the sole source of the seven organic constituents in question. Therefore, even if we proposed an alternative treatment standard of combustion for the seven organic pharmaceuticals, hazardous waste incinerators would still be required to test their ash for these constituents to demonstrate compliance with numeric treatment standards if they received the organics from another, non-pharmaceutical source.

b. Incineration of mercury-containing hazardous waste pharmaceuticals. It is rare, but some pharmaceuticals contain mercury (e.g., thimerosal, a mercury-containing preservative). When discarded, a mercury-containing pharmaceutical would be a D009 hazardous waste if the leachate generated by the toxicity characteristic leaching procedure (TCLP), or if the pharmaceutical itself (when the waste contains < 0.5% filterable solids), contains ≥ 0.2 mg/L mercury (see § 261.24).⁷³ As indicated in Table 2, a D009 hazardous waste with mercury content ≥ 260 mg/kg of total mercury and that also contains organics, must be treated by IMERC (incineration) or RMERC (mercury retorting). However, hazardous waste pharmaceuticals that are D009 are expected to have mercury content < 260 mg/kg, in which case the treatment standards are numeric and treatment by RMERC or IMERC is not required. With numeric treatment standards, the generator has flexibility regarding which hazardous waste treatment method to use to meet the treatment standard. As explained previously, incineration of mercury-bearing hazardous waste with > 1% total organic carbon is not considered impermissible dilution (see § 268.3(c))

and therefore is an allowable form of treatment.

Emissions from combustion units that burn hazardous waste⁷⁴ are regulated under RCRA and the Clean Air Act (CAA). The implementing regulations under these statutory authorities include emission limits for new and existing combustion units for mercury, semi-volatile metals (cadmium and lead), low volatility metals (arsenic, beryllium, and chromium), particulate matter, chlorinated dioxins and furans, other toxic organic compounds, hydrogen chloride and chlorine. The regulations also (1) specify when and how combustion sources must comply with the emission standards and operating requirements, (2) prescribe detailed monitoring requirements to show continuous compliance with the emission standards, and (3) prescribe performance testing requirements to demonstrate compliance with the emission standards (see 40 CFR part 63, subpart EEE).

To ensure continuous compliance with the emission limits, hazardous waste combustors are required to establish limits on (1) the feedrate of metals (including mercury), chlorine, and (for some types of hazardous waste combustors) ash; (2) combustor operating parameters such as minimum combustion chamber temperature; and (3) operating parameters of the air pollution control device. For mercury, continuous compliance requirements would generally include a limit on the total feedrate of mercury in all feedstreams to the combustion unit, limits on the operation of a wet scrubber (depending on the species of mercury in the combustion gases, wet scrubbers can be efficient at removing mercury), and operating limits on the activated carbon injection or carbon bed system, if such systems are used.

In addition, RCRA directs permitting authorities to impose additional terms and conditions on a site-specific basis as may be necessary to protect human health and the environment (see § 270.32(b)). Thus, if the mercury emission limits specified previously are not protective in an individual instance, the permit writer will establish permit limits that are protective.

Nevertheless, EPA is aware that some stakeholders are concerned about the risks associated with incinerating mercury-bearing hazardous wastes and we encourage healthcare facilities and pharmaceutical reverse distributors to

consider the use of treatment technologies other than incineration for meeting the numeric treatment standards for mercury-bearing hazardous waste pharmaceuticals. Thimerosal-containing pharmaceuticals are expected to be non-wastewaters as defined by § 268.2, because they have more than 1% total organic carbon. For low mercury non-wastewaters, the numeric treatment standard can be achieved by stabilization/solidification, either with or without subsequent encapsulation.⁷⁵

9. Shipments of Non-Creditable Hazardous Waste Pharmaceuticals Off-site From Healthcare Facilities

The Agency is proposing to maintain the current RCRA Subtitle C tracking requirement by requiring that a hazardous waste manifest be prepared for each off-site shipment of non-creditable hazardous waste pharmaceuticals from healthcare facilities. Accordingly, each off-site shipment of hazardous waste pharmaceuticals must be transported to an interim status or permitted TSDF via a hazardous waste transporter. However, the Agency is proposing that for hazardous waste pharmaceuticals shipped by healthcare facilities, the RCRA hazardous waste codes do not need to be listed on the manifest. This is intended to accommodate the fact that healthcare providers generating the hazardous waste pharmaceuticals are generally unfamiliar with RCRA and are focused on providing healthcare to patients. One function of the hazardous waste codes is to determine the appropriate hazardous waste treatment standards under the land disposal restrictions (part 268). However, virtually all hazardous waste pharmaceuticals sent for off-site treatment are sent to hazardous waste incinerators, even when the treatment standard does not require incineration. The fact that EPA is proposing to not require hazardous waste codes for shipping hazardous waste pharmaceuticals is not intended to alter or impact any Department of Transportation (DOT) requirements for the shipment of these hazardous wastes. For a more detailed discussion of these proposed requirements, as well as the basis for these requirements, please see Section V.F.1 of this document.

⁷⁵ EPA is not aware of any testing done to demonstrate the effectiveness of this treatment method specifically for thimerosal-containing hazardous wastes, so vendors performing such treatment may need to do treatability studies to identify optimal use of stabilization/solidification treatment technologies.

⁷² See comment number 0125 in the docket for this rulemaking. EPA-HQ-RCRA-2007-0932.

⁷³ The Agency is not aware of any hazardous waste pharmaceuticals that would be considered U151 because mercury would have to be the sole active ingredient.

⁷⁴ Combustors that burn hazardous waste include the following types of combustion units: Incinerators, cement kilns, lightweight aggregate kilns, industrial boilers and process heaters, and hydrochloric acid production furnaces.

10. Rejected Shipment From Healthcare Facilities of Non-creditable Hazardous Waste Pharmaceuticals

In rare circumstances, a healthcare facility may send its non-creditable hazardous waste pharmaceuticals to a designated facility that is unable to manage the hazardous waste. For such situations, we are proposing that healthcare facilities follow the same procedures listed in 40 CFR part 262 (see § 262.23(f)). Specifically, if a designated facility is unable to accept the hazardous waste pharmaceuticals, and it returns the hazardous waste pharmaceuticals to the healthcare facility, the healthcare facility must sign the manifest that was used to return the shipment, provide the transporter a copy of the manifest, send a copy of the manifest within thirty days to the designated facility that returned the shipment and retain a copy of the manifest for three years from the date of delivery of the returned shipment. EPA believes that it is appropriate to continue current practices for rejected shipments that are part of the generator regulations of 40 CFR part 262 because rejected shipments are relatively rare and the procedures currently used for rejected shipments is relatively straightforward. In addition, healthcare facilities should be familiar with these procedures already.

11. Reporting Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to SQGs regulated under 40 CFR part 262—that is, the exception reporting requirement under § 262.44(b) and the additional reporting requirement under § 262.44(c). In addition, we are proposing that healthcare facilities that are LQGs would no longer be required to include their hazardous waste pharmaceuticals on their biennial report (BR). Each of these reporting requirements for healthcare facilities is discussed below.

First, as part of the current RCRA Subtitle C generator requirements, healthcare facilities that are LQGs must submit a BR to the Regional Administrator by March 1st of every even numbered year (see § 262.41). Among other requirements, the BR must include a description (EPA hazardous waste number and DOT hazard class) and quantity of each hazardous waste shipped off-site to a TSDF during each odd numbered year. If a healthcare

facility is an LQG due to its non-pharmaceutical hazardous waste, it will continue to be required to submit a BR. However, it need not include its hazardous waste pharmaceuticals in its BR. As discussed previously, the Agency is no longer requiring healthcare facilities to count hazardous waste pharmaceuticals when determining their generator category. Instead, all healthcare facilities, with the exception of CESQGs, will be subject to this proposed rule. The Agency has determined that it does not need the information to be included in the BR because this proposed rule will bring a consistent approach to managing pharmaceutical hazardous wastes. Nevertheless, the Agency is soliciting public comment on whether the Agency should require healthcare facilities—that is, all healthcare facilities subject to the 40 CFR part 266, subpart P requirements—to submit a BR, and if so, the type of information that should be included.

Second, the Agency is proposing that healthcare facilities follow the same reporting procedures for exception reporting that generators operating under the 40 CFR part 262 must follow. We are proposing to incorporate the generator exception reporting procedures in this new subpart. Specifically, if a healthcare facility does not receive a copy of the hazardous waste manifest from the designated facility within 60 days, the healthcare facility must submit to the EPA Regional Administrator a copy of the manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Likewise, if a shipment of hazardous waste pharmaceuticals from a healthcare facility is rejected by the designated facility and it is shipped to an alternate facility and if the healthcare facility does not receive a signed copy of the hazardous waste manifest from the alternate facility within 60 days, it must submit to the EPA Regional Administrator a copy of the hazardous waste manifest with a statement that the healthcare facility did not receive confirmation of the hazardous waste pharmaceuticals' delivery along with an explanation of the efforts taken to locate the hazardous waste pharmaceuticals and the results of those efforts. Again, the Agency believes it is advantageous to use established procedures that should be familiar to healthcare facilities, especially given that rejected shipments are relatively rare.

Finally, the Agency proposes that the Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals. This is already the case for generators operating under the 40 CFR part 262 requirements. As with 40 CFR part 262, it is a codification of statutory authority under §§ 2002(a) and 3002(a)(6) that provides the Agency some flexibility in what reports may be required. The Agency solicits public comment on the proposed reporting requirements for healthcare facilities managing their hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

12. Recordkeeping Requirements for Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

The Agency is proposing that healthcare facilities managing non-creditable hazardous waste pharmaceuticals maintain records similar to the records that must be kept by generators regulated under 40 CFR part 262 (see § 262.40). Specifically, healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. If the healthcare facility is required to file an exception report because it does not receive a signed copy of the manifest from the designated facility within 60 days of the date that the hazardous waste pharmaceutical was accepted by the initial transporter, then the healthcare facility must keep a copy of the each exception report for a period of at least three years from the due date of the report.⁷⁶ In addition, EPA is proposing that a healthcare facility must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals regarding which pharmaceuticals are hazardous wastes for three years from the date of the test, analysis, or other determination.

⁷⁶ § 262.40 requires that generators keep a copy of each BR for a period of at least three years from the due date of the report. However, since we are not requiring a healthcare facility to include its hazardous waste pharmaceuticals on its a BR, the Agency is also not including in subpart P a requirement that a BR be kept at the healthcare facility. If healthcare facility must submit a BR due to its non-pharmaceutical hazardous waste, the § 262.40 recordkeeping requirements will apply (see the discussion under Reporting Requirement for Healthcare Facilities Managing Non-creditable Hazardous Waste Pharmaceuticals for the Agency's basis of not requiring healthcare facilities to include hazardous waste pharmaceuticals on the BR).

The Agency is also proposing that any of the retention periods be extended during the course of enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action. The Agency solicits public comment on the proposed recordkeeping requirements for healthcare facilities managing their non-creditable hazardous waste pharmaceuticals in accordance with the standards proposed in this document.

13. Response to Releases by Healthcare Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

For hazardous waste pharmaceuticals generated and managed by healthcare facilities under the proposed standards, the Agency is proposing basic release responses, including the requirement that healthcare facilities immediately contain all releases of, and other residues from, hazardous waste pharmaceuticals. In addition, this proposal would require healthcare facilities to determine whether any material, residue, or debris resulting from the release is or contains a hazardous waste pharmaceutical and, if so, to manage it under the management standards for hazardous waste pharmaceuticals proposed in this document. These proposed release response procedures are the same as those under the Universal Waste program (see § 273.17 for small quantity universal waste handlers, and § 273.37 for large quantity universal waste handlers). Commenters to the 1993 proposed rule that established the Universal Waste program overwhelmingly supported the release response measures (60 FR 25528; May 11, 1995). Thus, we believe it is appropriate to include it again in this proposal.

Any releases of hazardous waste pharmaceuticals not cleaned up immediately would generally constitute illegal disposal, which may result in further action by EPA or an authorized state under RCRA. In addition, hazardous wastes under RCRA are included in the definition of hazardous substances for purposes of the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) (see CERCLA Section 101(14)⁷⁷). Thus, any releases into the environment of hazardous substances above the reportable quantity (RQ) thresholds must be reported under

CERCLA (see CERCLA Section 103). That is, since hazardous waste pharmaceuticals are hazardous wastes and, hazardous substances under CERCLA, reporting for hazardous waste pharmaceutical releases is required when RQs are exceeded (see 40 CFR 302.4 for a list of RQs and hazardous substances). Such reports provide notification to the Agency (through the National Response Center) concerning releases into the environment and help inform whether EPA should take action, if necessary, under either RCRA or CERCLA.

The Agency solicits comment regarding the proposed standard for the response to releases of hazardous waste pharmaceuticals at healthcare facilities.

14. Long-Term Care Facilities Managing Non-Creditable Hazardous Waste Pharmaceuticals

Long-term care facilities differ in one respect from other types of healthcare facilities subject to these proposed standards. Unlike hospitals, who own the pharmaceuticals they dispense to patients, many of the hazardous waste pharmaceuticals generated at long-term care facilities belong to the residents of the facility. That is, the pharmaceuticals are dispensed under the patient's name. However, as previously discussed in this preamble, EPA is proposing to no longer allow hazardous waste pharmaceuticals generated at long-term care facilities (as defined under this proposed regulation) to be eligible for the household hazardous waste exemption. As a result, long-term care facilities must manage all hazardous waste pharmaceuticals generated on-site, regardless of ownership, in accordance with these same proposed management standards for healthcare facilities. EPA understands that while long-term care facilities often maintain each individual's pharmaceuticals in a centralized location, such as a pharmaceutical cart, there are instances where some individuals may keep and self-administer their own pharmaceuticals. EPA is proposing that the long-term care facilities collect and manage all hazardous waste pharmaceuticals generated at their facilities in accordance with these proposed requirements. This requirement means that in addition to the hazardous waste pharmaceuticals kept in the centralized location, long-term care facilities will need to collect all other hazardous waste pharmaceuticals from individuals that self-administer these pharmaceuticals and manage them in accordance with these proposed standards, which, among other things, prohibits the

sewering of hazardous waste pharmaceuticals. The Agency solicits comment on the extent to which long-term care facilities keep an inventory of the pharmaceuticals that individuals self-administer, as this would facilitate the collection of the hazardous waste pharmaceuticals for proper disposal.

Although long-term care facilities would not be required under this rule to collect non-hazardous waste pharmaceuticals, or hazardous waste pharmaceuticals from the independent living portion of a continuing care facility, EPA recommends that long-term care facilities collect all waste pharmaceuticals to ensure proper management, avoid flushing, and minimize the potential for accidental poisonings, misuse or abuse. As discussed later in this preamble, DEA regulations govern the management of controlled substances (see Section V.E.2.a of the preamble for a discussion of DEA's 2014 final rule for the disposal of controlled substances and the implications of that rule and this proposed rule for long-term care facilities.⁷⁸) Also discussed later in more detail, EPA is proposing to exempt from RCRA those hazardous waste pharmaceuticals that are also controlled substances, provided they are combusted at a permitted or interim status hazardous waste incinerator or permitted municipal solid waste incinerator and managed in compliance with applicable DEA regulations (see Section V.E.2 of the preamble for a detailed discussion of the exemption).

The Agency solicits comment regarding this requirement, and specifically requests comment on the various approaches that long-term care facilities use, or could use in collecting hazardous waste pharmaceuticals from individuals that self-administer their pharmaceuticals.

15. Healthcare Facilities That Accept Hazardous Waste Pharmaceuticals From Off-Site Conditionally Exempt Small Quantity Generators (CESQGs)⁷⁹

Typically, hazardous waste pharmaceuticals from healthcare facilities are transported either to a reverse distributor, if it is potentially creditable,⁸⁰ or to a permitted or interim

⁷⁸ DEA's final rule for disposal of controlled substances: 79 FR 53520; September 9, 2104.

⁷⁹ Unlike other sub-sections of Section V.C., which discusses the proposed standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals, this sub-section addresses both non-creditable and creditable hazardous waste pharmaceuticals.

⁸⁰ Potentially creditable hazardous waste pharmaceuticals include pharmaceuticals that are: (1) Unused or un-administered, (2) unexpired or

Continued

⁷⁷ <http://www.epw.senate.gov/cercla.pdf>.

status hazardous waste TSD. However, stakeholders have informed EPA that in some cases, hazardous waste pharmaceuticals are transported to another healthcare facility. We are aware of at least two situations in which this is occurring. First, patients at long-term care facilities who receive their pharmaceuticals from an off-site long-term care pharmacy sometimes return their unused pharmaceuticals to the long-term care pharmacy.⁸¹ Upon return, the long-term care pharmacy sorts through the returned pharmaceuticals to determine whether they will be disposed or restocked for reuse. Due to many factors, such as Medicare regulations and the cost of the pharmaceutical as compared to the cost of repackaging and restocking, only a small fraction of the returned pharmaceuticals are restocked for potential reuse. One long-term care pharmacy estimated that approximately 10 percent of the pharmaceuticals it sends to long-term care facilities come back as returns.⁸² Some portion of the returns would be considered hazardous waste pharmaceuticals when discarded.⁸³ In the second situation, the Army has established off-post health clinics to provide easier access to healthcare for military personnel, including veterans. The pharmacies at the off-post clinics receive their pharmaceutical products via couriers that deliver the pharmaceuticals from the on-post, main pharmacy. The off-post pharmacies also return their unused pharmaceuticals to the on-post, main pharmacy via courier.

EPA data indicates that the majority of long-term care facilities are CESQGs⁸⁴ and the Army has informed EPA that their off-post clinics are generally CESQGs, as well.⁸⁵ The

less than one year past the expiration date; or (3) in unopened or opened packaging or containers.

⁸¹ DEA controlled substances can be returned to a long-term care pharmacy only if they are subject to a recall (see 21 CFR 1317.85(a)).

⁸² See notes from 11–15–12 site visit to Omnicare, Inc. in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

⁸³ Due to the DEA regulations, a DEA registered long term care pharmacy may not accept returns of a controlled substances. DEA regulations define “reverse distribute” and reverse distributor” in 21 CFR 1300.01. A pharmacy is not authorized to accept returns of controlled substances from patients or reverse distribute (see 21 CFR 1301.13(e)(1)(iv)).

⁸⁴ Under these proposed requirements, hazardous waste pharmaceuticals will not count towards a facility’s generator category. Therefore, EPA expects that long-term care facilities will remain CESQGs, even though the Agency is proposing that all hazardous waste pharmaceuticals generated on the premises must be managed in accordance with these proposed requirements.

⁸⁵ See notes from 11–28–12 meeting with U.S. Army Institute of Public Health in the docket for this proposed rule (EPA–HQ–RCRA–2007–0932).

existing CESQG regulations do not allow a generator to send its hazardous waste off-site to another hazardous waste generator, unless the receiving generator is also one of the seven types of facilities listed in § 261.5(f)(3) for acute hazardous waste or § 261.5(g)(3) for hazardous waste, including municipal and non-municipal non-hazardous solid waste landfills. The Agency does not think that disposal in landfills is the best option for hazardous waste pharmaceuticals. Limited studies have shown active pharmaceutical ingredients are present in landfill leachate that is collected in municipal solid waste landfill leachate collection systems.⁸⁶ Landfill leachate is then typically transported to a wastewater treatment plant for treatment; however, active pharmaceutical ingredients can pass through the treatment system and into our Nation’s waters.

EPA thinks it would be preferable to allow healthcare facilities that are CESQGs to send their hazardous waste pharmaceuticals to another healthcare facility rather than send it to a municipal or non-municipal non-hazardous solid waste landfill. Therefore, EPA is proposing to allow healthcare facilities that are CESQGs operating under this subpart to send their hazardous waste pharmaceuticals to an off-site healthcare facility, without a hazardous waste manifest, provided four conditions are met. First, the receiving healthcare facility must be contracted to supply pharmaceutical products to the CESQG long-term care facility, or the CESQG healthcare facility and the receiving healthcare facility must both be under the control⁸⁸ of the same person, as defined by § 260.10 (e.g., the Army). Second, the receiving healthcare facility must be managing its hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule.⁸⁹ Third, the hazardous

⁸⁶ Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004), Pharmaceuticals and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. *Groundwater Monitoring & Remediation*, 24: 119–126.

⁸⁷ Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (June 2009), Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. *Bulletin of Environmental Contamination and Toxicology*, V82.6:635–659.

⁸⁸ For purposes of this provision, “control” means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate facilities on behalf of a different person shall not be deemed to control such healthcare facility.

⁸⁹ This condition is only applicable if the receiving healthcare facility is also a CESQG, since

waste pharmaceuticals from the CEQSG must be managed by the receiving healthcare facility as hazardous waste pharmaceuticals in accordance with the regulations of this proposed rule once it arrives at the receiving healthcare facility. Fourth, the receiving healthcare facility must keep and maintain records of the hazardous waste pharmaceuticals received from the off-site CESQG healthcare facilities for three years from receipt of shipment. These conditions should ensure the proper management of the hazardous waste pharmaceuticals, in that once they are received by the healthcare facility, they are subject to the same management standards EPA is proposing for hazardous waste pharmaceuticals managed by healthcare facilities, while at the same time would not impose an undue burden on healthcare facilities that are CESQGs, especially since these healthcare facilities always have the option of sending their hazardous waste pharmaceuticals to a municipal or non-municipal solid waste landfill.

The Agency solicits comment on this new provision under this subpart, including whether any additional conditions should be imposed. In recommending any additional conditions, the Agency requests that commenters provide their rationale for the additional condition(s), as well as why such additional condition(s) would not pose an undue burden on healthcare facilities that are CESQGs. In addition, the Agency solicits comment on whether it might be appropriate to allow facilities, other than those meeting the proposed definition of a healthcare facility, to accept hazardous waste pharmaceuticals from an off-site CESQG (e.g., a military medical logistics facility).

D. How does this proposed rule address healthcare facilities that accumulate potentially creditable hazardous waste pharmaceuticals prior to shipment to pharmaceutical reverse distributors?

1. Potentially Creditable Hazardous Waste Pharmaceuticals Are Not Products

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is the proposed interpretation of how RCRA applies to pharmaceuticals that are returned to reverse distributors to obtain manufacturers’ credit. Two previous agency policy memos set out EPA’s existing understanding of the status of these “creditable” pharmaceuticals. The

healthcare facilities that are SQGs and LQGs must comply with the requirements proposed in 40 CFR part 266 subpart P.

first, a letter to Merck Sharp & Dohme in 1981, explained that pharmaceuticals sent for credit may be reclaimed and are not wastes since the decision to discard a particular material does not occur until after the product has been returned to the manufacturing plant.⁹⁰ The second, a letter to BFI Pharmaceutical Services, Inc. in 1991 states, “to the extent that the materials involved are unused commercial chemical products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.”⁹¹ In addition to these letters, EPA’s 2008 Pharmaceutical Universal Waste proposal stated, “Because unused or expired pharmaceuticals are returned (via the reverse distributor) for possible manufacturer’s credit, they still have potential value to the pharmacy or hospital and are thus not considered wastes.”⁹²

In this action, we are proposing to modify EPA’s position regarding the waste status of creditable pharmaceuticals. Because we understand that many participants in this sector have relied on the interpretations in the two letters and the 2008 Pharmaceutical Universal Waste preamble, we are providing notice of a change in EPA’s position and providing an opportunity for public comment. Until this rule is final and effective, however, EPA’s previous interpretations will continue to be in effect.

In terms of the concept that returned pharmaceuticals have value and are not waste, EPA confirms the general rule under RCRA that materials that are discarded are solid wastes, regardless of the economics of the system in which those discarded materials are handled. Therefore, the fact that a material may have monetary value (e.g., through a manufacturer’s credit) does not determine whether that material is a solid waste. Rather, the “decision point” on whether a pharmaceutical is a solid waste is when it has been discarded, or the decision has been made to discard the material. That is, a discarded pharmaceutical may retain value in the reverse distribution system, but still be considered a solid waste.

⁹⁰ Alan Corson to Steven Wittner on May 13, 1981 (RCRA Online #11012) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/B630CD51DC85EDC8525670F006BCE84/\\$file/11012.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/B630CD51DC85EDC8525670F006BCE84/$file/11012.pdf).

⁹¹ Sylvia Lowrance to Mark J. Schulz on May 16, 1991 (RCRA Online #11606) [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A3A7A7A8F297438B8525670F006BE5D8/\\$file/11606.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/A3A7A7A8F297438B8525670F006BE5D8/$file/11606.pdf).

⁹² 73 FR 73525; December 2, 2008.

Additionally, the economic value of hazardous waste can be one important consideration in determining whether a hazardous waste is legitimately recycled (see, for example, the discussion of *Useful Economic Information* in the 2008 Definition of Solid Waste final rule, 73 FR 84706–07, October 30, 2008) and therefore excluded from being a solid waste. The definition of legitimate recycling is codified at 40 CFR 260.43 and is discussed in the 2015 Definition of Solid Waste final rule (80 FR 1694, January 13, 2015).

Commenters to the 2008 Pharmaceutical Universal Waste proposal, the 2014 Retail Notice of Data Availability (NODA), stakeholders, and pharmaceutical reverse distributors themselves have informed EPA that pharmaceuticals transported to reverse distributors to receive credit are rarely, if ever, repurposed, recycled, or reused. One commenter wrote, “. . . EPA’s belief that reverse distributors first arrange to transport and receive the drugs, and then determine whether the drugs are useful products or wastes, is pure fiction.”⁹³ Another commenter wrote, “. . . the vast majority of the returned pharmaceuticals are to be collected for disposal or destruction once credit has been given.”⁹⁴ A third commenter wrote, “. . . drugs sent through reverse distribution are not reused or recycled due to economic and safety reasons.”⁹⁵ Regulations pertaining to the repurposing of pharmaceuticals vary by state, as they are established by each state’s Board of Pharmacy. However, stakeholders have overwhelmingly declared that state Boards of Pharmacy only allow pharmaceuticals to be repurposed under very narrow circumstances—that is, when a specific set of conditions are followed to ensure the viability and integrity of the pharmaceutical. The set of conditions vary by state; however, states have some restrictions in common when it comes to repurposing drugs. According to the National Conference of State Legislatures (NCSL), “Virtually all [state] laws include some restrictions designed to assure purity, safety and freshness of the products. Unless otherwise noted, all programs require:

- All donated drugs must not be expired and must have a verified future expiration date.

- Controlled substances, defined by the federal Drug Enforcement Administration (DEA) usually be excluded and prohibited.

⁹³ Comment EPA–HQ–RCRA–2007–0932–0125.

⁹⁴ Comment EPA–HQ–RCRA–2007–0932–0068.

⁹⁵ Comment EPA–HQ–RCRA–2012–0426–0025.

- A state-licensed pharmacist or pharmacy to be part of the verification and distribution process.

- Each patient who is to receive a drug must have a valid prescription form in his/her own name.”⁹⁶

Thus, in most, if not all cases, pharmaceuticals that are transported back to a reverse distributor for credit are discarded by the reverse distributor.⁹⁷ For that reason, the decision to send a pharmaceutical to a reverse distributor is essentially a decision to discard the pharmaceutical.

Therefore, EPA is proposing to reinterpret its position such that the decision to send a pharmaceutical to a reverse distributor is the point at which a decision has been made to discard the pharmaceutical. As a result, once the decision is made to send a hazardous waste pharmaceutical to a reverse distributor, it is a solid waste at the healthcare facility. In this document, EPA is proposing to define the term “potentially creditable hazardous waste pharmaceutical.” A portion of the potentially creditable pharmaceuticals at healthcare facilities that are transported to reverse distributors will likely meet the definition of hazardous waste. Of the set of pharmaceuticals that are hazardous wastes, only “potentially creditable” hazardous waste pharmaceuticals may be transported to a reverse distributor for manufacturer’s credit (see definition Section V.A.3).

The Agency notes that the management standards discussed below pertain only to potentially creditable hazardous waste pharmaceuticals that are managed via reverse distribution and do not apply to the reverse distribution or reverse logistics systems that may exist for other consumer products. In addition to the standards discussed in this section, EPA is proposing standards for shipping potentially creditable hazardous waste pharmaceuticals to pharmaceutical reverse distributors as well as associated recordkeeping (see Section V.F.2. of the preamble).

2. Hazardous Waste Determination for Potentially Creditable Hazardous Waste Pharmaceuticals

As with non-creditable hazardous waste pharmaceuticals discussed

⁹⁶ Content is copied from <http://www.ncsl.org/research/health/state-prescription-drug-return-reuse-and-recycling.aspx> (accessed May 13, 2015).

⁹⁷ Any facility, including a pharmaceutical manufacturer engaged in processing pharmaceutical hazardous waste for facilitation or verification of manufacturer’s credit would be considered a pharmaceutical reverse distributor under the proposed rule with respect to those operations, and would be subject to the proposed regulations for pharmaceutical reverse distributors.

previously, a healthcare facility must determine which potentially creditable pharmaceuticals are listed or characteristic hazardous wastes, in order to determine which potentially creditable pharmaceuticals are subject to regulation under this subpart. Potentially creditable hazardous waste pharmaceuticals must be managed under this subpart, while pharmaceuticals that do not meet the definition of hazardous waste but are potentially creditable, do not have to be managed under this subpart. However, a healthcare facility may choose to manage all of its potentially creditable pharmaceuticals (both hazardous and non-hazardous) as potentially creditable hazardous waste pharmaceuticals while accumulating on-site and when shipping off-site. If a healthcare facility chooses this approach, it would not need to make individual hazardous waste determinations, but would have made a generic decision that all of their potentially creditable waste pharmaceuticals are hazardous and manage them as potentially creditable hazardous waste pharmaceuticals in accordance with the proposed requirements in 40 CFR part 266, subpart P.

3. Accumulation Time, Container Management, and Labeling for Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities

Typically, EPA requires specific management standards for containers that hold hazardous waste. However, potentially creditable hazardous waste pharmaceuticals appear to pose lower environmental risk of release than patient care hazardous waste pharmaceuticals or traditional industrial hazardous waste. The risk of release is lower for several reasons. First, potentially creditable hazardous waste pharmaceuticals that are prepared for shipment to a reverse distributor are usually in their original containers as well as outer packaging, providing two layers of protection from leaks or spills.⁹⁸ Second, potentially creditable hazardous waste pharmaceuticals are typically generated in the pharmacy area of a healthcare facility where there is restricted access, creating a layer of security for these pharmaceuticals. Third, EPA has been informed that it is common practice at healthcare facilities for potentially creditable pharmaceuticals that are destined for a reverse distributor to be taken from the shelves of the pharmacy periodically and promptly boxed for off-site shipment. EPA anticipates that this

relatively quick timing is largely driven by the economic value of the manufacturer's credit for the returned pharmaceuticals. Therefore, because of the lower risk these pharmaceuticals pose, EPA is not proposing specific management standards for healthcare facilities that accumulate containers of potentially creditable hazardous waste pharmaceuticals. For the same reasons, we also are not proposing a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals. EPA requests comment on the assumption that healthcare facilities promptly remove potentially creditable hazardous waste pharmaceuticals from pharmacy shelves and send them to reverse distributors. EPA asks for comment on whether the expectation of credit provides sufficient incentive to ensure that the hazardous waste pharmaceuticals will be managed appropriately or whether it is necessary to establish management standards and/or a maximum time limit for the accumulation of potentially creditable hazardous waste pharmaceuticals prior to off-site shipment.

In the 2008 Pharmaceutical Universal Waste proposal, EPA specifically solicited comment on whether stakeholders have knowledge of problems with mixing incompatible pharmaceuticals during accumulation. In response, one commenter indicated that there were no issues encountered with the compatibility of pharmaceuticals during storage.⁹⁹ Since then, a 2011 article by Charlotte Smith states, "oxidizers, acids, and bases also are incompatible, but they occur infrequently as finished dosage forms."¹⁰⁰ It is important to note that the accumulation of some potentially creditable hazardous waste pharmaceuticals, such as liquids and aerosols, may pose more of a risk than solid pills due to possible spillage or leakage. However, EPA believes that the small quantities in which the liquid and aerosol potentially creditable hazardous waste pharmaceuticals are generated, along with the DOT packaging requirements (49 CFR parts 173, 178, and 180), would likely obviate these risks. In addition, to further mitigate the potential for spillage or leakages, as a best management practice, EPA encourages healthcare facilities to place the original containers and packaging containing liquids and aerosols

pharmaceuticals in separate individual containers, such as a sealed storage bag before placing them in the container that will be shipped.

EPA also is proposing not to require specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals, while they accumulate on-site. EPA does not want to deter the practice of co-mingling potentially creditable hazardous waste pharmaceuticals with potentially creditable non-hazardous waste pharmaceuticals since both are typically transported to a reverse distributor together.

In addition, due to concerns regarding diversion of pharmaceuticals, EPA believes that it is safer not to call attention to the fact that these containers hold pharmaceuticals. Unlike floor waste or patient care pharmaceutical waste, or most hazardous waste, the hazardous waste pharmaceuticals returned to a reverse distributor often have high street value that makes them susceptible to diversion. Thus, EPA is not proposing to require a label for potentially creditable hazardous waste pharmaceuticals during accumulation at a healthcare facility. The Agency seeks comment on its proposal not to require specific accumulation, container management or labeling standards for potentially creditable hazardous waste pharmaceuticals that will be transported to a reverse distributor, including no specific labeling standards for containers holding potentially creditable hazardous waste pharmaceuticals on-site prior to shipment off-site.

E. What are the proposed novel prohibitions, exemptions and other unique management requirements for hazardous waste pharmaceuticals?

1. Sewer Disposal Prohibition

a. Regulatory background on the domestic sewage exclusion. Under RCRA and the Subtitle C hazardous wastes regulations, if a material is not a solid waste, then it cannot be considered a hazardous waste. Under § 261.4(a)(1)(ii) of the RCRA regulations, "Any mixture of domestic sewage and other wastes that passes through a sewer system to a publicly-owned treatment works for treatment" is not a solid waste for purposes of Subtitle C regulation. This exclusion was finalized by EPA on May 19, 1980, based on the reasoning that "Mixed waste streams that pass through sewer systems to publicly-owned treatment works (POTW's) will be subject to controls under the Clean

⁹⁹ Commenter #EPA-HQ-RCRA-2007-0932-0091.

¹⁰⁰ Charlotte Smith, RPH, MS; Managing Pharmaceutical Waste: A New Implementation Blueprint; Pharmacy Practice News, Special Edition, 2011.

⁹⁸ See 73 FR 73529; December 2, 2008.

Water Act. The Agency's construction grants program provides financial assistance for the proper treatment of these wastes. In addition, the Agency's pretreatment program provides a basis for EPA and the local communities to ensure that users of sewer and treatment systems do not dump wastes in the system that will present environmental problems" (45 FR 33097).

In 1984, Congress enacted the Hazardous and Solid Waste Amendments (HSWA) to the Solid Waste Disposal Act (SWDA), as amended by RCRA. HSWA included a new Section 3018, entitled Domestic Sewage. This section directed EPA to do two things with respect to the 261.4(a)(1)(ii) exclusion for mixtures of domestic sewage and other wastes: (1) Submit a Report to Congress (RTC) that describes the types, size and number of generators which dispose of such wastes in this manner, the types and quantities of wastes disposed of in this manner, and identify significant generators, wastes and waste constituents not regulated under existing Federal law or regulated in a manner sufficient to protect human health and the environment; and (2) based on the report, revise the existing regulations that are necessary to "ensure that substances . . . which pass through a sewer system to a publicly owned treatment works are adequately controlled to protect human health and the environment."

EPA submitted its Report to Congress on February 7, 1986 (Domestic Sewage Study). Subsequent to the Report to Congress, EPA issued an advance notice of proposed rulemaking (ANPR) on August 22, 1986 (51 FR 30166); a response to comments on the ANPR on June 22, 1987 (52 FR 23477); a notice of proposed rulemaking (NPR) on November 23, 1988 (53 FR 47632); and a final rule on July 24, 1990 (55 FR 30082). That final rule prohibits the discharge of pollutants which create a fire or explosion hazard in the POTW, which includes, but is not limited to, wastestreams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Celsius using the test methods specified in 40 CFR 261.21" (55 FR 30087). Although the exclusion for mixtures of domestic sewage and other wastes is found under the RCRA regulations in § 261.4(a)(1)(ii), the sewer ban of liquid ignitable hazardous wastes (*i.e.*, with the hazardous waste code D001) was established under 40 CFR 403.5(b)(1), which is under the Clean Water Act (CWA) regulations. The Agency seeks comment on whether it would be helpful to incorporate in 40 CFR

261.4(a)(1)(ii), a cross-reference to the CWA regulations prohibiting the sewerage of liquid ignitable hazardous wastes.

b. Prevalence of flushing in lieu of hazardous waste management. In the preamble to the July 1990 final rule, EPA stated its intent "to carefully review the effect of this rule and promulgate in the future any additional regulations that experience reveals are necessary to improve control over hazardous waste and other industrial user discharges to POTWs" (55 FR 30084). Since then, studies have found that many healthcare facilities, particularly long term-care facilities, use drain disposal as a routine disposal method for pharmaceutical wastes in lieu of collection and shipment off-site for management. For example,

- A 2008 study of 59 long-term care facilities showed that 46 percent of the long-term care facilities dispose of their pharmaceuticals by dumping them down the drain.¹⁰¹
- A 2003 King County, Washington survey of healthcare facilities showed that the vast majority of liquids, and nearly half of the pills, were disposed of down the drain.¹⁰²
- In a study by The Albany Medical Center, funded by an EPA Pollution Prevention Grant, the author states, "up to now, toilet wasting has been the common practice for drug wasting by patient care staff."¹⁰³
- In a detailed study about the waste management practices within the healthcare industry, EPA's Office of Water also found that sewerage of waste pharmaceuticals was common practice.¹⁰⁴
- EPA staff from the Office of Research and Development (ORD) have published numerous articles on the subject of active pharmaceutical ingredients (APIs) in the environment. One such paper states that "unit-packaged pills are probably not frequently disposed via toilets, whereas liquids are probably routinely poured down drains," although the authors acknowledge that "gaining an understanding of the types and quantities of APIs introduced directly and purposefully to the environment by

¹⁰¹ Kansas State University. January 31, 2008. Nancy J. Larson. *Pharmaceutical Waste Outreach Project*.

¹⁰² King County Pharmaceutical Waste Survey Final Report. King County, Washington. April 2003.

¹⁰³ The Albany Medical Center, October 29, 2009, Russell F. Mankes, Progress Report on the Source Reduction Demonstration Project, EPA Grant #X9-97256506-0.

¹⁰⁴ Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA-821-R-08-013.

the disposal of unwanted, leftover drugs has been more problematic because of a dearth of comprehensive or reliable data."¹⁰⁵

c. Inadequacy of POTW treatment to remove pharmaceuticals. Under the Clean Water Act (CWA), EPA establishes national regulations (called effluent limitations guidelines and pretreatment standards) to reduce discharges of pollutants from industries to surface waters and POTWs. However, there are currently no national effluent limitations or pretreatment standards that apply to discharges of pharmaceuticals by healthcare facilities to POTWs. Furthermore, traditional wastewater treatment operations implemented in the 1970s and 1980s at POTWs are designed to remove conventional pollutants, such as suspended solids and biodegradable organic compounds. They are not designed to remove pharmaceuticals that are present in discharges from medical and veterinary facilities. While some POTWs may have implemented advanced treatment technologies at their facilities, these technologies are also not designed to remove pharmaceuticals. EPA released a study in 2009 in which over 100 chemicals (including some pharmaceuticals) were analyzed in the influent and effluent at nine POTWs.¹⁰⁶ Although it was a limited study and difficult to generalize the results to all POTWs, it does indicate that the capabilities of treatment technologies currently employed by POTWs does not include treatment to remove APIs.¹⁰⁷ In addition, as stated in the Health Services Industry study, "synthetic compounds, such as pharmaceuticals, are often manufactured to be resistant to metabolic transformation. As a result, some pharmaceutical compounds that are present in the influent to POTWs may pass through treatment systems at conventional POTWs and discharge to receiving waters."¹⁰⁸

d. Adverse impacts to human health and the environment due to pharmaceuticals in the environment.

¹⁰⁵ Ruhoy and Daughton; Beyond the medicine cabinet: An analysis of where and why medications accumulate; Environment International 34(2008) 1157-1169.

¹⁰⁶ EPA, Occurrence of Contaminants of Emerging Concern in Wastewater from Nine Publicly Owned Treatment Works, August 2009; EPA-821-R-09-009.

¹⁰⁷ Eggen RI, Hollender J, Joss A, Schärer M, Stamm C, "Reducing the Discharge of Micropollutants in the Aquatic Environment: The Benefits of Upgrading Wastewater Treatment Plant." Environmental Science and Technology 2014, 48(14) 7683-7689.

¹⁰⁸ Health Services Industry Study: Management and Disposal of Unused Pharmaceuticals (Interim Technical Report) August 2008; EPA-821-R-08-013.

The pharmaceuticals entering the environment, through flushing or other means, are having a negative effect on aquatic ecosystems and on fish and animal populations. The Regulatory Impact Analysis for this proposed rulemaking summarizes the scientific literature with regard to ecological effects (see the Regulatory Impact Analysis in the docket for this proposed rule EPA-HQ-RCRA-2007-0932). The scientific research with regard to human health effects due to pharmaceuticals in the environment is still ongoing. Nevertheless, the important features and risks of the problem can be summarized as follows:¹⁰⁹

(1) Pharmaceuticals are intrinsically bioactive compounds; therefore, they are potentially able to impact living systems.

(2) There is a continuous and worldwide increase in their use and, thus, on their subsequent input into the environment.

(3) Many of the hundreds of frequently prescribed pharmaceuticals are known for targeted effects and adverse off-target side effects, a problem that can be exacerbated by interactive effects during therapy involving co-administration.

e. Banning sewerage of hazardous waste pharmaceuticals. Given the demonstrated negative ecological effects and the potential for negative human health effects, EPA is proposing to impose a sewer ban on all hazardous waste pharmaceuticals managed by healthcare facilities and pharmaceutical reverse distributors that are subject to this proposed rule—that is, they are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (*i.e.*, ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (*e.g.*, sink, toilet, or floor drain).

In addition, while healthcare facilities that are CESQGs are generally not subject to this proposed rule, EPA is proposing that the sewer ban of hazardous waste pharmaceuticals also apply to healthcare facilities that are CESQGs. The vast majority of healthcare facilities are CESQGs (84 percent). Some particular types of healthcare facilities have an even larger proportion of CESQGs: Over 94 percent of dental offices are CESQGs, and 94 percent of continuing care retirement communities

are CESQGs (see the Regulatory Impact Analysis in the docket for this proposed rule EPA-HQ-RCRA-2007-0932).

EPA is concerned that these smaller healthcare facilities are more likely to dispose of their hazardous waste pharmaceuticals via the sewer. EPA estimates that there are more than 145,000 healthcare facilities that are CESQGs. Given this large number, the combined impact of sewer disposal by healthcare facilities that are CESQGs has an even greater potential to provide a substantial impact on the environment, as well as human health.

EPA solicits comment on EPA's proposal to ban the sewer disposal of hazardous waste pharmaceuticals at all healthcare facilities, including healthcare facilities that are CESQGs that generate such wastes. As part of its solicitation of comments, the Agency especially requests comment on the risk-risk tradeoffs inherent in prohibiting sewer disposal, which extends the life cycle of pharmaceutical waste, resulting in additional opportunities for diversion and increasing the possibility of inadvertent exposures for certain workers (and possibly even patients or visitors) as a tradeoff for a reduction in aquatic risks. EPA also solicits comment on whether the ban on sewer disposal should be limited to those healthcare facilities that are currently LQGs and SQGs, and not extended to CESQGs.

Under 40 CFR 403.12(p) of the CWA regulations, industrial users that discharge a substance to a POTW that, if otherwise disposed of, would be a hazardous waste, must notify in writing the POTW, the EPA Regional Waste Management Division Director and State hazardous waste authorities. POTWs should be made aware that under this proposal, if made final, the notifications they receive from healthcare facilities will no longer include hazardous waste pharmaceuticals since the healthcare facilities will be prohibited from sewerage their hazardous waste pharmaceuticals.

We note that EPA's proposed ban on sewerage hazardous waste pharmaceuticals is consistent with other federal and state actions. For example, the Drug Enforcement Administration (DEA) has finalized new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 (September 9, 2014; 79 FR 53520). DEA's new regulations require a "non-retrievable" method of destruction of controlled substances. The preambles to DEA's proposed and final rules state that flushing does not meet the non-

retrievable standard for destruction.¹¹⁰ According to the preamble of the DEA final rule, DEA received 20 comments supporting their position against flushing controlled substances.¹¹¹ The comments supporting the prohibition against sewerage came from states, regional and local hazardous waste management programs, recycling associations, non-governmental organizations (NGOs), trade associations and environmental organizations. Many of these commenters noted that wastewater treatment systems do not eliminate many of the drugs that are flushed into the sewers and requested that DEA clearly state in the regulatory language, not just preamble, that sewerage is not allowable as a means of destruction.

In addition, three states and the District of Columbia have taken action to limit the sewerage of pharmaceuticals and a third has introduced a bill. In 2009, Illinois passed the Safe Pharmaceutical Disposal Act, which prohibits healthcare facilities from flushing any unused medication into public sewers or septic systems.¹¹² In 2012, New Jersey passed a similar law that prohibits healthcare facilities from discharging prescription medications into public sewers or septic systems.¹¹³ In 2002, California banned the use of lindane in pharmaceuticals after it found that lindane was adversely impacting wastewater quality. The authors of the paper "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecologic Impacts" state that "This is the first time that a pharmaceutical has been outlawed to protect water quality."¹¹⁴ After researching and documenting environmental benefits of the ban, the authors conclude, "This ban serves as a model for governing bodies considering limits on the use of lindane or other pharmaceuticals." And the District of Columbia has promulgated municipal regulations, effective January 1, 2011, that prohibits healthcare facilities from flushing pharmaceutical products.¹¹⁵ The Connecticut legislature has also considered a bill to ban the discharge of medication into public or private waste water collection systems or septic

¹¹⁰ Proposed rule: December 21, 2012; 77 FR 75784 (see page 75803) and Final rule: September 9, 2014; 79 FR 53520 (see page 53548).

¹¹¹ September 9, 2014; 79 FR 53520 (see page 53548).

¹¹² Illinois Public Act 096-0221.

¹¹³ Nicknamed Bateman's Law, after Senator Christopher "Kip" Bateman (R-Somerset) that sponsored the legislation.

¹¹⁴ Humphreys, *et al.* Environmental Health Perspectives. 2008 March; 116(3) 297-302.

¹¹⁵ Title 22-B Chapter 5 Safe Disposal of Unused Pharmaceuticals in Health Care Facilities.

¹⁰⁹ A. Ginebreda et al, Environmental risk assessment of pharmaceuticals in rivers: Relationships between hazard indexes and aquatic macroinvertebrate diversity indexes in the Llobregat River (NE Sapin). Environ Int. (2009), doi:10.1016/j.envint.2009.10.003.

systems, although it has not yet become law.¹¹⁶

Finally, we would note that although the sewer ban is limited to pharmaceuticals that are RCRA hazardous wastes, EPA strongly recommends as a best management practice to not sewer any waste pharmaceutical (*i.e.*, hazardous or non-hazardous), except when sewerage is specifically directed by FDA guidance (as noted on pharmaceutical packaging).¹¹⁷

For household pharmaceutical waste, we refer the public to the guidelines developed by the U.S. Office of National Drug Control Policy (ONDCP), the FDA, and EPA for the disposal of unwanted

household pharmaceuticals. In summary, these guidelines are as follows:

- (1) Use a drug take-back event or program, when available;
- (2) Dispose in household trash, after mixing the unwanted medicines with an undesirable substance such as kitty litter or coffee grounds and placing in a sealed container; and
- (3) Only if the drug label specifically instructs you to, flush the unwanted medicine down the toilet.¹¹⁸

2. Conditional Exemption for Hazardous Waste Pharmaceuticals That Are Also Controlled Substances

When a pharmaceutical that is discarded is both a hazardous waste and

a controlled substance, its management and disposal is regulated under both the RCRA Subtitle C hazardous waste regulations, which is under EPA's or the authorized state's purview, and the Controlled Substances Act (CSA) and its implementing regulations, which is under DEA's purview. EPA understands that only a handful of pharmaceuticals are in common usage that are both hazardous waste and controlled substances and therefore subject to dual regulation by both EPA and the DEA. These are identified in Table 5:

Table 5: Pharmaceuticals Still Used in Healthcare that Are DEA Controlled Substances & RCRA Hazardous Wastes

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supporettes	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content
Testosterone gels	Androgel, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to gel base
Valium injectable	Diazepam	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

Chloral hydrate, U034, is the only dually regulated hazardous waste/controlled substance that is a listed hazardous waste. It is listed for toxicity (note that EPA's U034 listing includes chloral hydrate, see memo dated April 6, 1998; Brandes to Knauss, RCRA Online #14175). On the other hand, the remaining four dually regulated

hazardous wastes/controlled substances in common use are considered hazardous because they exhibit the characteristic of ignitability (D001). However, the active ingredient is not ignitable, but these particular forms of the pharmaceuticals are ignitable because they are prepared in ignitable solutions, such as alcohol.

EPA is aware of three additional hazardous waste pharmaceuticals that are DEA controlled substances, but it is our understanding that they are no longer in common usage, although there may be legacy supplies remaining in healthcare facilities. See Table 6.

¹¹⁶ State of Connecticut General Assembly, January Session 2013, Raised Bill No. 6439. An Act Concerning the Disposal and Collection of Unused Medication.

¹¹⁷ <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf>.

¹¹⁸ <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/UCM337803.pdf>.

Table 6: DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal	D001 ignitable	III	No longer in common use
Opium Tincture	Laudanam	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use

Similarly, as noted in Table 7, phentermine is a controlled substance, but the medical form is a phentermine

salt, and the salts are no longer considered to be within the scope of the P046 listing (see memo dated February

17, 2012; from Devlin to RCRA Division Directors, RCRA Online #14831).

Table 7: Pharmaceuticals that are DEA Controlled Substances & RCRA Hazardous Wastes Salt(s) No Longer Considered Hazardous Waste

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Phentermine	alpha, alpha-Dimethylphenethyl amine; Benzeneethanamine, alpha, alpha-dimethyl-; Adipex-P, Atti Plex P, Fastin, Ionamin, Kraftobese, Panshape M, Obex-Nix, Pentercot, Phentride, Pro-Fast, Raptre, Supramine, Tara-8, Termene, Termine, Zantryl	Appetite suppressant	P046 Acutely toxic	IV	If in salt form, it does not meet the P046 listing and medical dosage forms are salts

EPA requests comment on whether these are, indeed, the only pharmaceuticals in common usage that are regulated both as DEA controlled substances, and when discarded, RCRA hazardous waste.

Common practices that healthcare facilities have used in the past in order to comply with the DEA regulations for destroying controlled substances include sewerage and incineration. However, DEA's new regulation requires that controlled substances must be destroyed, such that they are "non-retrievable." As discussed previously,

the preambles for DEA's proposed and final rules state that flushing will not meet their new non-retrievable standard, a position which EPA fully supports. However, EPA is concerned that flushing will continue to be used by healthcare facilities for eliminating their controlled substances. In part, this concern is due to a 2009 EPA report which concluded, "controlled substances are the pharmaceuticals most commonly poured down the drain, especially the partially-used IVs

containing controlled substances."¹¹⁹ In addition, stakeholders have informed EPA that it is expensive and difficult to manage controlled substances that are also hazardous wastes under both DEA and EPA regulatory schemes and therefore the unintended consequence is that they are often sewerage on-site in order to avoid the expense of complying with dual regulation en route to incineration.

¹¹⁹Pathways for Environmental Releases of Unused Pharmaceuticals, October 12, 2009, Memo from ERG to EPA, EPA-HQ-OW-2008-0517-0518.

EPA wants to eliminate the flushing of pharmaceuticals in order to reduce potential environmental contamination. Sewering hazardous wastes that are ignitable (D001) is already banned and EPA is now proposing to eliminate the sewerage of all other hazardous waste pharmaceuticals.¹²⁰ To eliminate duplicative regulation and thereby further reduce the incidence of flushing, EPA is proposing to conditionally exempt from RCRA Subtitle C regulation those hazardous wastes that are also DEA controlled substances. Specifically, EPA is proposing that hazardous wastes that are also controlled substances will be exempt from all RCRA Subtitle C requirements, including 40 CFR part 266, subpart P, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances.

The first condition is to ensure that the controlled substances are destroyed in an environmentally protective manner by a high-temperature combustor, such as a large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln). The majority of the hazardous wastes that are also controlled substances are hazardous because they exhibit the characteristic of ignitability. The best demonstrated available technology (BDAT) developed for ignitable hazardous waste under the LDRs includes combustion (see § 268.40). In addition, although chloral hydrate (U034) is listed because of its toxicity, its BDAT is also combustion. Therefore, in an effort to eliminate the sewerage of these dually regulated hazardous wastes/controlled substances, and because combustion of these pharmaceuticals is a suitable technology for destruction, EPA is proposing to allow the few hazardous wastes pharmaceuticals that are also controlled substances to be combusted at municipal solid waste combustors, although as noted previously, a hazardous waste incinerator (permitted or interim status) would also be allowed.

We realize that DEA may allow a technology other than combustion to be used to destroy controlled substances. However, if the RCRA hazardous waste pharmaceuticals that are DEA controlled

substances are exempt from RCRA, the other destruction technologies may lack environmental controls and permits. Therefore, combustion of the hazardous wastes/controlled substances, which requires permitting, operating and monitoring standards, is a condition of the exemption. EPA requests comment on whether there are additional technologies that would be appropriate to include for the destruction of hazardous waste pharmaceuticals that are also controlled substances. Under this proposal, if DEA allows a technology other than incineration for the destruction of controlled substances, it would be allowed only for DEA controlled substances, but not for those that are also RCRA hazardous wastes.

The second condition is to ensure that dually regulated hazardous wastes/controlled substances are managed under another rigorous regulatory program since they will not be managed in accordance with the RCRA Subtitle C regulations. Although developed for different reasons, both EPA's hazardous waste and DEA's controlled substance regulatory programs are designed to track the regulated material from cradle to grave. DEA regulations have requirements similar to EPA's hazardous waste manifest. In particular, in order to ship a schedule II controlled substance, a DEA registrant must submit a DEA Form 222 to the supplier of the schedule II controlled substance. The DEA Form 222 is a numerically controlled form issued by the DEA to authorized registrants, containing certain pre-printed information. The supplier must indicate on the DEA Form 222, the quantity of packages shipped and the date the packages were shipped. Like a hazardous waste manifest, a copy of Form 222 must accompany the shipment and it must be kept by both the supplier and purchaser for at least two years (copies of manifests must be kept for three years). Suppliers and distributors may utilize the electronic version of the DEA Form 222, which requires the same information and retention period. Similarly, DEA Schedule III, IV and V controlled substances must be accompanied by an invoice, which also must include a detailed inventory of the contents shipped. A copy of the invoice must also be retained by the supplier and purchaser of the controlled substances for a period of two years. EPA believes that the DEA tracking and shipping requirements are sufficient to act in lieu of the RCRA hazardous waste manifest and hazardous waste transporter requirements. EPA requests comment on this assessment.

DEA has previously stated that controlled substance "pharmaceutical wastage" may be disposed of in accordance with applicable federal, state, and local laws, regulations, and healthcare facility policies, to include sewerage or putting down the drain.¹²¹ The term "pharmaceutical wastage" refers to leftover, unadministered pharmaceuticals ("e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized"¹²²). EPA is proposing that the few hazardous waste pharmaceuticals that are also controlled substances would be exempt from RCRA, but only on the condition that they are incinerated at a permitted hazardous waste or municipal solid waste incinerator and managed in accordance with DEA regulations. As a result, if pharmaceutical wastage is both hazardous waste and controlled substance it would not be allowed to be sewerage; it would have to be incinerated. Prior to incineration, the pharmaceutical wastage would be exempt from RCRA and could be collected in a container at the healthcare facility. As an alternative, we request comment on whether to allow the sewerage of the pharmaceutical wastage for the five hazardous wastes that are also controlled substances. We are concerned, however, that this alternative approach will lead to the sewerage of all pharmaceutical wastage as healthcare providers are unlikely to keep track of which hazardous waste pharmaceuticals are allowed to be sewerage and which are not. We request comment on these approaches for pharmaceutical wastage and request data on the impact on healthcare facilities of not allowing pharmaceutical wastage to be sewerage.

a. Long-term care facilities and the DEA final rule. As discussed previously, EPA is proposing that hazardous waste from long-term care facilities will no longer be considered exempt as household hazardous waste. Instead it will need to be managed as regulated hazardous waste. This interpretation will apply to all the hazardous waste generated by a long-term care facility, not just its hazardous waste pharmaceuticals, although the Agency expects that much of the hazardous waste generated by long-term care facilities consists of hazardous waste pharmaceuticals. However, there are

¹²¹ See DEA letter to registrants re: clarifying disposal of pharmaceutical wastage dated Oct 17, 2014; http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf.

¹²² *Ibid.*

¹²⁰ See 40 CFR 403.5 for specific pretreatment prohibitions.

two exceptions. First, hazardous waste pharmaceuticals that are also controlled substances will not be subject to RCRA, provided they meet two conditions: (1) They are combusted at a permitted large or small municipal waste combustor or a permitted or interim status hazardous waste combustor (incinerator or cement kiln), and (2) they are managed and disposed of in compliance with all applicable DEA regulations for controlled substances. Second, as discussed previously, EPA estimates that only 28% of long-term care facilities generate hazardous waste pharmaceuticals and of those, 85% generate small enough quantities of hazardous waste that they will qualify as CESQGs and will be subject to the reduced regulatory requirements of 40 CFR 261.5, and only the sewer ban provision of this new subpart.¹²³

DEA's new regulations to implement the Secure and Responsible Drug Disposal Act of 2010 are expected to help alleviate the problem that long-term care facilities face when discarding controlled substances. DEA's new regulations allow retail pharmacies and hospital/clinics with an on-site pharmacy that are DEA registrants to modify their registrations and become "collectors" to place collection receptacles at long-term care facilities (or at the retail pharmacy or hospital/clinic with an on-site pharmacy) for the collection of controlled substances from ultimate users (*i.e.*, consumers).

Under the new DEA regulations, long-term care facilities have three options, two of which are new, for managing their patients' controlled substances. First, if a DEA registered retail

pharmacy or hospital/clinic with an on-site pharmacy places a collection container at a long-term care facility, the staff from the long-term care facility may place the patients' controlled substances in the collection receptacles. Second, although long-term care facilities will not be able to conduct collection events for their patients' controlled substances for mail-back programs, they will be allowed to assist patients who choose to use a mail-back program for their own controlled substances, on an individual-by-individual basis. And third, law enforcement will continue to be allowed to pick up patients' controlled substances for disposal. With these changes to DEA's regulation, long-term care facilities can now dispose of patients' controlled substances in a more environmentally protective way. Because we are proposing that hazardous waste pharmaceuticals that are also controlled substances are conditionally exempt from RCRA, these wastestreams may also be managed in any of these three ways allowed by DEA, provided the waste is managed to meet the conditions of the RCRA conditional exemption.

The new DEA regulations do not mandate the placement of collection receptacles or patient participation in mail-back programs or take-back events. However, if long-term care facilities are prohibited from disposing of pharmaceuticals down the toilet or drain under RCRA (and as a method of destruction under DEA regulations), then the only way for patients at long-term care facilities to lawfully dispose of DEA controlled substances that are

also RCRA hazardous wastes would be through participation in one of DEA's collection methods. Long-term care facilities are allowed to place patients' hazardous waste pharmaceuticals that are controlled substances in the DEA collection receptacles; the other hazardous waste pharmaceuticals generated by long-term care facilities must be managed under the proposed RCRA management standards for healthcare facilities. However, we note that if the long-term care facility is a CESQG, we are proposing as an acceptable method of disposal of the long-term care facility's hazardous waste pharmaceuticals would be to place them in a DEA collection receptacle, even if they are not controlled substances (see § 266.504(b)). DEA already allows controlled substances to be co-mingled with non-controlled substances. Therefore, EPA believes it is consistent to allow CESQG hazardous waste pharmaceuticals that are not controlled substances to be placed in DEA collection receptacles with controlled substances. EPA believes that management of CESQGs' hazardous wastes as DEA controlled substances is preferable to management as municipal solid waste because it provides greater protection to patients, visitors and workers at long-term care facilities to have the hazardous waste pharmaceuticals in DEA collection receptacles rather than in the regular trash. See Table 8 for a summary of the intersection of RCRA and DEA regulations for the disposal of hazardous waste pharmaceuticals at long-term care facilities:

TABLE 8—RCRA & DEA REGULATIONS AT LONG-TERM CARE FACILITIES

Types of pharmaceutical waste at long-term care facilities	Regulatory requirements	
	RCRA	DEA Authorized collection methods allowed for <i>patients'</i> pharmaceuticals
Hazardous Waste Pharmaceuticals that are also Controlled Substances.	Conditionally exempt from RCRA	Yes.
Hazardous Waste Pharmaceuticals that are not Controlled Substances.	
if LTCF is a CESQG	261.5 and sewer ban	Yes.
if LTCF is not a CESQG	Part 266, subpart P	No.

b. Household hazardous waste collected in DEA authorized collection receptacles. In response to questions that EPA has received since the DEA rule was published, we are taking this opportunity to clarify the current RCRA regulatory status of the pharmaceuticals

collected in DEA authorized collection receptacles. DEA's regulations allow the co-mingling of controlled substances and non-controlled substances in its collection receptacles. In some instances, the pharmaceuticals that are collected by retail pharmacies and law

enforcement in DEA authorized collection receptacles may contain pharmaceuticals that are RCRA hazardous waste. However, as household wastes, these hazardous waste pharmaceuticals would be excluded from regulation by

¹²³ See the docket for this rulemaking for data about long-term care facilities which was developed

using data in the economic analysis: EPA-HQ-RCRA-2007-0932.

§ 261.4(b)(1) because the exclusion applies even when the household hazardous wastes are collected. It is important to note that in order to maintain the exclusion, a retail pharmacy (or other DEA authorized collector pharmacy) can use the DEA authorized collection receptacle to collect waste generated only at households and brought to the store for collection. The hazardous waste generated by the retail pharmacy and store, including hazardous waste pharmaceuticals, are not excluded household wastes under RCRA and may not be placed in the DEA authorized receptacle.¹²⁴ Furthermore, states generally regulate non-hazardous waste and they may have licensing or permitting requirements for the collection of solid waste. Because EPA would like to see the use of DEA authorized collection receptacles become widespread, we encourage states to streamline any requirements that may create a barrier to the use of the collection receptacles.

Under this proposal, pharmaceuticals collected in DEA authorized collection receptacles will continue to be excluded from regulation as household hazardous waste, with some conditions. The Agency has a long-standing recommendation that household hazardous waste collection programs manage the collected waste as hazardous waste. We strongly believe that if a program goes to the expense of collecting the waste, including waste pharmaceuticals, it should manage the waste as hazardous waste, rather than manage it as municipal solid waste, which the household could do absent the collection program. However, the current household waste exemption does not *require* an entity that hosts a household hazardous waste collection event to manage the collected waste as hazardous waste. Typically, the parties conducting household hazardous waste collection events have been government entities—municipalities and counties. It is relatively new that retail pharmacies and others are becoming interested in performing this function. To encourage this practice, while at the same time ensuring that collection programs are managing the collected waste properly, we are proposing that pharmaceuticals that are household hazardous waste (*i.e.*, “household waste pharmaceuticals”) and are collected in DEA authorized collection receptacles

where they may be co-mingled¹²⁵ with controlled substances continue to be excluded from RCRA regulation, provided they are:

(1) Combusted at a municipal solid waste or hazardous waste combustor, and

(2) managed in accordance with all applicable DEA regulations (see § 266.506(a)(2)). The Agency solicits comments on all these provisions.

On a separate, but related matter, EPA has received a number of inquiries about the exemption in the Clean Air Act regulations for Other Solid Waste Incinerator (OSWI) “units that combust contraband or prohibited goods” (see the exemption at 40 CFR 60.2887(p) for new OSWIs and 40 CFR 60.2993(p) for existing OSWIs). As indicated in a previous guidance memo, EPA does not consider pharmaceuticals, voluntarily collected from ultimate users in a take-back program, to be contraband or prohibited goods.¹²⁶ Likewise, EPA will not consider pharmaceuticals that are voluntarily dropped off at collection receptacles to be contraband or prohibited goods. Therefore, the OSWI exemption does not apply and law enforcement may not destroy voluntarily collected pharmaceuticals in the same way that it is allowed to destroy contraband or prohibited goods.

3. Management of Residues in Pharmaceutical Containers

a. Regulatory background. Over the years, EPA has received numerous inquiries regarding the regulatory status of various types of containers that once held pharmaceuticals that are considered hazardous waste when discarded because of the hazardous waste residue in the containers. Stakeholders have been particularly concerned about containers that once held pharmaceuticals that are on the “P-list” of acutely hazardous commercial chemical products in § 261.33(e) because a generator becomes an LQG if it generates more than 1 kg of acute hazardous waste per calendar month or accumulates more than 1 kg of acute hazardous waste at any time.¹²⁷ The current regulatory status of acute and non-acute commercial chemical product

residues remaining in a container are specifically addressed in § 261.33:

The following materials or items are hazardous wastes if and when they are discarded or intended to be discarded

(c) Any *residue* remaining in a container or in an inner liner removed from a container that has held any commercial chemical product or manufacturing chemical intermediate having the generic name listed in paragraphs (e) or (f) of this section, unless the container is *empty* as defined in § 261.7(b). [emphasis added]

According to § 261.7(b)(1), there are two ways a container that held a non-acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held any hazardous waste, except a waste that is a compressed gas or that is identified as an acute hazardous waste listed in § 261.31 or § 261.33(e) of this chapter is empty if:

(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *e.g.*, pouring, pumping, aspirating, *and*

(ii) No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner, *or*

(iii) (A) No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; *or*

(B) No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.

Therefore, if the container that held the non-acute hazardous waste pharmaceutical does not have its contents removed by a commonly employed practice *and* either has one inch or less of residue remaining or has 3 percent or less by weight of the total capacity of the container remaining,¹²⁸ then the container is *not* considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as hazardous waste (since the residues are within the container, the container must be managed as hazardous waste, as well, even if it is not itself hazardous waste). On the other hand, if the contents of the container have been removed by a commonly employed

¹²⁵ DEA does not prohibit co-mingling of controlled substances with non-controlled substances provided they are all then managed as controlled substances.

¹²⁶ Rudzinski to RCRA Division Directors, September 26, 2012, RCRA Online #14833 <http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175fjcb11dd6f61d4b1685257afe005eb5ce!OpenDocument>.

¹²⁷ Additionally, acute hazardous wastes are included on the F-list of § 261.31; however none of those acute hazardous wastes are pharmaceuticals.

¹²⁸ We are assuming that containers that hold pharmaceuticals are in containers less than 119 gallons in size.

¹²⁴ DEA regulations also prohibits retail pharmacy stock/inventory from being placed in the collection receptacle or mail-back envelopes (see 21 CFR 1317.05(a)).

practice *and* either have one inch or less of residue remaining, or 3 percent or less of weight of the total capacity of the container remaining, then the container is considered “RCRA empty,” and may be managed as non-hazardous waste.

Likewise, according to § 261.7(b)(3), there are three ways that a container that held an acute hazardous waste can be considered “empty”:

A container or an inner liner removed from a container that has held an acute hazardous waste listed in §§ 261.31 or 261.33(e) is “empty” if:

(i) The container or inner liner has been triple rinsed using a solvent capable of removing the commercial chemical product or manufacturing chemical intermediate;

(ii) The container or inner liner has been cleaned by another method that has been shown in the scientific literature, or by tests conducted by the generator, to achieve equivalent removal; or

(iii) In the case of a container, the inner liner that prevented contact of the commercial chemical product or manufacturing chemical intermediate with the container, has been removed.

Therefore, if the container that held the P-listed pharmaceutical is not triple rinsed, or cleaned by another method that has been demonstrated to achieve equivalent removal, or had the inner liner removed, the container is not considered “RCRA empty,” even though the pharmaceutical may have been fully dispensed. If the container is not “RCRA empty,” then the residues are regulated as acute hazardous waste.

In November 2011, EPA issued guidance about containers that once held P-listed pharmaceuticals¹²⁹ that provides three possible regulatory approaches for generators:

(1) Count only the weight of the residue toward generator category

(2) Demonstrate an equivalent removal method to render containers RCRA empty

(3) In the case of warfarin, show that the concentration in the residue is below the P-listed concentration.

This guidance was intended as a short-term solution that worked within the confines of the existing RCRA hazardous waste regulations and EPA indicated at the time that a more comprehensive solution would require notice and public comment that occurs during a rulemaking. We are proposing to amend the regulations that pertain to

containers that once held pharmaceuticals that are RCRA hazardous wastes. We are proposing different regulatory solutions for different types of containers found in healthcare settings. Specifically, we address the following three types of containers: (1) Unit-dose containers (*e.g.*, packets, cups, wrappers, blister packs, and delivery devices) and dispensing bottles and vials; (2) dispensed syringes; and (3) other containers, including delivery devices. If finalized, these new regulations for pharmaceutical containers would replace the November 2011 guidance; however, in the meantime, the guidance remains in effect.

b. Unit-dose containers. First, with regard to unit-dose containers and dispensing bottles and vials up to 1 liter or 1000 pills, we are proposing a conditional exemption from the empty container regulations of § 261.7 for containers from which the pharmaceuticals have been fully dispensed. Specifically, we are proposing that the removal of the pharmaceuticals from the unit-dose containers, and dispensing bottles and vials (up to 1 liter or 1000 pills), is equivalent to rendering the container “RCRA empty.” Therefore, for containers that once held non-acute hazardous wastes, it will not be necessary to measure the remaining contents, and for containers that once held acute hazardous wastes, it will not be necessary to triple-rinse the containers or demonstrate an equivalent removal method. Rather, if the contents of the container have been fully dispensed by removing all pharmaceuticals that can be removed using the practices commonly employed to remove materials from that type of container, the residues (and therefore the container) may be disposed of as non-hazardous waste.

We are proposing this conditional exemption for two reasons. First, we want to eliminate the sewerage of pharmaceuticals. We are particularly concerned that in a healthcare setting, when containers are triple rinsed, the rinsate will be poured down the drain which is not a good environmental practice. We think it is important that the residues be managed in a more controlled manner—such as municipal solid waste management—rather than poured down the drain. Second, although the “empty container”

regulations of § 261.7 apply to all sizes of containers, they were developed with larger, industrial-sized containers in mind. For the most part, the containers that hold pharmaceuticals range in size from a few milliliters (*e.g.*, packaging for nicotine gum, paper cups used to dispense pharmaceuticals to in-patients) to a liter (*e.g.*, bottles that hold bulk quantities of pills). In rare circumstances, containers with pharmaceuticals are as large as two or three liters (*e.g.*, powders that are reconstituted with water). This differs significantly from the 55-gallon drums that are typically used in other sectors that generate hazardous waste. Consequently, the amount of residues in the containers was anticipated to be much more substantial than is the case for containers typically used for pharmaceuticals.

EPA has received data from three stakeholders demonstrating that there is very little residue remaining in fully dispensed containers of pharmaceuticals. In addition, EPA’s ORD conducted similar research. The results from each of the four sources are summarized below; the full results are included in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

i. Consulting Firm. One stakeholder, with a hazardous medical materials consulting firm, provided some laboratory testing. They had the residues from single-unit dose packaging of four different P-listed pharmaceuticals tested using gas chromatography/mass spectrometry (GC/MS) and high performance liquid chromatography/ultraviolet detector (HPLC/UV). The amount of active pharmaceutical ingredient in the residues remaining in containers was quantified and the results from containers that had been triple rinsed were compared with containers that had not been triple rinsed. For the containers that were triple rinsed, the active ingredient in the residues was non-detect in all cases. For the containers that were not triple rinsed, the highest level detected was 35.8 µg (or 0.0358 mg). The laboratory results submitted to EPA are summarized in Table 9; the full laboratory results are included in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932).

¹²⁹ Rudzinski to RCRA Division Directors, November 11, 2011, RCRA Online #14827 <http://>

yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/

[57B21F2FE33735128525795F00610F0F/\\$file/14827.pdf](http://57B21F2FE33735128525795F00610F0F/$file/14827.pdf).

Table 9: Active Pharmaceutical Ingredient in Residues in Single-Unit Dose Packaging

Drug (packaging type)	HW Code	Active pharmaceutical ingredient in Triple-Rinsed Packaging (μg)	Active pharmaceutical ingredient in Non-Triple-Rinsed Packaging (μg)	Reporting Limit (μg)
Nicotine gum* (blister pack)	P075	ND	ND	0.00005
Nicotine patch* (single use packet)	P075	ND	35.8	0.00005
Warfarin** (blister pack)	P001	ND	6.4	5.0
Physostigmine** (ampoule)	P204	ND	ND	100

*Method EPA 8720B

**HPLC/UV

ND = non-detect

ii. *Large Retailer*. The second stakeholder that submitted data to EPA was a large retailer. Their data provide the weight of active pharmaceutical ingredient residues remaining in bulk

containers (*i.e.*, 100-count) of various dosage strengths of warfarin. The residues were quantified using HPLC–UV/Vis (high performance liquid chromatography/ultraviolet/visible light

detector). The data are summarized in Table 10; the full results submitted to EPA are included in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).

Table 10: Warfarin Residues in 100-Count Dispensing Bottles

Warfarin Dose	Number of Bottles Tested	Total Warfarin Residue in all Containers (mg)	Average Warfarin Residue/Bottle (mg)
Low (1 - 3 mg)	17	2.638	0.155
Medium (5 - 7.5 mg)	18	12.820	0.712
High (10 mg)	18	21.530	1.196

The results from each of the first two stakeholders reflect only the weight of the active pharmaceutical ingredient, not the full weight of the hazardous waste residues. Since it is the Agency's position that it is the full weight of the hazardous waste residues and not just the weight of the active pharmaceutical ingredients that must be counted in determining generator status, we have used the results to calculate the weight of the total residues. In the retailer's case, they have informed EPA that a typical pill with a 10 mg dose of Coumadin (brand name of warfarin) weighs 200 mg. The active ingredient represents 10 mg, or 5% of the weight of the pill, while 190 mg, or 95% of the weight of the pill, consists of ingredients other than the active ingredient. As indicated in Table 10, the average weight of warfarin residue remaining in a fully dispensed bottle of

the high dose of warfarin (10 mg) is 1.196 mg. If we assume that the residue in the container has the same proportions of ingredients (*i.e.*, 5% of the residue is warfarin and 95% of the residue are other ingredients), then there would be an average of 23.92 mg of total hazardous waste residue remaining in a 100-count bottle of 10 mg pills of warfarin. The amount of hazardous waste residue remaining in a 100-count bottle of pills is very small compared with the residue that would remain in a 55-gallon drum, which is what the regulations for container residues envisaged.

iii. *Riverside County*. The third stakeholder that provided data to EPA was the Riverside County Department of Environmental Health, Hazardous Materials Management Branch. The county received a grant from the California Certified Unified Program

Agency (CUPA) Forum Board to conduct a study of residues remaining in pharmaceutical containers. Researchers at the University of California, Riverside (UCR) conducted the study and provided their results in a report to Riverside County entitled, *Residue Analysis of P-Listed Pharmaceutical Containers for Warfarin and Nicotine*. The results are summarized below, but UCR's full results are in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932).¹³⁰

The intent of the study was to investigate the third regulatory approach suggested in the November 2011 memo discussed previously. That

¹³⁰ See Exhibit 2 of the CUPA Forum Board Trust Fund Grant Report submitted by the Riverside County Department of Environmental Health at the conclusion of the grant.

is, the study investigated whether the concentration of warfarin in the residues of warfarin pill bottles was greater than 0.3% and therefore met the listing criteria for P001 or whether the residues were at or below 0.3% and therefore met the listing criteria for U248. Although nicotine is not a concentration-based P-listing, packaging from nicotine-containing products were also investigated to determine total remaining residues.

The researchers collected a total of 59 samples containers, including 44 sample containers that had held warfarin pills but had been fully dispensed and another 15 sample containers from nicotine-containing products. The samples included warfarin and nicotine from several manufacturers, in a range of dose strengths and in various container types. The residues were solvent-extracted and then dried by rotary evaporation to determine the total weight of residues. Subsequently, the residues were re-dissolved in methanol and analyzed using HPLC to determine the concentration of the active pharmaceutical within the residues.

The majority of warfarin containers were plastic bottles, but some containers were blister packs and three samples were 30-pill blister packs, sometimes

referred to as a “bingo card.” The results indicate that the concentration of the active pharmaceutical ingredient warfarin in the residues in plastic bottles was usually over the 0.3% concentration. However, the concentration of warfarin in the residues on blister packs, including the 30-pack blister pack, was consistently below 0.3%. Overall, in the majority of cases, the warfarin within the residues was present at a high enough concentration to be considered P001 (33 of 44 samples, 75 percent of the samples).

However, the results also confirm the results from the first two stakeholders. That is, the total weight of residues remaining in the containers after they were emptied of the warfarin pills is negligible. For the plastic bottles, the total weight of residue ranged from 4.3–82.3 mg. For the single-dose blister packs, the total weight of residue ranged from 3.5–7.6 mg. And for the 30-pack blister pack, the total weight ranged from 134.8–273 mg. Taking the smallest amount of residue of 3.5 mg, it would take close to 300,000 containers per month to exceed the 1 kg threshold to be an LQG. Even on the conservative side, taking the largest amount of residue of 273 mg, it would take close

to 4000 containers per month to exceed the 1 kg threshold to be an LQG.

The results for nicotine residues were similar. For containers of gum and patches, the weight of total residues ranged from 9–111.2 mg, although the two containers of liquid nicotine solution contained more residues—1301 and 1616 mg. Although nicotine is not a concentration-based listing, it is worth noting that the active pharmaceutical ingredient of nicotine in the residues was below the quantifiable limit of 1.5 µg/ml in 8 of the 15 samples and for the other 7 samples, the concentration of nicotine ranged from 0.01–0.09%.

iv. EPA’s Office of Research and Development. Finally, EPA’s ORD conducted an analysis to evaluate whether simply removing a drug from the container is equivalent to triple rinsing the container. ORD’s results are summarized in Table 11, but the Final Project Report containing the full results is in the docket for this proposed rulemaking (EPA–HQ–RCRA–2007–0932). ORD analyzed three different P-listed pharmaceuticals: Warfarin, nicotine and physostigmine salicylate. Table 11 lists the 18 different combinations of active pharmaceutical ingredients, form, dosage strengths and packaging combinations that ORD analyzed.

TABLE 11—PHARMACEUTICAL COMBINATIONS TESTED BY EPA’S ORD

Active pharmaceutical ingredient	Manufacturer/Brand name	Form	Dosage	Packaging type	
Warfarin	Taro Pharmaceutical Industries, Ltd.	Tablet	1 mg	Plastic bottle.	
		Tablet	5 mg	Plastic bottle.	
		Tablet	10 mg	Plastic bottle.	
		Tablet	2 mg	Single-dose blister pack.	
Nicotine	Upsher-Smith/Jantoven	Tablet	1 mg	Single-dose blister pack	
		Tablet	10 mg	Single-dose blister pack.	
		GlaxoSmithKline/Nicorette	Gum	2 mg	Single-dose blister pack.
			Gum	4 mg	Single-dose blister pack.
Nicotine	Rugby Laboratories	Gum	2 mg	Single-dose blister pack.	
		Gum	4 mg	Single-dose blister pack.	
	GlaxoSmithKline/Nicorette	Lozenge ...	2 mg	Plastic vial	
		Lozenge ...	4 mg	Plastic vial.	
	Rugby Laboratories	Patch	7 mg	Peel-off plastic.	
	Habitrol	Patch	14 mg	Peel-off plastic.	
	Rugby Laboratories	Patch	21 mg	Peel-off plastic.	
	Physostigmine Salicylate.	Akron Inc.	Spray	10 mg/ml ..	Glass vial.
Inhaler			10 mg	Plastic container.	
		Liquid	1 mg/ml	Glass ampoule.	

All combinations in Table 11 were analyzed in triplicate using the following three-step approach:

(1) After removing the tablets, gum, lozenges, etc from the containers, the amount of total residuals remaining in the container was determined using a sensitive balance to weigh the container before and after triple rinsing,

(2) The “maximum possible weight of residual drug/total residual/container” was calculated for each compound and packaging combination. This calculated result was used to infer a theoretical upper limit for the amount of active pharmaceutical compound in the total residue remaining in the container, and

(3) Thermal gravimetric analysis (TGA) was used to qualitatively evaluate the presence of active pharmaceutical ingredient in the residuals removed from the containers before and after triple-rinsing.

With respect to the weight of the remaining residuals in the containers, ORD’s results are similar to the results

from the first three sources. That is, the weight of the total residuals remaining in the packaging of P-listed pharmaceuticals is minimal. For single-dose blister packs, lozenge vials and the peel-off plastic from nicotine patches the weight of the residuals was negligible and within the range of error of the balance, but all results were below 0.0002 grams. For plastic containers that held tablets, the weight of residuals were higher, but still very low, ranging from 0.0152–0.0157 grams. For containers that held liquids, the weight of residuals was the highest, but still very low, ranging from 0.0472 grams for glass vials of nicotine spray, to 0.0651 grams for glass ampoules that held liquid physostigmine salicylate. The residuals in the nicotine inhaler were not experimentally determined; rather, the manufacturer (Pfizer) states on the packaging that the 10 mg cartridge delivers a 4 mg dose, so the residuals are assumed to be 6 mg (or 0.006 grams).¹³¹

Unlike the quantitative results from the HPLC analyses from outside stakeholders, the results from the TGA are qualitative only. That is, the TGA was only intended to evaluate the presence of the API and compare the results from containers that had been triple rinsed with those that had not been triple rinsed. Using TGA, the API was not detected in the residuals, with one exception: The liquid nasal spray (note that TGA was not used on the nicotine inhaler residuals). In most cases, the TGA detected other, unspecified ingredients in the residuals, but not the active pharmaceutical ingredient on the P-list. The total weight of the residuals was well under a gram and the active pharmaceutical ingredient is a small proportion of the total weight of the tablet, gum, etc. As a result, with the exception of the nicotine nasal spray, the TGA was not sensitive enough to detect the presence of the active pharmaceutical ingredient, regardless of whether the container had been triple rinsed or not.

EPA is aware that there are certain limitations with the data from the four sources. For instance, in the case of the

consulting firm, no replicate samples were tested. In the case of the retailer, only warfarin residues were tested. However, given the size of the containers involved and the nominal quantities of residues involved, the Agency is proposing to allow the residues in single-unit dose containers/packaging and dispensing bottles, vials and ampules that once held pharmaceuticals to be managed as non-hazardous waste pharmaceuticals provided the pharmaceutical product has been fully dispensed (e.g., all pills have been removed). EPA is soliciting comment on whether these studies are representative of the spectrum of formulations and containers that might be encountered.

Finally, we note that the Agency is concerned about the potential for diversion of the pharmaceutical containers that may occur when the pharmaceutical residues and containers are discarded in the municipal waste stream. In such instances, we are concerned that the containers could be diverted from the municipal waste stream and used for illicit purposes, such as packaging counterfeit pharmaceuticals. Therefore, EPA is proposing that “RCRA empty” pharmaceutical containers that are original pharmaceutical packages (and therefore are susceptible to diversion) should be destroyed prior to placing them in the trash. These types of containers would include dispensing bottles, vials or ampules typically used in pharmacies, but would not include paper or plastic cups, or blister packs used for dispensing single doses to patients. The means of destruction could include crushing or shredding the container. We do not believe that simply defacing the label would be sufficient to avoid diversion, since labels could be replaced if the container is intact.

We request comment on these proposed provisions, including whether it is necessary to limit the size of the dispensing bottle to which this provision would apply. In our observation, EPA has rarely seen pharmaceutical dispensing bottles that are larger than 1000-count, which are approximately 1 liter in size. EPA requests comment on whether larger containers are used for dispensing pharmaceuticals and, if so, which pharmaceuticals they are used for and what RCRA hazardous waste codes apply. We also seek comment as to whether “RCRA empty” pharmaceutical containers that are the original pharmaceutical packages should be destroyed prior to placing them in the trash.

c. Dispensed syringes. With regard to dispensed syringes, EPA is proposing a conditional exemption for syringes that have been used to administer pharmaceuticals that are listed or characteristic hazardous waste when discarded. The residues remaining in a dispensed syringe would not be regulated as hazardous waste provided the syringe has been used to administer a pharmaceutical to a patient and the syringe is placed in a sharps container (if appropriate) and is managed in accordance with all applicable state and federal medical waste regulations. This would apply to syringes used to administer pharmaceuticals that are P- or U-listed, or exhibit a hazardous waste characteristic.

EPA issued guidance regarding the regulatory status of residues in syringes in December 1994¹³² and April 2008.¹³³ In the December 1994 RCRA/Superfund Hotline Q&A about whether epinephrine in a discarded syringe would be P042, EPA stated, “Drug residues often remain in a dispensing instrument after the instrument is used to administer medication. EPA considers such residues remaining in a dispensing instrument to have been used for their intended purpose. The epinephrine remaining in the syringe, therefore, is not a commercial chemical product and not a P042 hazardous waste. The epinephrine could be a RCRA hazardous waste, however, if it exhibits a characteristic of hazardous waste.”¹³⁴

In the April 2008 memo, EPA clarified that the 1994 interpretation extends to other P- and U-listed pharmaceuticals that have been used to administer the pharmaceutical by syringe. This proposed conditional exemption for syringes, in large part, would maintain the existing interpretation. The primary difference is that under the proposed conditional exemption, healthcare facilities would not be required to determine if the residues in the syringes meet a listing description or exhibit a hazardous waste characteristic.

¹³² December 1994, RCRA Online #13718 [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/\\$file/13718.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/1C1DEB3648A62A868525670F006BCCD2/$file/13718.pdf).

¹³³ Memo from Dellinger to Chilcott, April 14, 2008, RCRA Online #14788 [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/\\$file/14788.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/6A5DEDF2FBA24FE68525744B0045B4AF/$file/14788.pdf).

¹³⁴ Note that since this Q&A was issued, EPA issued guidance indicating that epinephrine salts are not included in the scope of the P042 listing and therefore, most, if not all, medical applications of epinephrine are not P042 (October 15, 2007; RCRA Online #14778)

¹³¹ Optimizing drug dose is a major factor in improving the sustainability of healthcare. The prescriber needs to be cognizant that prescribed treatments can have unanticipated, collateral impacts that reach far beyond the healthcare setting. See: Daughton and Ruhoy, *Lower-dose prescribing: Minimizing “side effects” of pharmaceuticals on society and the environment*; *Sci Total Environ*, 443(2013), pp. 324–336, which presents a critical examination of the multi-faceted potential role of drug dose in reducing the ambient levels of APIs in the environment and in reducing the incidence of drug wastage, which ultimately necessitates disposal of leftovers. (<http://sciencedirect.com/science/article/pii/S004896712013927#>)

EPA believes this conditional exemption is important to minimize the potential for exposures to healthcare workers, which can happen if they are accidentally stuck with a needle. Typically, sharps containers are more readily available to a medical practitioner than a hazardous waste container. Therefore, the used syringe will be discarded more quickly into a sharps container and there will be less opportunity for accidental sticks to occur en route to disposing the sharp.

However, we also note that syringes in sharps containers are typically autoclaved prior to disposal. EPA is concerned that the residues remaining in the syringes could be aerosolized during autoclaving and inadvertently expose workers to the aerosolized hazardous waste residues, posing risks (via pulmonary exposure) to those present during venting of the autoclave. Research suggests that autoclaving may even increase the toxicity of certain drugs.¹³⁵ EPA seeks comment on the extent of risks associated with autoclaving hazardous waste residues leftover in syringes and whether it is necessary to place a limit on the volume of residue or the volume of the syringe to which this conditional exemption would apply or whether any other conditions would be appropriate. For instance, stakeholders have informed us that they will squirt the residues remaining in a syringe onto a gauze pad prior to placing the syringe in the sharps container. Then, if the residues on the gauze pad are hazardous waste, the gauze pad is managed as hazardous waste, while allowing the syringe to be fully dispensed before placing it in the sharps container. In EPA's view, this method of managing excess residues is preferred over another practice that is commonly used: The disposal of excess residues down the drain.

d. Other containers, including delivery devices. With regard to other containers, including delivery devices, EPA is proposing that the residues remaining in unused or used containers (such as IV bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels, or creams) would be regulated as hazardous waste if the residues are a P- or U-listed hazardous waste or exhibit a hazardous waste characteristic. In some cases, such as with IV bags, the volume of hazardous waste is much larger than with residues contained in syringes or

unit-dose containers. Stakeholders have stated that it is common practice for the leftover contents of IV bags and tubing to be emptied into a sink, which is a practice we are striving to eliminate. It is extremely difficult to determine how much residue remains in tubes of ointment, gel or cream. In the case of aerosols, it would be inadvisable to remove the contents of the container. Since hazardous waste pharmaceuticals managed under this proposed rule would not be counted towards a facility's generator category, managing these residues and containers as hazardous waste under proposed 40 CFR part 266, subpart P should not pose the same burden that generators currently face with keeping track of the monthly amount of residues in containers that are not "RCRA empty." Further, comments on the 2008 Pharmaceutical Universal Waste proposal indicated that stakeholders prefer clear distinctions in regulating the hazardous waste from healthcare facilities and this proposed standard for container residues responds to that comment. EPA seeks comment on whether these proposed provisions address stakeholder concerns, while protecting human health and the environment.

F. What are the proposed standards for shipping hazardous waste pharmaceuticals?

1. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals to Treatment, Storage, and Disposal Facilities

a. Shipping Standards for Non-Creditable Hazardous Waste Pharmaceuticals From Healthcare Facilities to TSDFs

Typically, hazardous waste pharmaceuticals generated in a healthcare facility fall into two categories: (1) Non-creditable (e.g., patient care) hazardous waste pharmaceuticals and (2) potentially creditable hazardous waste pharmaceuticals. This section discusses the proposed requirements for shipping of non-creditable, patient care/floor hazardous waste pharmaceuticals. For information regarding the shipment of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and pharmaceutical reverse distributors, see Section V.F.2 of the preamble.

Generally, patient care/floor hazardous waste pharmaceuticals differ from potentially creditable hazardous waste pharmaceuticals in that they have

been partially administered and often are not in their original packaging. In addition, patient care/floor hazardous waste pharmaceuticals cannot receive manufacturer's credit and therefore may not be shipped to a reverse distributor. EPA is proposing that patient care/floor hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off-site, must be shipped to a designated facility (i.e., an interim status or permitted hazardous waste TSDF), as currently required (unless the healthcare facility has interim status or a RCRA permit to store or treat hazardous waste). Specifically, EPA proposes that non-creditable hazardous waste pharmaceuticals must continue to comply with the existing pre-transport requirements for packaging, labeling and marking, and that the non-creditable hazardous waste pharmaceuticals must continue to be shipped using a hazardous waste transporter and tracked with a hazardous waste manifest. However, to avoid unnecessarily burdening the healthcare facility staff, who are unfamiliar with RCRA, EPA proposes that the hazardous waste numbers (often called hazardous waste codes) are not required to be entered into the hazardous waste manifest for non-creditable hazardous waste pharmaceuticals. In lieu of hazardous waste codes, EPA is proposing that the words, "hazardous waste pharmaceuticals" must be entered in the "special handling and additional information" box on the manifest (box # 14). All existing RCRA recordkeeping requirements regarding hazardous waste manifesting continue to apply, (see Section V.C.12), as well as all applicable DOT shipping requirements. EPA requests comment on this proposed approach for manifesting non-creditable hazardous waste pharmaceuticals from a healthcare facility.

b. Shipping Standards for Evaluated Hazardous Waste Pharmaceuticals From Pharmaceutical Reverse Distributors to TSDFs

For pharmaceutical reverse distributors, once potentially creditable hazardous waste pharmaceuticals have been deemed non-creditable or credit has been issued and they do not require any additional verification of credit, EPA is proposing that the hazardous waste pharmaceuticals be referred to as "evaluated hazardous waste pharmaceuticals." As with shipping non-creditable hazardous waste pharmaceuticals, when evaluated hazardous waste pharmaceuticals are shipped off-site, EPA is proposing that they must be shipped in accordance

¹³⁵ Daughton CG, *Drugs and the Environment: Stewardship & Sustainability*, National Exposure Research Laboratory, Environmental Sciences Division, U.S. EPA, Las Vegas, NV; NERL-LV-ES 10/081, EPA/600/R-10/106; September 2010 (<http://www.epa.gov/nerled1/bios/daughton/APM200-2010.pdf>).

with the existing pre-transport requirements for packaging, labeling and marking, and that evaluated hazardous waste pharmaceuticals must be shipped via a hazardous waste transporter using a hazardous waste manifest to a designated facility. This continues current practices under existing regulations for this type of hazardous waste pharmaceutical and does not represent an increase in burden. EPA believes that use of a hazardous waste manifest and a hazardous waste transporter are appropriate at this point for two reasons. First, once credit for the hazardous waste pharmaceuticals has been issued and verified, the potential for mismanagement is greater. This is because the pharmaceuticals have lost their value and will cost the reverse distributor money to dispose. Second, TSDFs are accustomed to receiving hazardous waste via a hazardous waste transporter with a hazardous waste manifest and it would place administrative and compliance burdens on the receiving TSDF to accept shipments of hazardous waste with alternative tracking.

EPA is proposing that the pharmaceutical reverse distributor list the appropriate hazardous waste codes on the manifest (even though the healthcare facility is not required to provide such information to the reverse distributor). Hazardous waste pharmaceuticals received by pharmaceutical reverse distributors are in their original packaging with their label, so the information to determine the appropriate hazardous waste codes should be readily available. Also, reverse distributors are currently required to include hazardous waste codes on the manifest and it is expected that they have the necessary expertise in the management of these hazardous wastes that healthcare workers lack. As described in Section V.G.3 (pharmaceutical reverse distributor management standards), reverse distributors must keep copies of hazardous waste manifests for three years from the date of shipment.

EPA requests comment regarding the proposed manifest and transportation requirements for non-creditable hazardous waste pharmaceuticals from healthcare facilities and evaluated hazardous waste pharmaceuticals from pharmaceutical reverse distributors.

c. Importing/Exporting Non-Creditable or Evaluated Hazardous Waste Pharmaceuticals

Under the existing regulations, a healthcare facility or pharmaceutical reverse distributor may not import

hazardous waste pharmaceuticals unless it has a RCRA permit or interim status that allows it to accept hazardous waste from off-site and complies with the requirements for importing hazardous waste in 40 CFR part 262, subpart F. This proposal does not change the regulations as they apply to the import of non-creditable or evaluated hazardous waste pharmaceuticals. Likewise, under existing regulations, a healthcare facility or pharmaceutical reverse distributor may not export (non-creditable or evaluated) hazardous waste pharmaceuticals unless it complies with requirements for exporting hazardous waste in 40 CFR part 262, subpart E. This proposal also does not change the regulations as they apply to the export of (non-creditable or evaluated) hazardous waste pharmaceuticals.¹³⁶

EPA requests comment on the likelihood that non-creditable hazardous waste pharmaceuticals that are shipped from a healthcare facility to a domestic TSDF, would then be exported to a TSDF in a foreign country. In addition, EPA does not anticipate that hazardous waste pharmaceuticals would be destined for transboundary shipments for purposes of recovery operations and therefore potentially subject to 40 CFR part 262, subpart H; however, we also request comment on whether this is the case.

2. Shipping Standards for Potentially Creditable Hazardous Waste Pharmaceuticals

This section discusses the proposed requirements for shipping potentially creditable hazardous waste pharmaceuticals from healthcare facilities to pharmaceutical reverse distributors and between pharmaceutical reverse distributors. The return of potentially creditable pharmaceuticals (hazardous and non-hazardous) to reverse distributors can involve multiple shipping steps before the pharmaceuticals are transported for ultimate treatment and disposal. In comments on the 2008 Pharmaceutical Universal Waste proposal and in response to EPA's request for information,¹³⁷ pharmaceutical reverse

¹³⁶ The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

¹³⁷ EPA sent nine pharmaceutical reverse distributors a letter asking for more information about their business practices in an effort to more fully understand reverse distribution of pharmaceuticals. The seven responses representing the views of eight reverse distributors can be found in the docket of this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

distributors explained various scenarios that require extra shipping steps. For example, a healthcare facility typically sends pharmaceuticals to the reverse distributor with which it has a contract. However, some manufacturers will only provide manufacturer's credit after the pharmaceuticals have been returned to the reverse distributor with which the manufacturer has a contract. Thus, if the reverse distributor with which the healthcare facility has a contract differs from the reverse distributor with which the manufacturer has a contract, then the healthcare facility's reverse distributor must send the pharmaceuticals on to the manufacturer's reverse distributor for the manufacturer's credit to be given to the healthcare facility. In some cases, a pharmaceutical manufacturer may require the reverse distributor to ship the returned pharmaceuticals to the manufacturer so that the manufacturer itself can verify pharmaceutical amounts and credits. The estimate of the amount of pharmaceuticals transported from reverse distributors to manufacturers for verification varies. Based on our request for information, reverse distributors have indicated that the percent of potentially creditable pharmaceuticals transported to manufacturers ranged from an estimated 25 percent to 93 percent, depending on the contractual agreement between the reverse distributor and the manufacturer. Both of the scenarios described previously happen routinely and are part of the business of returning pharmaceuticals to reverse distributors (including manufacturers) for manufacturer's credit.

As explained in Section V.D.1, EPA is proposing that pharmaceuticals transported to pharmaceutical reverse distributors for credit are solid wastes, some of which will also be considered hazardous wastes. Under the current RCRA Subtitle C regulations, hazardous waste, including hazardous waste pharmaceuticals must be manifested to a permitted or interim status TSDF and shipped using a hazardous waste transporter to ensure the cradle-to-grave system of RCRA is maintained. However, compared to other hazardous wastes, EPA believes that the risk of environmental release posed by most potentially creditable hazardous wastes pharmaceuticals during accumulation and transport are relatively low. The risk is low because of the form and packaging of most potentially creditable hazardous waste pharmaceuticals, which is typically in small, individually packaged doses (such as with many tablets and capsules) or small vials.

These small volumes of individually wrapped or packaged pharmaceuticals, when aggregated in a larger container, are unlikely to spill or be released into the environment since they are essentially double-packed when transported to a reverse distributor.¹³⁸ Potentially creditable hazardous waste pharmaceuticals that are in liquid and aerosol forms may pose more of a risk during accumulation and transport due to possible spillage or leakage, but the small quantities in which they are generated, along with the DOT packaging requirements of 49 CFR parts 173, 178, and 180, would likely mitigate this risk (see EPA's recommendation regarding liquids and aerosols in Section V.D.2.). Further, the 2008 Pharmaceutical Universal Waste proposal specifically sought comment regarding the risks of transportation of hazardous waste pharmaceuticals and no commenters identified environmental risks.

Due to the low risk of release to the environment described previously, EPA is proposing to allow potentially creditable hazardous waste pharmaceuticals to be shipped *without* a hazardous waste manifest and *without* the use of hazardous waste transporters. However, this exemption from manifesting and use of hazardous waste transporters only applies if the healthcare facility is sending potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, or if a pharmaceutical reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor. Further, DOT shipping requirements continue to apply to shipments of potentially creditable hazardous waste pharmaceuticals.

In lieu of requiring a hazardous waste manifest and the use of hazardous waste transporters, EPA is proposing an alternate type of tracking for potentially creditable hazardous waste pharmaceuticals—with two requirements. First, for each shipment, healthcare facilities and pharmaceutical reverse distributors must provide in writing (via letter or electronic communication), advance notice of the shipment to the pharmaceutical reverse distributor. Second, for each shipment, the receiving pharmaceutical reverse distributors must provide confirmation to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous

waste pharmaceuticals has arrived. One way to comply with this requirement would be for the receiving reverse distributor to require the healthcare facility or pharmaceutical reverse distributor that initiates the shipment of potentially creditable hazardous waste pharmaceuticals to utilize some form of "delivery confirmation" mechanism that is provided by the shipper that confirms that a shipment to a reverse distributor has reached its destination and is under the custody and control of the recipient (e.g. delivery confirmation tracking with return receipt). This "delivery confirmation" notice can be paper-based or electronic. As part of the delivery confirmation system, a signature (paper or electronic) or other confirmation from a representative of the receiving pharmaceutical reverse distributor would be required. The signature by the pharmaceutical reverse distributor would provide assurance that the shipment was received by the reverse distributor. Without the signature or other confirmation of a representative of the pharmaceutical reverse distributor, it is possible for the shipper to state that delivery to the location has occurred, but it would not necessarily indicate that the recipient was there to receive the shipment. This proposed requirement is in direct response to concerns expressed by commenters over the lack of tracking of pharmaceuticals in the 2008 Pharmaceutical Universal Waste proposal.

Alternatively, EPA has learned that some stakeholders use bar-coding on the pharmaceuticals or on the boxes to track shipments. The barcodes contain detailed information, including the exact quantities and types of pharmaceuticals included in the shipment. Typically, when a reverse distributor receives a barcoded shipment, it will scan in the shipment and the sender will receive electronic notification that the shipment has arrived. This type of bar-code tracking would meet the delivery confirmation requirement of this proposed rule, but other mechanisms of "delivery confirmation" that are offered by common carriers, such as the U.S. Postal Service, FedEx or United Parcel Service (UPS), would also be acceptable.

Under this proposal, healthcare facilities and reverse distributors may use common carriers, such as the U.S. Postal Service, United Parcel Service, or FedEx¹³⁹ for shipments of potentially creditable hazardous waste pharmaceuticals to and between

pharmaceutical reverse distributors. EPA believes that common carriers are able to provide safe shipment since these potentially creditable hazardous waste pharmaceuticals present low transportation risk. We note that healthcare facilities and pharmaceutical reverse distributors must meet the applicable Pipeline and Hazardous Materials Safety Administration (PHMSA) Hazardous Materials Regulation (HMR; 49 CFR parts 171–180) shipping requirements, including preparing proper shipping papers when shipping potentially creditable hazardous waste pharmaceuticals. A RCRA hazardous waste that does not meet DOT hazard classes 1–8 in the HMR, are only Class 9 hazardous materials when defined as a RCRA hazardous wastes that requires a manifest. As a result, the DOT shipping requirements will apply when potentially creditable hazardous waste pharmaceuticals are shipped to pharmaceutical reverse distributors only when the hazardous wastes are DOT class 1–8 hazardous materials.

EPA notes that a pharmaceutical reverse distributor is not required to sort the potentially creditable hazardous waste pharmaceuticals from the potentially creditable non-hazardous waste pharmaceuticals when they are destined for another reverse distributor. However, if the potentially creditable pharmaceuticals are not sorted, the pharmaceutical reverse distributor must follow the tracking procedures in this proposal for the entire shipment. On the other hand, if a pharmaceutical reverse distributor chooses to sort the potentially creditable hazardous waste pharmaceuticals from the creditable non-hazardous waste pharmaceuticals prior to shipping to another reverse distributor, only the potentially creditable hazardous waste pharmaceutical portion would have to be shipped according to these proposed standards. EPA asks for comment on whether the proposed tracking system and controls are sufficient to protect human health and the environment.

a. What Happens if a Healthcare Facility or Pharmaceutical Reverse Distributor Initiates a Shipment and Does Not Get Confirmation of Delivery?

If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation from the intended recipient within seven calendar days, EPA is proposing that the healthcare facility or pharmaceutical reverse

¹³⁸ Pharmaceutical Universal Waste proposal, 73 FR 73529; December 2, 2008.

¹³⁹ Note EPA is not endorsing the use of any of the shipping companies cited.

distributor that initiated the shipment must contact the shipper and the intended recipient promptly to (1) report that the confirmation was not received and (2) to determine the status and whereabouts of the potentially creditable hazardous waste pharmaceuticals that were shipped. The Agency requests comment on whether any additional requirements, such as reporting to the implementing agency, are necessary in such cases.

b. Importing/Exporting Potentially Creditable Hazardous Waste Pharmaceuticals

If a healthcare facility or pharmaceutical reverse distributor imports potentially creditable hazardous waste pharmaceuticals, then it must comply with the proposed requirements for the shipment of potentially creditable hazardous waste pharmaceuticals. The proposed requirements would be in lieu of those for manifested hazardous waste imports found at 40 CFR part 262, subpart F. EPA requests comment on whether potentially creditable hazardous waste pharmaceuticals are imported into the U.S. and, if so, how they are currently declared to customs when imported.

If a healthcare facility or pharmaceutical reverse distributor exports potentially creditable hazardous waste pharmaceuticals then it must generally comply with 40 CFR part 262, subpart E, except that it is not required to manifest the potentially creditable hazardous waste pharmaceuticals.¹⁴⁰

c. Recordkeeping for Shipments of Potentially Creditable Hazardous Waste Pharmaceuticals

EPA is proposing to require healthcare facilities and reverse distributors to keep records of the shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Specifically, we are proposing that healthcare facilities and reverse distributors that initiate a shipment to another pharmaceutical reverse distributor keep (1) records of advance notification regarding shipments of potentially creditable hazardous waste pharmaceuticals, (2) shipping papers, and (3) confirmation of receipt of shipment for three years after the shipment was initiated. These records are necessary to ensure that potentially creditable hazardous waste pharmaceuticals are reaching their intended destination and not diverted.

¹⁴⁰ The Controlled Substances Import and Export Act prohibits controlled substances from being imported or exported unless permitted by DEA, even when the controlled substances are wastes. See 21 U.S.C. 952 and 953.

In most cases, retaining records for 3 years should be sufficient for inspection purposes; however, we are proposing that the periods of retention are automatically extended during unresolved enforcement activity, or at the request of the EPA Regional Administrator. The Agency seeks comment on whether additional recordkeeping is necessary to document the cases when the pharmaceutical reverse distributor does not receive a shipment of potentially creditable pharmaceuticals within 7 calendar days and the steps must be taken to locate the shipment.

G. What are the proposed standards for pharmaceutical reverse distributors?

1. Background on Pharmaceutical Reverse Distributor Operations

Pharmaceutical reverse distributors act as intermediaries between healthcare facilities and pharmaceutical manufacturers. They receive shipments of potentially creditable hazardous waste pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these pharmaceuticals. From stakeholder input and EPA site visits, EPA's understanding is that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its computer system. Based on manufacturers' return goods policies, the pharmaceutical reverse distributors determine which potentially creditable hazardous waste pharmaceuticals can be credited, as well as which must be sent on to another reverse distributor for completion of the crediting process.

In many cases, there is more than one reverse distributor involved in establishing and verifying manufacturer's credit for a particular potentially creditable hazardous waste pharmaceutical. For instance, reverse distributors may have contracts with specific pharmaceutical manufacturers such that only a specific pharmaceutical reverse distributor may facilitate credit for a particular manufacturer's pharmaceuticals. If the receiving reverse distributor has a contract with the healthcare facility, but not with the pharmaceutical manufacturer, then the receiving pharmaceutical reverse distributor sends the returned pharmaceutical on to the reverse distributor that has a contract with the pharmaceutical manufacturer in order to facilitate the credit process.

Because manufacturers' return goods policies change over time, sometimes a pharmaceutical reverse distributor receives a potentially creditable hazardous waste pharmaceutical that is not eligible for credit immediately, and the pharmaceutical reverse distributor retains the potentially creditable hazardous waste pharmaceutical on-site until it is credit eligible. EPA requests comment on how often this happens and how long the potentially creditable hazardous waste pharmaceuticals are kept on-site at reverse distributors to await changes in manufacturers' return goods policies.

In some cases, even after the pharmaceutical reverse distributor has awarded credit, a pharmaceutical manufacturer may request that the hazardous waste pharmaceuticals be transported back to the manufacturer to inventory and verify the amount of pharmaceuticals and credit. In developing this proposed rule, EPA considered all of the previous scenarios as part of the crediting process.

On the other hand, if the potentially creditable hazardous waste pharmaceuticals are not sent onward to another pharmaceutical reverse distributor, the pharmaceutical reverse distributor awards the manufacturer's credit to the healthcare facility and then manages the hazardous waste pharmaceuticals on-site until they are sent off-site for treatment and disposal. As discussed previously in this proposal, after a potentially creditable hazardous waste pharmaceutical has been evaluated and either credited or deemed non-creditable and no additional pharmaceutical reverse distributors will be involved in the crediting process, EPA proposes to use the term "evaluated hazardous waste pharmaceutical." This is to distinguish between the potentially creditable hazardous waste pharmaceuticals awaiting determination within the reverse distribution system versus credited and non-creditable hazardous waste pharmaceuticals that have been through the reverse distributor process and are destined to be managed by a permitted or interim status TSDF. Both are considered hazardous waste pharmaceuticals, but they are managed differently under the proposed regulations.

EPA is not aware of any pharmaceutical reverse distributors that facilitate manufacturer's credit that also has interim status or a permit to treat or dispose of hazardous waste on-site. Therefore, EPA anticipates that pharmaceutical reverse distributors eventually send all evaluated hazardous waste pharmaceuticals off-site for

treatment and disposal. EPA requests comment on whether the processes described previously are representative of the pharmaceutical reverse distribution process.

2. EPA's Rationale for Proposing New RCRA Management Standards for Pharmaceutical Reverse Distributors

This proposed rule is establishing standards for the management of both potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that pharmaceutical reverse distributors receive and manage. The Agency notes that the management standards discussed in this section apply only to reverse distributors of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals and do not apply to reverse distribution or reverse logistics systems that may exist for other consumer products.

The current federal RCRA hazardous waste regulations at 40 CFR part 262 provide that only RCRA-permitted and interim status TSDFs may receive hazardous waste from off-site for treatment, storage, or disposal. However, the Agency does not believe it is necessary for pharmaceutical reverse distributors to obtain permits or have interim status to store hazardous waste pharmaceuticals in order to protect human health and the environment. Thus, EPA proposes a new category under RCRA called a "pharmaceutical reverse distributor," which we proposed to define as any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. The definition specifies that any person, including forward distributors and pharmaceutical manufacturers, which processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor. EPA is proposing that pharmaceutical reverse distributors are not required to have interim status or a RCRA permit to accumulate hazardous waste pharmaceuticals and they may only accept potentially creditable hazardous waste pharmaceuticals from off-site provided they comply with the proposed standards in this rule. Pharmaceutical reverse distributors may not treat or dispose of hazardous waste on-site unless authorized to do so as a RCRA-permitted or interim status TSDF.

As discussed previously, EPA's existing interpretation allows pharmaceutical reverse distributors to be generators of hazardous waste pharmaceuticals after a decision is made

about whether the pharmaceuticals will be repurposed. As a generator, a pharmaceutical reverse distributor currently must comply with the LQG, SQG, or CESQG generator requirements, depending on the total volume of hazardous waste generated in a calendar month. Some smaller pharmaceutical reverse distributors might stay under the hazardous waste quantity limits for CESQGs, which would mean that under the federal RCRA requirements, these CESQG pharmaceutical reverse distributors would not have to notify EPA as a generator and their hazardous waste pharmaceuticals could be disposed of with municipal and non-municipal solid waste (see § 261.5). However, the Agency has concerns with CESQG pharmaceutical reverse distributors not notifying EPA that they are managing hazardous waste. EPA is even more concerned about pharmaceutical reverse distributors that currently qualify as CESQGs placing the hazardous waste pharmaceuticals into the municipal and non-municipal solid waste stream and sending them to non-hazardous waste landfills. Some limited studies have shown active pharmaceutical ingredients present in landfill leachate that is collected in municipal solid waste landfill leachate systems.¹⁴¹ ¹⁴² Landfill leachate is generally transported to a wastewater treatment plant to be treated before discharge; however, some pharmaceutical compounds pass through treatment and are discharged, becoming a potential contributor of the pharmaceutical compounds detected in our nation's waters.

EPA is proposing to revise its position regarding potentially creditable hazardous waste pharmaceuticals, such that they will be first considered discarded at the healthcare facilities, not at the reverse distributors. This revision is based on new information demonstrating to EPA that pharmaceuticals returned to a reverse distributor are rarely, if ever, recycled or reused, and therefore the decision to send a potentially creditable hazardous waste pharmaceutical to a

pharmaceutical reverse distributor is a decision to discard the pharmaceutical (as discussed previously in Section V.D.1). Other comments on the December 2008 Pharmaceutical Universal Waste proposal indicated that notification to EPA by pharmaceutical reverse distributors and tracking of shipments of potentially creditable hazardous waste pharmaceuticals are critical and must be included in any regulatory scheme to ensure the safe management of potentially creditable hazardous waste pharmaceuticals.

As previously discussed, only between 2–6 percent of the potentially creditable hazardous wastes that are received by pharmaceutical reverse distributors are listed or characteristic hazardous wastes.¹⁴³ Therefore, the vast majority of the potentially creditable pharmaceutical waste that a pharmaceutical reverse distributor receives is not considered a characteristic or listed hazardous waste pharmaceutical under the existing definition of hazardous waste. This stands in contrast to a typical TSDF, which primarily manages hazardous waste. As a result, a pharmaceutical reverse distributor generally manages a smaller volume of hazardous waste than a typical permitted TSDF.

In addition, because the pharmaceuticals in the reverse distribution system are receiving credit, they are moved through the system efficiently. In fact, one national pharmacy retail chain informed EPA that the value of the credit they receive from manufacturers for returned pharmaceuticals is approximately \$1 billion a year.¹⁴⁴ Healthcare facilities and reverse distributors have a vested interest in having potentially creditable hazardous waste pharmaceuticals processed and credited quickly and managed appropriately so money is not lost in the process.

Furthermore, potentially creditable hazardous waste pharmaceuticals generally present a low risk of release to the environment as they typically are still in the manufacturer's packaging. Since there is a low human health and environmental risk of release associated with the low volumes of potentially creditable hazardous waste pharmaceuticals shipped to reverse distributors for crediting purposes, and because EPA is not aware of any incidents of mismanagement resulting

¹⁴¹ Barnes, K. K., Christenson, S. C., Kolpin, D. W., Focazio, M. J., Furlong, E. T., Zaugg, S. D., Meyer, M. T. and Barber, L. B. (2004). Pharmaceutical and Other Organic Waste Water Contaminants Within a Leachate Plume Downgradient of a Municipal Landfill. *Groundwater Monitoring & Remediation*, 24: 119–126.

¹⁴² Buszka, P.M., Yeskis, D.J., Kolpin, D.W., Furlong, E.T., Zaugg, S.D., and Meyer, M.T. (2009). Waste-Indicator and Pharmaceutical Compounds in Landfill-Leachate-Affected Ground Water near Elkhart, Indiana, 2000–2002. *Bulletin of Environmental Contamination and Toxicology*, 82.6:635–659.

¹⁴³ See EPA's request of information from reverse distributors, as well as their responses to EPA in the docket for this rulemaking: EPA–HQ–RCRA–2007–0932.

¹⁴⁴ Meeting with representatives from CVS/Caremark (November 8, 2012); see the docket for meeting notes (EPA–HQ–RCRA–2007–0932).

in environmental harm or releases of hazardous waste pharmaceuticals by reverse distributors, EPA believes that is not necessary to require reverse distributors to obtain RCRA hazardous waste storage permits with respect to typical reverse distribution operations, such as receiving, sorting, consolidating, and reshipping potentially creditable hazardous waste pharmaceuticals.

Thus, EPA is proposing to take a “middle-of-the-road” approach to regulating pharmaceutical reverse distributors by regarding them as a new type of RCRA hazardous waste entity—a pharmaceutical reverse distributor. This proposed approach addresses comments that EPA received on the December 2008 Pharmaceutical Universal Waste proposal and reflects EPA’s proposed revised interpretation that the point of generation for potentially creditable hazardous waste pharmaceuticals is at the healthcare facility, not the reverse distributor.

EPA proposes to establish management standards for pharmaceutical reverse distributors in 40 CFR part 266, subpart P. These entities would not be subject to 40 CFR parts 262, 264, or 265. Generally, EPA is proposing that pharmaceutical reverse distributors comply with standards that are similar to the current federal LQG standards, in combination with certain requirements that permitted or interim status hazardous waste TSDFs must meet. We are establishing one set of requirements for all pharmaceutical reverse distributors, regardless of the amount of potentially creditable hazardous waste pharmaceuticals they receive. EPA believes this uniform set of standards will make it easier for pharmaceutical reverse distributors to comply with the new proposal, since the burden of having to count hazardous waste pharmaceuticals on a monthly basis, especially the 1 kg of acute hazardous waste pharmaceuticals, will be removed.

EPA proposes that a pharmaceutical reverse distributor will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the proposed pharmaceutical reverse distributor standards. However, for activities such as treatment or disposal of hazardous waste pharmaceuticals or other hazardous waste, a pharmaceutical reverse distributor must either obtain a RCRA permit or have interim status. This proposal requires pharmaceutical reverse distributors to comply with standards that are similar to LQG standards for on-site accumulation of

hazardous waste that are found in § 262.34(a) and (b). We are proposing these requirements because, as discussed previously, the value of the potentially creditable pharmaceuticals creates an incentive for proper management and the risk of release is low. Furthermore, many pharmaceutical reverse distributors are already LQGs and therefore this proposed rule should not represent a large shift in current practices or increased burden. However, once credit is provided, the value of the pharmaceuticals is eliminated and therefore the evaluated hazardous waste pharmaceuticals have a greater potential for mismanagement. As a result, we are proposing that pharmaceutical reverse distributors have additional standards for the management of evaluated hazardous waste pharmaceuticals. Note that while the LQG accumulation standards are found in §§ 262.34(a) and (b), these generator regulations reference many interim status TSDF standards in part 265. However, in the regulatory text and preamble for this rule, we reference the standards in part 265 directly for the applicable accumulation standards for pharmaceutical reverse distributors (rather than § 262.34(a) which would then simply refer the reader to part 265). However, the Agency requests comment as to whether we should include the regulatory standard directly in 40 CFR part 266, subpart P, instead of providing a cross-reference to the standard in 40 CFR part 265 in an effort to make the rules easier to follow and comply with.

3. Detailed Discussion of Proposed Pharmaceutical Reverse Distributor Standards

The proposed standards for pharmaceutical reverse distributors are organized into three sections. The first section applies to the pharmaceutical reverse distributor for the management of all potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. The second section includes additional standards that would apply to the management of the potentially creditable hazardous waste pharmaceuticals that will be sent to another pharmaceutical reverse distributor for further evaluation or verification of credit and therefore continue to be regulated as potentially creditable hazardous waste pharmaceuticals. The third section includes additional standards that apply to the management of the evaluated hazardous waste pharmaceuticals that will not be sent to another pharmaceutical reverse distributor, but instead will be sent to a permitted or interim status TSDF.

a. Standards for Pharmaceutical Reverse Distributors

This portion of the preamble discusses the proposed standards that apply to pharmaceutical reverse distributors for the management of all hazardous waste pharmaceuticals on-site. Unlike the following two sections, the standards discussed in this section apply to all pharmaceutical reverse distributors, regardless of the subsequent destination of the hazardous waste pharmaceuticals. We note that a pharmaceutical reverse distributor must follow the proposed standards for the management of hazardous waste pharmaceuticals even if it generates other, non-pharmaceutical hazardous waste that is managed under 40 CFR part 262.

i. *Notification.* The first proposed requirement is that a pharmaceutical reverse distributor must notify EPA of its hazardous waste pharmaceutical activities via the Site ID form (EPA form 8700–12). Under the current RCRA Subtitle C program, both LQGs and TSDFs must submit a Site ID form to EPA. Thus, EPA believes it is appropriate, and in line with comments received on the 2008 Pharmaceutical Universal Waste proposal, to require pharmaceutical reverse distributors to notify EPA. A pharmaceutical reverse distributor that does not have an EPA ID number will be required to submit the Site ID form to obtain one. If this proposal is finalized, the Agency plans on revising the Site ID form to include a box to allow notifications by pharmaceutical reverse distributors. For those pharmaceutical reverse distributors that already have an EPA ID number, they will need to re-notify EPA as a pharmaceutical reverse distributor. Some pharmaceutical reverse distributors may also be generators of other types of hazardous waste (e.g., from cleaning and maintenance operations). Therefore, it is possible that a pharmaceutical reverse distributor may notify on the same notification form as both a generator of hazardous waste and as a pharmaceutical reverse distributor.

ii. *Inventory.* EPA is proposing a new provision that is specific to pharmaceutical reverse distributors: the requirement is to keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on-site. The inventory must include the identity (e.g., name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceuticals. EPA

also recommends as a best management practice that pharmaceutical reverse distributors also keep an inventory of their non-hazardous waste pharmaceuticals as well. An inventory is a key requirement to protect public health by helping to prevent the diversion of hazardous waste pharmaceuticals. An inventory will allow the pharmaceutical reverse distributor to know which pharmaceuticals they have on-site at any time. The Agency believes that in many cases, pharmaceutical reverse distributors already maintain inventories and this proposed requirement is not expected to be burdensome for the pharmaceutical reverse distributors to implement. In fact, according to responses from pharmaceutical reverse distributors to a request for information, four out of eight of them indicated that they already keep inventories as best management practices or because it is required by the Board of Pharmacy in their state.¹⁴⁵ However, EPA requests comment on whether this practice is already commonly followed.

iii. *Security of the pharmaceutical reverse distributor.* EPA is proposing that pharmaceutical reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. Specifically, due to increased thefts of narcotics from pharmacies reported in recent years in major media outlets,¹⁴⁶ EPA is concerned that pharmaceutical reverse distributors could also face such thefts since they accumulate unused pharmaceuticals or those that have exceeded their expiration date. Further, commenters on the 2008 Pharmaceutical Universal Waste proposal suggested that pharmaceutical universal waste handlers should meet the TSDF facility security requirement. EPA agrees with the commenters that the requirements that appear in the interim status TSDF security regulations would be appropriate to adopt and apply to pharmaceutical reverse distributors to prevent the illicit use of these pharmaceuticals and safeguard human health and thus, has included this requirement for pharmaceutical reverse distributors. The security of the facility requirement of § 265.14(a) requires a facility to “prevent the unknowing

entry, and minimize the possibility for the unauthorized entry, of persons or livestock onto the active portion of his facility.” EPA is proposing a similar requirement for pharmaceutical reverse distributors: they must prevent unknowing entry, and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable and evaluated hazardous waste pharmaceuticals are kept (e.g., a receiving area and accumulation area).

Based on site visits, EPA recognizes that many pharmaceutical reverse distributors may already meet the proposed security standard through the use of key cards that allow only authorized personnel into specific areas of the pharmaceutical reverse distributor, camera surveillance systems, and cages for storing pharmaceuticals. Some pharmaceutical reverse distributors may use fences and signs. EPA is including several examples of acceptable security measures in the regulatory text, but pharmaceutical reverse distributors are not limited to the examples provided. Further, if a pharmaceutical reverse distributor already meets the performance-based security standard by complying with other regulations, such as DEA’s regulations, then the pharmaceutical reverse distributor would not need to install additional security.

iv. *Maximum 90 days for on-site accumulation and petition for an extension of accumulation time.*

EPA is proposing that, like LQGs, pharmaceutical reverse distributors may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for up to 90 calendar days without having interim status or a permit. However, because of the value of the potentially creditable hazardous waste pharmaceuticals, and the low risk these materials present, the Agency has decided not to propose specific container management standards.

The 90-day time limit begins when the potentially creditable hazardous waste pharmaceuticals initially arrive at the pharmaceutical reverse distributor. The 90-day time limit follows the potentially creditable pharmaceutical, even after it becomes an evaluated hazardous waste pharmaceutical. That is, there is a single 90-day accumulation limit for the hazardous waste pharmaceutical at each pharmaceutical reverse distributor. However, some potentially creditable hazardous waste pharmaceuticals travel through more than one pharmaceutical reverse

distributor to receive manufacturer’s credit. In such cases, each pharmaceutical reverse distributor that receives the potentially creditable hazardous waste pharmaceuticals has a new 90-day accumulation limit. EPA requests comment on the 90-day timeframe and whether this timeframe is sufficient, or whether an alternative timeframe should be allowed.

As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must inventory potentially creditable hazardous waste pharmaceuticals upon arrival. Many pharmaceutical reverse distributors utilize barcoding and scanners to log potentially creditable pharmaceuticals into a database upon arrival or soon after a shipment arrives. Current inventory systems may be adapted to provide verification of the time limits. For example, if a pharmaceutical reverse distributor includes the date of arrival in the inventory, then the pharmaceutical reverse distributor will be able to use the inventory to verify that potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are not accumulated on-site for more than 90 calendar days. EPA is not proposing a specific method that pharmaceutical reverse distributors must use to document that accumulation does not exceed 90 calendar days. We anticipate that most pharmaceutical reverse distributors would use the inventory system to verify the 90-calendar day timeframe rather than using an additional requirement of labeling containers with dates for verification, but we request comment on this issue. We also request comment on whether EPA needs to specify a method of documenting that 90 calendar days is not exceeded.

Pharmaceutical reverse distributors have informed EPA that there are times when pharmaceutical returns may need to be consolidated for longer periods because they are subject to litigation and the pharmaceutical reverse distributor is not allowed to move them.

Pharmaceutical reverse distributors may also need to handle large recalls of hazardous waste pharmaceuticals and might not be able to process all of the returned items within 90 calendar days. Therefore, EPA is proposing to allow a pharmaceutical reverse distributor to request from EPA an extension of the 90-day accumulation time limit for situations when the hazardous waste pharmaceuticals are involved in litigation, a recall, or in unforeseen circumstances beyond the control of the pharmaceutical reverse distributor. A pharmaceutical reverse distributor

¹⁴⁵ See all the responses EPA received from pharmaceutical reverse distributors in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

¹⁴⁶ “Pharmacies Besieged by Addicted Thieves” by Abby Goodnough Published: February 6, 2011 <http://www.nytimes.com/2011/02/07/us/07pharmacies.html>.

seeking an extension must submit a written request to the EPA Regional Administrator (in writing or electronically), explaining the reason for the extension, the approximate volume or weight of the hazardous waste pharmaceuticals that will be stored for more than 90-days and the amount of additional time requested. Under the existing RCRA subtitle C regulations, the extension of time typically allowed is limited to an extra 30 days for LQGs. However, due to the complex nature of pharmaceutical litigation and recalls, EPA is proposing to allow the EPA Regional Administrator to grant a time extension at their discretion on a case-by-case basis. EPA requests comment on whether it is necessary to place a limit on the length of time for which an extension may be granted.

v. *Contingency plan and emergency procedures.* The Agency is proposing to require that pharmaceutical reverse distributors meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan and emergency procedures at 40 CFR part 265, subpart D. EPA believes that a pharmaceutical reverse distributor should be prepared to respond to potential emergencies just like LQGs and TSDFs. Since many pharmaceutical reverse distributors are already LQGs, they should already have contingency plans to address the hazards on-site. It may be possible that the pharmaceutical reverse distributors will have to amend their contingency plans to include the potentially creditable hazardous waste pharmaceuticals, which have been considered products, not hazardous waste, but we believe that such modifications should not impose much burden.

vi. *Closure.* Due to the generally low risk of release of the hazardous waste pharmaceuticals that pharmaceutical reverse distributors will accumulate on-site, as well as the value of the hazardous waste pharmaceuticals, EPA is proposing to require a performance-based closure standard that is based on the federal LQG closure standard found at § 265.111. Specifically, when a pharmaceutical reverse distributor closes its operations related to hazardous waste pharmaceuticals, it must control or minimize post-closure releases of hazardous waste constituents into the environment. This will entail removing the containers of hazardous waste pharmaceuticals (both potentially creditable hazardous waste pharmaceuticals as well as evaluated hazardous waste pharmaceuticals) from the facility before closure.

vii. *Reporting.* In some instances, a pharmaceutical reverse distributor may receive a shipment from a healthcare facility that includes items that are not potentially creditable pharmaceuticals. These shipments can include wastes that are clearly not eligible to receive credit, such as patient care waste (e.g., IV tubing), contaminated personal protective equipment (PPE), medical waste, or other inappropriate wastes. Pharmaceutical reverse distributors are not the appropriate waste management facility for medical or infectious wastes and these wastes must be managed and transported from the healthcare facility directly to an appropriate waste disposal facility. In some cases, these non-creditable wastes may be hazardous waste. These non-creditable hazardous wastes are prohibited from being transported from a healthcare facility to a pharmaceutical reverse distributor; rather they should be manifested to a designated facility, such as a permitted or interim status TSDF. Nevertheless, a healthcare facility might incorrectly ship non-creditable hazardous wastes to a pharmaceutical reverse distributor.

EPA is proposing that if a pharmaceutical reverse distributor receives a shipment from a healthcare facility that includes hazardous waste that it is not authorized to receive, such as non-creditable hazardous waste or hazardous waste that is not a pharmaceutical, the pharmaceutical reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 15 days of receiving the hazardous waste. We have adapted the existing requirement for situations when permitted and interim status TSDFs receive unmanifested hazardous waste (§ 264.76 and § 265.76, respectively) to make it appropriate for pharmaceutical reverse distributors that receive unauthorized hazardous waste. However, we are also proposing two additional requirements for pharmaceutical reverse distributors that receive inappropriate hazardous waste. First, the pharmaceutical reverse distributor must send a copy of the unauthorized hazardous waste report to the healthcare facility that sent the unauthorized hazardous waste. This requirement is intended to alert the healthcare facility of its mistake in order to prevent further shipments of non-creditable hazardous waste or non-pharmaceutical hazardous waste. Second, the pharmaceutical reverse distributor must manage the unauthorized hazardous waste that it receives in accordance with all applicable regulations. The Agency expects that the pharmaceutical reverse

distributor will likely pass these additional costs (e.g., medical waste incineration) on to the healthcare facility for the management of the hazardous waste and this will act as an incentive for the healthcare facility to take measures to prevent further shipments of unauthorized hazardous waste. We request comment on whether EPA's understanding regarding this type of situation is representative.

In order to prevent exposing employees to unnecessary risk, EPA recommends as a best management practice that pharmaceutical reverse distributors avoid sorting through shipments that contain non-creditable waste since the shipment may include hazardous waste, including infectious or radioactive healthcare waste. As a result, it is possible that a pharmaceutical reverse distributor receiving a shipment that includes non-creditable waste may be unsure whether the shipment includes hazardous waste. In such cases, EPA recommends that the pharmaceutical reverse distributor assume the shipment includes hazardous waste and submit an unauthorized waste report. Further, we recommend that pharmaceutical reverse distributors work with their clients to reduce the occurrence of inappropriate shipments.

viii. *Recordkeeping.* EPA is proposing three recordkeeping requirements to provide transparency for the movement of potentially creditable hazardous waste pharmaceuticals and as a means of verification upon inspection. First, a pharmaceutical reverse distributor must keep a copy of its notification (EPA form 8700-12) to EPA to indicate that it is a pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P. A pharmaceutical reverse distributor must keep the record of notification for as long as it is subject to these requirements. Second, a pharmaceutical reverse distributor must keep copies of the records associated with shipments of potentially creditable hazardous waste pharmaceuticals that it receives. This includes a copy of the advance notification from the healthcare facility or other pharmaceutical reverse distributor, a copy of delivery confirmation, shipping papers and any unauthorized waste reports. We propose that these shipping records must be kept for three years from the date the pharmaceutical reverse distributor receives the shipment. We request comment on whether additional recordkeeping is necessary to document cases when shipments of potentially creditable hazardous waste pharmaceuticals do not reach their intended destination within 7 calendar

days. Third, a pharmaceutical reverse distributor must keep a copy of its current inventory at all times as long as the pharmaceutical reverse distributor remains in operation. The inventory is a living document that will constantly be updated and must be available for inspection. Finally, we propose that periods of record retention indicated previously for a pharmaceutical reverse distributor will be automatically extended during an enforcement action, or as requested by the EPA Regional Administrator to ensure that the appropriate records are available and can be reviewed as part of any enforcement action.

Note that additional recordkeeping requirements may also pertain to pharmaceutical reverse distributors. For example, a pharmaceutical reverse distributor that manifests its non-pharmaceutical hazardous waste is subject to the manifest recordkeeping requirements of § 262.40. Further, as discussed in subsequent sections, there are additional recordkeeping requirements that apply to pharmaceutical reverse distributors for the management of potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor and others that apply to pharmaceutical reverse distributors for the management of evaluated hazardous waste pharmaceuticals.

ix. *Evaluating potentially creditable hazardous waste pharmaceuticals within 21 days.* Based on stakeholder input and site visits, EPA has learned that when a pharmaceutical reverse distributor receives a shipment of potentially creditable hazardous waste pharmaceuticals, the reverse distributor sorts through the shipment and often uses barcodes to scan items into its system. The pharmaceutical reverse distributor then determines which potentially creditable hazardous waste pharmaceuticals must be transported to another reverse distributor and which ones will be credited and then sent off-site for treatment and disposal. EPA is proposing that this evaluation process must be completed within 21 days of arriving at the pharmaceutical reverse distributor. Likewise, if the pharmaceutical reverse distributor is a manufacturer, EPA is proposing that the manufacturer must finish verifying the appropriate credit within 21 calendar days of receiving the shipment of potentially creditable hazardous waste pharmaceuticals.

EPA has chosen to propose 21 calendar days to ensure that the pharmaceutical reverse distributor has a long enough of time to make the

evaluation, yet a short enough time to ensure that potentially creditable hazardous waste pharmaceuticals do not linger awaiting evaluation. The Agency requests comment on this timeframe and whether it should be shortened or lengthened. We also want to emphasize that the 21 calendar days for evaluating the potentially creditable hazardous pharmaceuticals counts as part of the total 90 calendar days that the hazardous waste pharmaceuticals are allowed to accumulate on-site.

Once an evaluation is made on the incoming potentially creditable hazardous waste pharmaceuticals, if they are destined for another pharmaceutical reverse distributor, they are still considered potentially creditable hazardous waste pharmaceuticals. There are additional regulations in this proposal at § 266.510(b) that pertain to these potentially creditable hazardous waste pharmaceuticals (discussed in Section V.G.3.b.). If, however, they are destined for an interim status or permitted TSDF, they are considered “evaluated hazardous waste pharmaceuticals.” There are additional regulations in this proposal at § 266.510(c) that pertain to these evaluated hazardous waste pharmaceuticals (discussed in Section V.G.3.c.).

b. *Additional Standards for Pharmaceutical Reverse Distributors Managing Potentially Creditable Hazardous Waste Pharmaceutical Destined for Another Pharmaceutical Reverse Distributor*

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of potentially creditable hazardous waste pharmaceuticals that require further evaluation or verification of manufacturer’s credit at another pharmaceutical reverse distributor. These hazardous waste pharmaceuticals continue to be considered potentially creditable hazardous waste pharmaceuticals. Until manufacturer’s credit is finalized, the potentially creditable hazardous waste pharmaceuticals retain their value and there is greater incentive to manage them carefully in order to receive full manufacturer’s credit. Therefore, EPA is proposing few regulatory standards for the management of the potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor.

i. *Where potentially creditable hazardous waste pharmaceuticals can be sent.* The proposed regulations for

pharmaceutical reverse distributors are structured so that there is a limit to the number of transfers of potentially creditable hazardous waste pharmaceuticals that may occur before they are ultimately transported to a TSDF for treatment and disposal. Stakeholders expressed concern that the 2008 Pharmaceutical Universal Waste proposal would have allowed hazardous waste pharmaceuticals to be shipped repeatedly and indefinitely from one universal waste handler to another. From discussions with pharmaceutical reverse distributors and reviewing information submitted via EPA’s request for information, the Agency believes a reasonable limit is three transfers of potentially creditable hazardous waste pharmaceuticals before the pharmaceutical hazardous waste is ultimately transported to a TSDF. The three possible types of transfers are:¹⁴⁷

(1) a healthcare facility may send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor, which may or may not be a manufacturer;

(2) the first pharmaceutical reverse distributor may send the potentially creditable hazardous waste to another pharmaceutical reverse distributor, which may or may not be a manufacturer

(3) the second pharmaceutical reverse distributor can only send the potentially creditable hazardous waste pharmaceuticals on to a pharmaceutical reverse distributor that is a manufacturer.

EPA anticipates that healthcare facilities that are CESQGs will send their potentially creditable hazardous waste pharmaceuticals directly to pharmaceutical reverse distributors, and that the accumulation mechanism that we are proposing will be used to send only non-creditable hazardous waste pharmaceuticals to off-site healthcare facilities (see Section V.C.15.). However, EPA requests comment on whether CESQG healthcare facilities would benefit from being able to consolidate potentially creditable hazardous waste pharmaceuticals off-site, as well. Depending on comments, EPA will consider allowing a fourth transfer (for this limited situation) when potentially creditable hazardous waste pharmaceuticals are sent from a CESQG healthcare facility to an off-site healthcare facility for accumulation, as would also be allowed by proposed § 266.504(a).

¹⁴⁷ A healthcare facility or pharmaceutical reverse distributor also has the option of sending its hazardous waste pharmaceuticals to a RCRA permitted or interim status TSDF.

This chain of transfers ensures that the potentially creditable hazardous waste pharmaceuticals will be accumulated for no more than 270 days in total after leaving a healthcare facility and before being transported to a RCRA-permitted or interim status TSDF for treatment and disposal (assuming no accumulation time extensions are granted). EPA requests comment as to whether the three-transfer and 90-day limits are appropriate and whether more or fewer transfers are necessary for verification of manufacturer's credit.

Put another way, if a pharmaceutical reverse distributor receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility, the pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor (which may or may not be a manufacturer) or must manage them as evaluated hazardous waste pharmaceuticals under proposed § 266.510(c). However, a pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor is more limited in where it can send the potentially creditable hazardous waste pharmaceuticals. It can send potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is the manufacturer or else must manage them as evaluated hazardous waste pharmaceuticals under § 266.510(c).

Regardless of the destination, each pharmaceutical reverse distributor must make an evaluation of the hazardous waste pharmaceuticals within 21 calendar days and may only accumulate the hazardous waste pharmaceuticals on-site for a maximum of 90 calendar days, unless an extension is granted by the Regional Administrator before it ships them off-site to another pharmaceutical reverse distributor or a RCRA-permitted or interim status TSDF. In addition, all shipments of evaluated hazardous waste pharmaceuticals are subject to proposed § 266.508 and shipments of all potentially creditable hazardous waste pharmaceuticals are subject to proposed § 266.509.

ii. *Recordkeeping for pharmaceutical reverse distributors shipping of potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor.* Pharmaceutical reverse distributors must keep records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to

another pharmaceutical reverse distributor (whether it is a manufacturer or not). This includes a copy of the advance notification provided to the other pharmaceutical reverse distributor, a copy of delivery confirmation, as well as shipping papers or bill of lading. We propose that these shipping records must be kept for 3 years from the date it initiates the shipment.

c. **Additional Standards for Pharmaceutical Reverse Distributors Managing Evaluated Hazardous Waste Pharmaceuticals**

This section discusses the additional standards that apply to a pharmaceutical reverse distributor for the management of evaluated hazardous waste pharmaceuticals (*i.e.*, a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification). Evaluated hazardous waste pharmaceuticals have been through the entire crediting process. In order to minimize the potential for their mismanagement, EPA believes it is necessary to have additional standards for the evaluated hazardous waste pharmaceuticals.

i. *Accumulation area.* As discussed previously, EPA is proposing that a pharmaceutical reverse distributor must complete its evaluation of a potentially creditable hazardous waste pharmaceuticals within 21 calendar days of arriving at the pharmaceutical reverse distributor. Once the evaluation has been completed and the pharmaceutical reverse distributor knows that it is destined for treatment and disposal at a RCRA-permitted or interim status TSDF, rather than another pharmaceutical reverse distributor, the pharmaceutical is considered an evaluated hazardous waste pharmaceutical. Under the proposal, a pharmaceutical reverse distributor must establish an on-site accumulation area where it will accumulate these evaluated hazardous waste pharmaceuticals. An on-site accumulation area is needed so that the evaluated hazardous waste pharmaceuticals are segregated and clearly distinguished from the potentially creditable hazardous waste pharmaceuticals.

ii. *Weekly inspections.* EPA is proposing that the accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at

least weekly to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. Under the recordkeeping requirements for pharmaceutical reverse distributors, we are proposing that a pharmaceutical reverse distributor must keep a log of the weekly inspections of the on-site accumulation area and that the log must be retained for at least three years from the date of inspection. The log is necessary to validate the weekly inspections.

iii. *Personnel training.* EPA is proposing to require that pharmaceutical reverse distributors meet the same federal classroom or on-the-job personnel training requirements that LQGs must meet (§ 265.16). However, we specify in this proposal that the personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals in the on-site accumulation area. EPA believes that these personnel are the individuals handling and managing the hazardous waste pharmaceuticals and must have appropriate hazardous waste training. The Agency requests comment on whether the training standards are appropriate for the specific reverse distributor personnel.

iv. *Labeling and management of containers in on-site accumulation area.* EPA is proposing container labeling similar to what was proposed under the 2008 pharmaceutical universal waste proposed rule. While containers of hazardous waste pharmaceuticals are in the accumulation area, they must be marked with the words, "Hazardous Waste Pharmaceuticals." We are proposing this term in order to distinguish them from the non-hazardous waste pharmaceuticals and from the hazardous waste pharmaceuticals that are still considered potentially creditable. We are not proposing to require an accumulation start date on the label for the containers, because the reverse distributor's inventory will likely be used to verify the accumulation start date. However, a pharmaceutical reverse distributor may choose an alternate method, such as marking the date on each container as it arrives, to ensure that the hazardous waste pharmaceuticals are not accumulated at the pharmaceutical reverse distributor for more than 90 days, provided an extension is not granted. As explained previously, EPA prefers to allow a performance-based standard that allows flexibility to verify the 90-day accumulation time rather than require dating on the container labels, but we request comment regarding this requirement and whether

it is necessary to specify a method for how a pharmaceutical reverse distributor must verify that the 90-day maximum accumulation time is not exceeded.

In terms of container management standards, the Agency is proposing requirements that are similar to the container management standards for LQGs—that is, the standards in 40 CFR part 265, but the Agency is also proposing to include some additional management requirements specific to hazardous waste pharmaceuticals. Specifically, under 40 CFR 262.34(a)(1)(i), LQGs must comply with the container management standards in 40 CFR part 265, subpart I, which includes a requirement that containers of hazardous waste must be kept closed, except when adding or removing waste. In this document, EPA is proposing to require that only containers with hazardous waste pharmaceuticals that are liquids or gels be kept closed during accumulation due to the low potential for release for those hazardous waste pharmaceuticals that are in a solid form. However, because most potentially creditable hazardous waste pharmaceuticals are in their original packaging, if the original packaging for gels or liquids is intact and sealed or the pharmaceuticals have been repackaged (e.g., for unit dosing) and the repackaged packaging for gels and liquids is intact and sealed, they are considered to meet the closed container standard. EPA requests comment on whether additional forms of hazardous waste pharmaceuticals (other than liquids and gels) need to be specified in the regulations and subject to the closed container requirement.

EPA is also proposing that containers of hazardous waste pharmaceuticals must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. In addition, we are proposing to require that a pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals or that mixes or comingles incompatible evaluated hazardous waste pharmaceuticals must manage the container to prevent dangerous situations, such as fire, explosion, or release of toxic fumes.

Similar to healthcare facilities that accumulate non-creditable hazardous waste pharmaceuticals, pharmaceutical reverse distributors that accumulate evaluated hazardous waste pharmaceuticals must segregate the pharmaceuticals that are prohibited from being combusted because of the

dilution prohibition of § 268.3(c) and accumulate them in separate containers from other evaluated hazardous waste pharmaceuticals.

There are also several existing LQG accumulation unit management standards in § 262.34(a) that EPA believes are not necessary to include for the management of evaluated hazardous waste pharmaceuticals. For instance, this proposal only sets standards for the accumulation of evaluated hazardous waste pharmaceuticals in containers. EPA does not think it is necessary to include accumulation units such as tanks, containment buildings, or drip pads because pharmaceutical reverse distributors do not currently use these types of accumulation units. However, if EPA is mistaken in this understanding and commenters indicate they would like to be able to use tanks, containment buildings, or drip pads, EPA would consider including in this proposal the LQG standards for accumulation in these units. The Agency solicits comment on this matter.

In addition, the Agency is not proposing to require pharmaceutical reverse distributors to meet the air emission standards found in 40 CFR part 265, subpart CC as required in § 262.34(a)(1)(i) because we anticipate that they will not be applicable. Specifically, § 265.1083(c) exempts tanks, surface impoundments, and containers from the organic air emission standards if the hazardous waste entering the accumulation unit has an average volatile organic concentration of less than 500 parts per million by weight, while § 265.1080(b)(2) exempts containers with a capacity of less than 0.1 m³ (26 gallons) from the standards. EPA understands that the only evaluated hazardous waste pharmaceuticals that have the potential for air emissions are liquids and gels, but they generally do not contain volatile organics. Thus, they do not release organic air emissions, which is what the 40 CFR part 265, subpart CC, air emission standards for tanks, surface impoundments, and containers were promulgated to control. Moreover, because hazardous waste pharmaceuticals are often in their original packaging, and we are proposing to require that liquid and gel hazardous waste pharmaceuticals must be in intact, sealed packaging or otherwise in closed containers, EPA believes that the container air emission standards are unnecessary. In addition, the Agency anticipates that the packaging and containers for hazardous waste pharmaceuticals will often have a capacity less than 0.1 m³ (26 gallons)

further limiting the applicability of the container air emission standards.

Similarly, EPA does not anticipate that the 40 CFR part 265, subpart AA—air emissions standards for process vents—and subpart BB—air emission standards for equipment leaks—are applicable to the activities of a pharmaceutical reverse distributor and its management of hazardous waste pharmaceuticals. Therefore, like 40 CFR part 265, subpart CC discussed previously, EPA is not proposing to require that 40 CFR part 265, subparts AA and BB apply to pharmaceutical reverse distributors. EPA requests comments on whether its current understanding is correct and whether the 40 CFR part 265, subparts AA, BB, and CC RCRA air emission standards should be applied to pharmaceutical reverse distributors.

v. *Hazardous waste numbers (codes)*. EPA is proposing to require that the containers of evaluated hazardous waste pharmaceuticals be labeled with the appropriate RCRA hazardous waste numbers. The hazardous waste numbers may be placed on the container label at any time during on-site accumulation, but they must be added prior to when the evaluated hazardous waste pharmaceuticals are transported off-site. The hazardous waste numbers must be marked on the container label in order to ensure that it is readily visible and cannot be separated from the hazardous waste. The hazardous waste numbers are necessary so that transporters, transfer facilities, and TSDFs to know how to properly transport, consolidate, treat, store and dispose of the hazardous waste in compliance with the applicable RCRA regulations. We are not requiring that the pharmaceutical reverse distributor be the party that adds the hazardous waste numbers to the containers. The proposed regulations allow a vendor to perform this duty on behalf of the pharmaceutical reverse distributor. In practice, however, if a vendor is responsible for assigning hazardous waste numbers, personnel from the pharmaceutical reverse distributor may need to assist in the process.

vi. *Shipping evaluated hazardous waste pharmaceuticals*. Although it is already stated in § 266.508(a) under the section of the regulations that pertains to shipping standards, for clarity, we propose to repeat in § 266.510 (the pharmaceutical reverse distributor section of the regulations) the requirement that pharmaceutical reverse distributors that ship evaluated hazardous waste pharmaceuticals off-site must do so in accordance with the proposed shipping requirements in

§ 266.508(a). This includes the applicable DOT packaging, marking and labeling requirements, as well as the requirement to utilize the hazardous waste manifest when shipping the evaluated hazardous waste to a designated facility.

vii. *Rejected shipments.* The Agency is proposing to require in § 266.510(c)(7) that pharmaceutical reverse distributors meet the same procedures as LQGs must meet for rejected shipments in § 262.42(c). If a designated permitted or interim status TSDF identified on the hazardous waste manifest cannot accept a shipment of evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor and the TSDF returns the shipment to the pharmaceutical reverse distributor, the pharmaceutical reverse distributor must sign the applicable item on the manifest. In addition, the pharmaceutical reverse distributor may consolidate the rejected hazardous waste pharmaceuticals on-site for up to 90 days provided they are managed in the on-site accumulation area and in accordance with this proposal's pharmaceutical reverse distributor standards for evaluated hazardous waste pharmaceuticals. The reporting requirements associated with rejected shipments are discussed separately under the reporting section.

viii. *Land disposal restrictions.* EPA is proposing in § 266.510(c)(8) that pharmaceutical reverse distributors are subject to the same land disposal restrictions (LDRs) that apply to LQGs with respect to their evaluated hazardous waste pharmaceuticals. In addition, EPA is proposing to amend the testing, tracking, and recordkeeping requirements for generators, treaters and disposal facilities at § 268.7 to add the words, "pharmaceutical reverse distributors" to the title of that section to make the applicability of the treatment standards clear.

ix. *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.*

(1) *Biennial report.* EPA is proposing that pharmaceutical reverse distributors submit a BR for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF in order for the Agency to have as complete a picture of the amount of hazardous waste generated, treated, stored, or disposed of annually. However, the BR should only include the evaluated hazardous waste pharmaceuticals, and not the potentially creditable hazardous waste pharmaceuticals that a pharmaceutical reverse distributor sends to another pharmaceutical reverse distributor. Specifically, we are proposing in § 266.510(c)(9)(i) that a pharmaceutical

reverse distributor comply with the LQG BR requirements in § 262.41, except for § 262.41(a)(7), which includes the requirement to report changes in volume and toxicity of waste achieved during the year in comparison to previous years. The reason we are not requiring the pharmaceutical reverse distributor to provide such information is that they do not have control of the volume or toxicity of the hazardous waste pharmaceuticals it receives from the healthcare facility, and thus have no ability to reduce the volume or toxicity of the hazardous waste pharmaceuticals. Thus, EPA is not requiring the pharmaceutical reverse distributor to report this information in its BR.

(2) *Exception reporting.* For the reasons that EPA requires exception reporting generally—that is, to maintain the cradle to grave tracking system, EPA is proposing in § 266.510(c)(9)(ii)(A) that pharmaceutical reverse distributors provide an exception report when a TSDF does not return the hazardous waste manifest to the pharmaceutical reverse distributor for shipments of hazardous waste pharmaceuticals to a designated facility. Likewise, we are proposing in § 266.510(c)(9)(ii)(B) that pharmaceutical reverse distributors meet LQG exception reporting when a shipment from a pharmaceutical reverse distributor is rejected by the designated facility and forwarded onto an alternate facility.

x. *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* Many of the proposed recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals have been discussed in the sections previously, but for clarity, it is useful to restate them in this recordkeeping section, so that pharmaceutical reverse distributors can refer to one section to determine their recordkeeping requirements related to evaluated hazardous waste pharmaceuticals. In particular, we are proposing five recordkeeping requirements that pertain to evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors. First, EPA is proposing that a pharmaceutical reverse distributor keeps a log (written or electronic) of its weekly inspections of the on-site accumulation area. The other four recordkeeping requirements that we are proposing in § 266.510(c)(10) for pharmaceutical reverse distributors are the same as the LQG recordkeeping requirements that appear in §§ 262.40–42 and § 265.16; these include hazardous waste manifest records, records of biennial reports, exception reporting and training documentation.

EPA believes that these recordkeeping requirements are appropriate for pharmaceutical reverse distributors, many of whom are currently LQGs, but requests comment on this requirement.

EPA asks commenters to review the standards EPA is proposing for pharmaceutical reverse distributors and provide specific comment on whether the standards are appropriate and sufficient to protect human health and the environment.

d. When a Pharmaceutical Reverse Distributor Must Have a RCRA Hazardous Waste Permit

EPA is proposing to not require that a pharmaceutical reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the pharmaceutical reverse distributor follows all the conditions of the permitting exemption in § 266.510. In other words, a pharmaceutical reverse distributor would be subject to regulation as a TSDF and require a RCRA permit (or interim status) if it does not meet the conditions of § 266.510. In addition, a pharmaceutical reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on-site or if it accepts manifested hazardous waste from off-site. A pharmaceutical reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off-site because a pharmaceutical reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste via a manifest. EPA believes that this approach to regulation of pharmaceutical reverse distributors that accumulate hazardous waste pharmaceuticals strikes an appropriate balance because it recognizes that pharmaceutical reverse distributors are different from typical hazardous waste TSDFs for permitting purposes, while it still imposes certain conditions for exemption from permitting requirements that provide the necessary environmental protection.

VI. Implementation and Enforcement

A. Healthcare Facilities

1. Determining Whether a Healthcare Facility is Subject to Part 266, Subpart P

EPA is proposing that healthcare facilities that are currently considered LQGs or SQGs are subject to the new 40 CFR part 266, subpart P requirements for the management of hazardous waste pharmaceuticals. Thus, a healthcare facility that generates (or accumulates)

more than 100 kg hazardous waste per calendar month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg of any residue or contaminated soil, waste, or other debris resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in §§ 261.31, or 261.33(e), must manage its hazardous waste pharmaceuticals in compliance with the 40 CFR part 266, subpart P requirements. In addition, healthcare facilities that are CESQGs are subject to the prohibition on sewerage hazardous waste pharmaceuticals in § 266.5052.

To determine whether a healthcare facility is a subject to 40 CFR part 266, subpart P, or a CESQG regulated under § 261.5, a healthcare facility must count all the hazardous waste—pharmaceutical and non-pharmaceutical—it generates in a calendar month. In counting the amount of hazardous waste generated per calendar month, we note that EPA is proposing to change which pharmaceuticals will be considered hazardous wastes (*i.e.*, potentially creditable hazardous waste pharmaceuticals). Specifically, EPA is proposing that potentially creditable hazardous waste pharmaceuticals transported to a pharmaceutical reverse distributor will be considered solid waste from the point of generation at the healthcare facility and therefore must be counted when determining whether the healthcare facility is a CESQG regulated under § 261.5, or whether it is regulated under 40 CFR part 266, subpart P. This differs from current practice where, although a healthcare facility must count the non-creditable hazardous waste pharmaceuticals it generates each calendar month toward its hazardous waste generator category, it does not count the potentially creditable hazardous waste pharmaceuticals it sends to a pharmaceutical reverse distributor. Therefore, although a healthcare facility *currently* may be considered a CESQG, when it begins counting its potentially creditable hazardous waste pharmaceuticals, it may no longer be a CESQG. In that case, the healthcare facility would be subject to the 40 CFR part 266, subpart P requirements.

2. Healthcare Facilities Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

EPA is proposing that all healthcare facilities, with the exception of CESQGs, will be subject to the same regulations for the management of their hazardous waste pharmaceuticals, regardless of the quantity of hazardous waste

pharmaceuticals generated. A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward the facility's monthly hazardous waste generator category. In addition, if a healthcare facility does not want to keep track of the amount of hazardous waste it generates to ensure it does not exceed the CESQG quantity limits, it could choose to operate under this proposed rule. If it chooses to operate under this proposed rule, however, a healthcare facility must comply with all the requirements of this subpart for the management of its hazardous waste pharmaceuticals.

B. Pharmaceutical Reverse Distributors

1. Pharmaceuticals Sent to Pharmaceutical Reverse Distributors Are Solid Wastes

One difference between this proposal and the 2008 Pharmaceutical Universal Waste proposal is how RCRA would apply to pharmaceuticals returned to pharmaceutical reverse distributors to obtain manufacturer's credit. EPA is proposing to change its existing position on this issue. If this rule is finalized, this change would mean that the decision by a healthcare facility to send a pharmaceutical to a pharmaceutical reverse distributor is the decision to discard the pharmaceutical. Therefore, under this proposed rule, once the healthcare facility makes the decision to send a pharmaceutical to a pharmaceutical reverse distributor for credit, it is a solid waste at the healthcare facility. It is likely that a portion of the potentially creditable solid waste pharmaceuticals at healthcare facilities that are destined for a pharmaceutical reverse distributor will also meet the definition of hazardous waste and as a result, these potentially creditable hazardous waste pharmaceuticals would need to be managed in accordance with the standards proposed in this document. However, until this rule is final and effective, EPA's current position will remain in effect.

In addition, the Agency notes that the proposed change in EPA's position concerning reverse distribution and the management standards discussed in this document pertain only to the reverse distribution of hazardous waste pharmaceuticals and does not apply to reverse distribution or reverse logistics systems that may exist for other consumer products. This limitation is because EPA has studied and collected

data for reverse distribution systems for hazardous waste pharmaceuticals, and not all consumer products.¹⁴⁸

2. Pharmaceutical Reverse Distributors Managing Hazardous Waste Pharmaceuticals Under Part 266, Subpart P

Under this proposal, all pharmaceutical reverse distributors are subject to 40 CFR part 266, subpart P and will be subject to the same standards with respect to their hazardous waste pharmaceuticals, regardless of the amount of hazardous waste pharmaceuticals they manage. Even pharmaceutical reverse distributors that are currently CESQGs will be regulated under 40 CFR part 266, subpart P for the management of their hazardous waste pharmaceuticals. Therefore, as with healthcare facilities, a pharmaceutical reverse distributor subject to 40 CFR part 266, subpart P will no longer have to keep track of the amount of hazardous waste pharmaceuticals that it generates on a monthly basis.

C. Healthcare Facilities and Pharmaceutical Reverse Distributors Managing Non-Pharmaceutical Hazardous Waste in Accordance With 40 CFR Part 262 or Part 273

Most, if not all, healthcare facilities and pharmaceutical reverse distributors generate hazardous wastes other than pharmaceuticals. These, non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 (and other applicable Subtitle C regulations). However, because a healthcare facility or pharmaceutical reverse distributor operating under 40 CFR part 266, subpart P no longer has to count its hazardous waste pharmaceuticals, including acute hazardous waste pharmaceuticals such as warfarin, it could result in a change in the facility's overall generator category and thus change how its non-pharmaceutical hazardous waste must be managed. For example, the generator category for a healthcare facility or pharmaceutical reverse distributor may be reduced from an LQG to an SQG or even a CESQG, when it stops counting its hazardous waste pharmaceuticals, especially acute hazardous waste pharmaceuticals, toward its generator category.

If finalized, the standards established by this rulemaking apply only to the management of hazardous waste

¹⁴⁸ EPA is examining the reverse logistics of non-pharmaceutical hazardous wastes as part of its analysis of comments received on the Retail Notice of Data Availability that was published on February 14, 2014 (79 FR 8926).

pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors. Healthcare facilities and pharmaceutical reverse distributors likely generate or manage other types of wastes. For example, hospitals may generate non-pharmaceutical hazardous wastes, such as solvents in their diagnostic laboratories; those hazardous wastes must still be managed in accordance with the RCRA Subtitle C requirements (such as the RCRA satellite accumulation regulations (§ 262.34(c)), or if it is a teaching hospital, the Academic Laboratories Rule (if it has opted into part 262, subpart K). Retail pharmacies in retail stores and grocery stores may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 requirements and all other applicable RCRA Subtitle C regulations. For example, fluorescent bulbs may be managed under the universal waste program (40 CFR part 273). For pharmaceutical reverse distributors, this proposed rule only applies to the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals. Some pharmaceutical reverse distributors may generate other non-pharmaceutical hazardous wastes from activities, such as cleaning and maintenance; other RCRA requirements will apply to those non-pharmaceutical hazardous wastes.

D. State Enforcement Activities and Interpretations

States have taken a variety of approaches regarding pharmaceutical hazardous wastes. One major goal of this proposed rule is to provide clarity on this topic, and thereby promote national consistency, which, in turn, should promote better compliance among healthcare facilities, including pharmacies.

California has taken numerous enforcement actions against national retail chains with pharmacies for not complying with the RCRA hazardous waste regulations. In recent years, the state took enforcement actions and imposed fines on the following chains: Kmart (2009), Walmart (2010), Target (2011), CVS (2012), Costco (2012), Walgreens (2012) and Rite-Aid (2013). In at least two settlement agreements, California directed the defendants (CVS and Costco) to “initiate work with appropriate stakeholders from business and government, including the U.S. Environmental Protection Agency, the U.S. Food and Drug Administration, and the DTSC [Department of Toxic Substances Control], and thereafter either directly or through trade

associations or informal coalitions of interested parties, undertake to promote federal regulatory reform regarding the proper management of nondispensable pharmaceuticals, including over-the-counter medications, through “reverse distribution.”¹⁴⁹ Through these settlement agreements, California is seeking clarity from EPA about its longstanding interpretation about the regulatory status of pharmaceuticals that are routed through pharmaceutical reverse distribution systems.

In 2012, Connecticut’s Department of Energy and Environmental Protection (DEEP) took enforcement actions at seven CVS stores for violations of the RCRA hazardous waste regulations. Consent orders from Connecticut DEEP direct CVS stores in the state to follow a set of best management practices.¹⁵⁰ A number of the practices developed in these consent orders mirror some of the practices we are proposing in this rule, particularly with regard to pharmaceuticals destined for a pharmaceutical reverse distributor. Connecticut DEEP asserts RCRA jurisdiction over the pharmaceuticals destined for pharmaceutical reverse distributors by applying specific practices to their management. For example, CVS must maintain records of each shipment of non-dispensable pharmaceuticals to a pharmaceutical reverse distributor, including confirmation of receipt of the non-dispensable pharmaceuticals from the pharmaceutical reverse distributor receiving them. The best practices also include procedures for addressing situations when CVS does not receive delivery confirmation of shipment to a pharmaceutical reverse distributor. Further, the consent order sets out separate, more comprehensive practices for the non-dispensable pharmaceuticals that are not suitable for pharmaceutical reverse distribution.

Aside from best management practices developed by Connecticut as part of a consent order, at least two other states have developed guidance documents that apply conditions to the management of hazardous wastes pharmaceuticals in exchange for enforcement discretion. In particular, in 2008, the Washington State Department of Ecology issued guidance titled, Interim Enforcement Policy:

¹⁴⁹ <http://www.calepa.ca.gov/enforcement/orders/2012/CVSStipFinal.pdf> and <http://www.calepa.ca.gov/enforcement/orders/2012/CostcoFinal.pdf> or see the docket for this rulemaking EPA-HQ-RCRA-2007-0932.

¹⁵⁰ <http://www.ct.gov/deep/lib/deep/enforcement/consentorder/COWSWDH13005.pdf> or see the docket for this rulemaking EPA-HQ-RCRA-2007-0932.

Pharmaceutical Waste in Healthcare.¹⁵¹ Like Connecticut’s consent orders with CVS, this enforcement discretion policy has some elements in common with this proposed rule for hazardous waste pharmaceuticals. For instance, a healthcare facility must notify the Department of Ecology that it is operating under the policy and must train its staff involved in pharmaceutical waste management. Only a time limit, rather than a quantity limit, applies to the accumulation of the hazardous waste pharmaceuticals on-site. Of particular note is that Washington State prohibits disposing of most hazardous waste pharmaceuticals down the toilet or drain.

In 2011, Minnesota’s Pollution Control Agency (MPCA) issued a fact sheet titled Reverse Distribution of Pharmaceuticals: Guidance for Minnesota Healthcare Providers.¹⁵² In this guidance, Minnesota states, “Whether a pharmaceutical is eligible for return credit does not affect its *product* or *waste* status. In Minnesota, if a pharmaceutical is not used or reused for its intended purpose, it is a *waste*. The MPCA considers health care practitioners and pharmacies to be *generators* of these pharmaceutical wastes. Nevertheless, the MPCA believes that the established reverse distribution system provides an environmentally protective method for handling waste pharmaceuticals. Therefore, it will allow Minnesota health care practitioners and pharmacies to manage certain pharmaceuticals through reverse distribution, subject to additional requirements discussed in this fact sheet.” This is similar to the approach that EPA is proposing for potentially creditable hazardous waste pharmaceuticals. For example, like EPA’s proposed rule, MPCA does not require hazardous waste pharmaceuticals destined for a pharmaceutical reverse distributor to be counted toward determining a healthcare facility’s generator category, and MPCA does not require hazardous waste pharmaceuticals to be accompanied by a hazardous waste manifest when shipped to a pharmaceutical reverse distributor. By adopting a rule that is consistent with state approaches, EPA is bringing national consistency to the management

¹⁵¹ See the interim enforcement policy in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932) or see it online at <https://fortress.wa.gov/ecy/publications/documents/0704024.pdf>.

¹⁵² See the guidance document in the docket for this rulemaking (EPA-HQ-RCRA-2007-0932) or see it online at <http://www.pca.state.mn.us/index.php/view-document.html?gid=4004>.

of hazardous waste pharmaceuticals, while avoiding disruption to practices already in place.

VII. Request for Comment on EPA's Efforts To Identify Additional Pharmaceutical Hazardous Wastes

Some of the comments EPA received in response to the 2008 Universal Waste proposal recommended that EPA add additional pharmaceutical wastes to the P and U hazardous waste lists (see § 261.33). Some commenters suggested that EPA assess the hazards from all discarded pharmaceuticals (especially chemotherapy drugs) that have come into the market since the promulgation of the original P and U hazardous waste lists¹⁵³ and that EPA update these lists to include discarded pharmaceuticals that are hazardous. In response to these comments, the Agency began gathering and reviewing information related to pharmaceuticals that may exhibit hazardous properties. EPA identified 204 drugs, which include 172 drugs that the National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) identified as hazardous, and 32 drugs that NIOSH proposed for addition to its hazardous drug list.¹⁵⁴ EPA also collected toxicity data and other information for these 204 drugs. These findings, along with additional information regarding the management of pharmaceutical wastes, are presented in the final report entitled *Data Collection on the Toxicity, Use, and Disposal of Hazardous Drugs Report* (September 2011) placed in the docket for this proposed rulemaking (EPA-HQ-RCRA-2007-0932).

Commenters specifically referred to EPA's P and U hazardous waste lists under the RCRA subtitle C regulations. Generally, in its hazardous waste determinations, EPA has evaluated both "production wastes" (from specific or non-specific sources; see §§ 261.31 and 261.32) and "commercial chemical products" that, when discarded, become wastes (§ 261.33). This latter category (commercial chemical products that are discarded) is the most relevant of the listed hazardous wastes to the

pharmaceutical wastes discussed elsewhere in this preamble, and to which commenters referred in the 2008 Universal Waste proposal. As discussed in Section IV.A. of this preamble, commercial chemical products listed in § 261.33 are (when discarded) defined as either P-listed "acute" hazardous wastes, or U-listed (non-acute) hazardous wastes. The criteria for listing a solid waste as hazardous under RCRA Subtitle C are described in § 261.11. A waste may be identified as a P-listed waste if it is shown to be fatal to humans or animals at low doses (see § 261.11(a)(2)). Thus, lethality data for any chemical is the principal factor for making a determination that a discarded commercial chemical product is a P-listed hazardous waste.¹⁵⁵

In contrast, a waste may be identified as a U-listed waste if it contains any of the toxic constituents listed in Appendix VIII of 40 CFR part 261, and if, after examining each of 10 factors in § 261.11(a)(3), it is determined that the waste is capable of posing a "substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed."¹⁵⁶ Examples of these 10 factors include the toxicity and concentration of the hazardous constituent in the waste, the plausible types of improper management to which the waste could be subjected, the quantities of the waste generated at individual generation sites or on a regional or national basis, the nature and severity of the human health and environmental damage that has occurred as a result of the improper management of wastes, and action taken by other governmental agencies or regulatory programs based on the health or environmental hazard posed by the waste or waste constituent. EPA may

¹⁵⁵ § 261.11(a)(2) states "The Administrator shall list a solid waste as a hazardous waste only upon determining that the solid waste . . . has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity (rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness. (Waste listed in accordance with these criteria will be designated Acute Hazardous Waste.)"

¹⁵⁶ The Agency cannot list hazardous wastes under section § 261.11(a)(3) based on inherent toxicity alone without considering exposure factors, particularly the likelihood of mismanagement. That is, EPA needs to examine each of the 10 factors and, to the extent it does not use one or more of them, must explain why they are irrelevant or unimportant. See *Dithiocarbamate Task Force v. EPA* (No. 95-1249).

only revise either of these lists of commercial chemical products through notice-and-comment rulemaking.

In its September 2011 report, EPA found that 11 drugs on the NIOSH or OSHA lists of hazardous drugs meet the specific criteria for acute toxicity in § 261.11(a)(2) (identified as "Tier 1" drugs in the report). An additional 114 drugs on the NIOSH or OSHA lists did not meet the specific criteria in § 261.11(a)(2) for acute toxicity, but did have lethal doses for other animals or humans ("Tier 2" drugs). The remaining 79 drugs had limited human or animal toxicity data, and no lethality data, and were designated "Tier 3" in the report. Thus, the vast majority of the NIOSH/OSHA hazardous drugs evaluated in the EPA 2011 report do not meet the criteria for listing as acute hazardous waste under RCRA subtitle C.¹⁵⁷ As discussed previously, to include a drug on the U-list, the Agency must demonstrate that a discarded drug would be "capable of posing a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed." Therefore, for the NIOSH/OSHA drugs that do not meet the listing criteria for inclusion on the P-list, the Agency would have to examine the 10 factors in § 261.11(a)(3) to determine whether a drug meets the criteria to be included on the U-list. In addition to toxicity data (which is lacking in particular for the drugs identified as Tier 3), the types of information that would be relevant include waste volumes, plausible management scenarios, exposure potential, damage cases, and actions taken by other governmental agencies or regulatory programs. To obtain this information for this class of materials poses a challenge. While EPA has some information—the September 2011 report includes summaries of drug management practices and references to others—there remain significant gaps.

In addition, as discussed in Section IV.D. of this preamble, the EPA's OIG has recommended that EPA identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste, and establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste. While EPA has an existing process generally for defining whether or not a solid waste is a listed hazardous

¹⁵⁷ EPA emphasizes that this finding reflects the manner in which EPA defines acute hazardous waste under the RCRA subtitle C program; the NIOSH/OSHA lists are based upon different criteria related to preventing occupational exposure to these drugs.

¹⁵³ May 19, 1980 *Federal Register* (45 FR 33084) and November 25, 1980 *Federal Register* (45 FR 78525).

¹⁵⁴ See NIOSH's Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Healthcare Settings (<http://www.cdc.gov/niosh/docs/2004-165/>) and OSHA Technical Manual Section VI: Chapter 2—Controlling Occupational Exposure to Hazardous Drugs (https://www.osha.gov/dts/osta/otm/otm_vi_2.html). Note that the "hazardous" classification used by NIOSH and OSHA is not the same as the definition of hazardous under the RCRA subtitle C regulations.

waste (*i.e.*, EPA has regulatory criteria for defining listed hazardous waste described previously; EPA has established policies for evaluating risk and other factors in making listing determinations;¹⁵⁸ and EPA must use the notice-and-comment rulemaking process when proposing listing determinations), the OIG observed that EPA's hazardous waste program has not kept pace with the large number of pharmaceuticals that have been developed since 1980. EPA plans to regularly review the NIOSH/OSHA lists of hazardous drugs, as they represent a source of valuable information on pharmaceuticals that have already been identified as having the possibility of posing risks that might warrant regulation as hazardous waste.

EPA is also exploring ways to identify new sources of information, along with alternative approaches that can most efficiently address these concerns. EPA is using the opportunity in this preamble to seek stakeholders' input on the best course of action concerning regulation of additional pharmaceuticals as hazardous wastes. It is also an opportunity for stakeholders to provide additional information that they may have about potentially hazardous pharmaceuticals. Thus, before deciding on a possible proposal to list additional pharmaceuticals as hazardous wastes, we request comment on the September 2011 final report, and solicit information regarding additional potentially hazardous pharmaceuticals. We request information on the sources and identity of additional potentially hazardous pharmaceuticals along with annual product generation data, annual waste generation data, use information, toxicity data, waste storage and handling information, and disposal information.

In addition, we request stakeholder input for alternative approaches to making hazardous waste listing determinations for pharmaceuticals that do not meet the acute hazardous criteria. Based on the existing listing determination process described previously for non-acute wastes, there is no single toxicity effect (*e.g.*, LD₅₀) to readily determine whether or not the waste is hazardous under RCRA subtitle C. As such, we are seeking ideas on alternative approaches to more efficiently evaluate potentially hazardous non-acute discarded pharmaceuticals. For example, should EPA develop and promulgate new

criteria specific to discarded pharmaceuticals that would allow it to establish a single hazardous waste listing for all discarded pharmaceuticals that meet the new criteria? Such approaches could also include consideration of whether discarded pharmaceuticals are already managed under a regulatory scheme that prevents mismanagement that a hazardous waste designation would otherwise address (similar to the hazardous waste listing factor that takes into account "actions taken by other governmental agencies or regulatory programs"). We also are seeking information on any innovative processes or programs that states may have for identifying, reviewing, and making a hazardous waste determination for discarded pharmaceuticals.

The Agency emphasizes that no regulatory action is being proposed with respect to expanding the number of pharmaceuticals that are considered hazardous waste. We will use the comments we receive to help inform how to proceed with evaluating discarded pharmaceuticals as listed or characteristic hazardous wastes. Any action taken would be part of a separate, proposed rulemaking in the future.

VIII. Request for Comment on EPA's Efforts To Amend the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)

A. Background

In 1980, as part of its final and interim final regulations implementing Section 3001 of RCRA, EPA promulgated the list of commercial chemical products or manufacturing chemical intermediates (40 CFR 261.33) that are hazardous wastes if they are discarded or intended to be discarded, which included nicotine and salts (45 FR 33124; May 19, 1980). The phrase "commercial chemical product or manufacturing chemical intermediate" refers to a "chemical substance which is manufactured or formulated for commercial or manufacturing use which consists of the commercially pure grade of the chemical, any technical grades of the chemical that are produced or marketed, and all formulations in which the chemical is the sole active ingredient" (see the *Comment* following 40 CFR 261.33(d)). A chemical substance is listed in 40 CFR 261.33(e) as an acutely hazardous waste if it meets any of the criteria in 40 CFR 261.11(a)(2), which states that the waste "has been found to be fatal to humans in low doses or, in the absence of data on human toxicity, it has been shown in studies to have an oral LD 50 toxicity

(rat) of less than 50 milligrams per kilogram, an inhalation LC 50 toxicity (rat) of less than 2 milligrams per liter, or a dermal LD 50 toxicity (rabbit) of less than 200 milligrams per kilogram or is otherwise capable of causing or significantly contributing to an increase in serious irreversible, or incapacitating reversible, illness."

B. Basis for Original Listing

EPA listed nicotine and salts (referred to commonly as just nicotine) as acutely hazardous waste (P075) in § 261.33(e) based on an estimated oral LD50 toxicity to humans of 1 mg/kg and a dermal LD50 toxicity to rabbits of 50 mg/kg.¹⁵⁹ As discussed previously, for humans, the standard in the regulations for acute toxicity is "fatal to humans in low doses" (see § 261.11(a)(2)). EPA's Background Document for Section 261.33 from 1981 provides a basis for what is meant by "fatal to humans in low doses" for chemicals that have been given through the oral route ("fatal to humans upon ingestion of ≤100 mg/kg"). The estimated oral LD50 to humans of 1 mg/kg falls within the criteria for "fatal to humans in low doses." However, the background listing document and its references do not provide sufficient detail to determine the concentration of nicotine that was used to establish the estimated oral LD50 in humans.

C. Rationale for EPA's Efforts To Amend the P075 Listing

On February 14, 2014, EPA published a Notice of Data Availability (NODA) and Request for Comment (79 FR 8926) entitled "Hazardous Waste Management and the Retail Sector: Providing and Seeking Information on Practices to Enhance Effectiveness to the RCRA Program." EPA received 44 comments in response to this NODA, many of which included comments related to pharmaceuticals, in particular comments concerning expired or returned low-concentration nicotine-containing smoking cessation products and e-cigarettes. The most detailed comments concerning the unsold low-concentration nicotine products were jointly submitted by the Retail Industry Leaders Association (RILA), the Food Marketing Institute (FMI), the National Association of Chain Drug Stores (NACDS), the National Retail Federation, and their members (referred to as the retail associations, retailers, or

¹⁵⁸ EPA's policy statement on hazardous waste listing determinations is contained in the **Federal Register** preamble to the first proposed Dyes and Pigments Listing Determination (59 FR 66072, December 22, 1994).

¹⁵⁹ See EPA's listing Background Document for Section 261.33, April 1981, in the docket for this proposed rule (EPA-HQ-RCRA-2007-0932).

commenters).¹⁶⁰ In their comments, the retail associations, representing a broad range of retailers within the retail industry, asked EPA to undertake a rulemaking to remove low-concentration nicotine products from the acute hazardous waste P075 classification under RCRA. The retailers believe these products do not meet RCRA's requirements for acute hazardous waste. Thus, according to the retailers, the acute hazardous classification is inappropriately making them subject to RCRA's LQG requirements, which become applicable when someone generates more than 1 kg/month of acute hazardous waste. The retailers also expressed concern that they are subject to increased economic burdens and reporting requirements because they are subject to RCRA's LQG requirements.

The commenters, to support their request to EPA, state that EPA's listing for nicotine and salts warrants a reevaluation, because in more recent literature concerning nicotine toxicity, doubts have been expressed about the estimated oral LD50 toxicity to humans of 1 mg/kg, used as a key basis for the listing. According to information provided by commenters, the estimated oral LD50 toxicity to humans of 1 mg/kg was based on extrapolations from toxicological effects observed as result of "self-experiments" performed with nonfatal doses of nicotine. However, according to the commenters, there are doubts about the 1 mg/kg estimate because people have survived after ingesting much larger amounts of nicotine.

The commenters also state that in 1980, when EPA listed nicotine and salts as acute hazardous wastes, the nicotine products in the market contained a high concentration of the chemical (e.g., pesticides which contained 40 percent nicotine sulfate), but that these products are no longer on the market. The commenters stressed that the current nicotine products on the market are low-concentration nicotine products that do not meet the regulatory criteria for acutely hazardous wastes. The low-concentration nicotine-containing products that are currently on the market were identified by commenters as nicotine replacement therapy products (e.g., gums, lozenges, patches, inhalers, and nasal sprays) and e-cigarettes. These products, according to the commenters, generally contain less than 3 percent nicotine.

¹⁶⁰ See comments by the retail associations in response to EPA's Retail NODA in the docket for the Retail NODA (EPA-HQ-RCRA-2012-0426-0019).

While it may be reasonable for the commenters to conclude that toxicity is higher at higher concentrations of a chemical and lower at lower concentrations of a chemical, EPA currently lacks sufficient information to conclude that low-concentration nicotine-containing products are not acutely toxic as defined under 40 CFR 261.11(a)(2). In addition, except for warfarin and zinc phosphide, the listings for commercial chemical products under 40 CFR 261.33(e) are not concentration-based listings. The warfarin and zinc phosphide listings were changed to concentration-based listings because companies using products containing lower concentration formulations of warfarin and zinc phosphide petitioned EPA to amend the listings and provided LD50 data for animals for the lower concentration products to support their petition (see 49 FR 19922; May 10, 1984). The Agency does not think that linear extrapolations from toxicity levels determined using higher-concentration nicotine products can be used to characterize the acute toxicity of low-concentration nicotine-containing products. Furthermore, although nicotine pesticides are no longer available, high concentration nicotine products still exist. For example, manufacturers of nicotine-containing products, such as e-cigarettes, buy concentrated nicotine solutions and dilute them for consumer use.

In summary, nicotine and salts are P075 listed acute hazardous wastes if the waste arises from the discard of an unused commercial chemical product, manufacturing chemical intermediate, or off-specification material. Additionally, the P075 waste code applies only if the nicotine is present in pure or technical grade form, or is the sole active ingredient in the chemical formulation when discarded. As such, unused (unsold, expired, or returned) nicotine-containing products, including patches, gums, lozenges,¹⁶¹ inhalers, nasal sprays and e-cigarettes,¹⁶² are classified as P075 listed acute hazardous wastes when discarded. When discarded, these unsold products are causing many retailers to notify and operate as LQGs, which has resulted in increased economic burdens and reporting requirements for retailers. EPA

¹⁶¹ See memo from Dellinger to Smith, dated August 23, 2010, RCRA Online # 14817 regarding unused patches, gums and lozenges [http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44E8C852577ED00624E8F/\\$file/14817.pdf](http://yosemite.epa.gov/osw/rcra.nsf/0c994248c239947e85256d090071175f/209444BADD44E8C852577ED00624E8F/$file/14817.pdf).

¹⁶² See memo from Johnson to DeWitt, May 8, 2015, regarding e-cigarettes, RCRA Online # 17850.

is aware that this is an issue of great concern to the retail associations and their members and would like to address the issue, if possible, by amending the P075 listing to conditionally exempt certain low-concentration nicotine-containing products. The Agency is considering two possible approaches, described below, for amending the P075 listing.

D. Two Possible Approaches for Amending the P075 Listing

1. Exemption from P075 Listing for FDA-Approved Over-the-Counter Nicotine-Containing Smoking Cessation Products

The over-the-counter (OTC) nicotine-containing smoking cessation products, referred to also as nicotine replacement therapy (NRT) products (i.e., nicotine patches, gums, and lozenges) are approved by the Food and Drug Administration (FDA), which ensures that the risk to the public using these products have been evaluated. EPA is currently trying to obtain the risk evaluation data for these products from FDA, which may provide data on the exact concentration of nicotine in the NRT products and any animal and/or human toxicity data associated with use of these products. The Agency is also trying to gather any publicly available animal and/or human toxicity data for these products, in particular toxicity data that could be compared to EPA's acute toxicity criteria under § 261.11(a)(2). If the Agency is successful in obtaining the toxicity data to support the conclusion that FDA-approved over-the-counter nicotine-containing smoking cessation products do not meet the criteria for listing as an acutely hazardous waste, then the Agency will propose to exempt these products from the P075 listing.

Since e-cigarettes have not been approved by the FDA as smoking cessation products, we do not anticipate being able to obtain animal or human toxicity data from the FDA on nicotine concentrations in e-cigarettes. To complicate matters, the concentration of nicotine in e-cigarettes is not limited by any regulation or approval process and is therefore unpredictable. As a result, this option would likely be limited to excluding FDA-approved over-the-counter nicotine-containing smoking cessation products from the P075 listing and would not include e-cigarettes.

2. Concentration-Based Exemption From P075 Listing for Low-Concentration Nicotine-Containing Products

The comments from the retail associations have stressed that the low

concentration nicotine products currently in the market (generally containing less than 3 percent nicotine) should not be classified as acutely hazardous wastes under RCRA. However, they did not submit any human toxicological data or animal LD50 data for these products to demonstrate that these products are not acutely toxic as defined under § 261.11(a)(2). Without these data, it is difficult for the Agency to justify exempting these products from the P075 listing. Furthermore, in order for the Agency to consider a concentration-based exemption for low-concentration nicotine-containing products from the P075 listing, the Agency needs human toxicological data and animal LD50 data for nicotine-containing products at maximum concentrations of nicotine in these products (e.g., 3 percent nicotine). If the toxicological data for nicotine-containing products at maximum concentrations of nicotine in these products show that these products are not acutely toxic as defined under § 261.11(a)(2), then the Agency could propose a concentration-based exemption for these products (including e-cigarettes) from the P075 listing. However, depending on the toxicity data, the Agency may also propose to list the P075 exempt nicotine-containing products as non-acute hazardous wastes (U-listed wastes) under 40 CFR 261.33(f). In that case, the concentration-based exemption for nicotine-containing products from the P075 listing would be similar to what the Agency proposed for warfarin and zinc phosphide listings (see 48 FR 7714; February 23, 1983).

E. Request for Comments

EPA invites comments on all possible approaches to amend the acute hazardous waste listing for nicotine and salts, including the two approaches discussed above in Section VIII.D. We also request toxicity information for low-concentration nicotine-containing products that could help determine whether or not these products meet the criteria for acute hazardous wastes under § 261.11(a)(2). The Agency emphasizes that no regulatory language is currently being proposed with respect to amending the P075 listing to exempt the low-concentration nicotine-containing products. However, depending on the information received during the comment period, EPA could finalize one of the approaches discussed previously without a separate proposed rulemaking in the future.

In addition, we request comments on whether we should exempt other low-concentration nicotine-containing

smoking cessation products, such as inhalers and nasal sprays, from the P075 listing under approach 1, described in the Section VIII.D, above. These products are also FDA-approved, but require a prescription to purchase. The nicotine-containing patches, gums, and lozenges are sold over-the-counter, so they do not require a prescription for purchase. We are interested in finding out what the differences are between nicotine-containing smoking cessation products requiring a prescription and those products that do not require a prescription (e.g., in concentrations of nicotine, amount of nicotine delivered over time, health effects).

Finally, we request comment on whether we should include e-cigarettes and nicotine-containing e-liquids for the e-cigarettes within the scope of the definition of pharmaceutical. As described in this proposal, pharmaceutical hazardous wastes do not count toward generator category. Therefore, since e-cigarettes and nicotine-containing e-cigarette refill liquids (sometimes referred to as e-liquids or e-juice) are P075, if they are considered pharmaceuticals, they would not impact the hazardous waste generator category of the retailers. The retailers, however, would have to manage e-cigarettes and nicotine-containing liquids as hazardous waste pharmaceuticals under part 266, subpart P. We will use the comments we receive to help us decide whether and how to proceed with amending the scope of the definition of pharmaceutical to include e-cigarettes and nicotine-containing e-liquids.

IX. State Authorization

A. Applicability of Rules in Authorized States

Under Section 3006 of RCRA, EPA may authorize a qualified State to administer its own hazardous waste program within the State in lieu of the Federal program. Following authorization, EPA retains enforcement authority under Sections 3008, 3013, and 7003 of RCRA, although authorized States have primary enforcement responsibility. The standards and requirements for State authorization are found at 40 CFR part 271.

Prior to enactment of the Hazardous and Solid Waste Amendments of 1984 (HSWA), a State with final RCRA authorization administered its hazardous waste program entirely in lieu of EPA administering the Federal program in that State. The federal requirements no longer applied in the authorized State, and EPA could not issue permits for any facilities in that

State, since only the State was authorized to issue RCRA permits. When new, more stringent federal requirements were promulgated, the State was obligated to enact equivalent authorities within specified time frames. However, the new federal requirements did not take effect in an authorized State until the State adopted the federal requirement as State law.

In contrast, under RCRA Section 3006(g) (42 U.S.C. 6926(g)), which was added by HSWA, new requirements and prohibitions imposed under HSWA authority take effect in authorized States at the same time that they take effect in unauthorized States. The statute directs EPA to implement these requirements and prohibitions in authorized States, including the issuance of permits, until the State is granted authorization to do so. While the State must still adopt HSWA related provisions as State law in order to retain final authorization, EPA implements the HSWA provisions in authorized States until the States do so.

Authorized States are required to modify their program only when EPA enacts federal requirements that are more stringent or broader in scope than the existing federal requirements. RCRA Section 3009 allows the States to impose standards more stringent than those in the federal program (see also § 271.1).¹⁶³ Therefore, authorized States may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.

B. Effect on State Authorization

This action proposes to add a new subpart P to 40 CFR part 266, and it is being proposed in part under the authority of HSWA and in part under non-HSWA authority. The bulk of 40 CFR part 266, subpart P is being proposed under non-HSWA authority. Thus, when finalized, the amendments promulgated under non-HSWA authority would be applicable on the effective date only in those states that do not have final authorization of their base RCRA programs. However, the prohibition of sewerage pharmaceutical hazardous wastes (§ 266.504) is being proposed under HSWA authority in section 3018 of RCRA. Thus, when finalized, the amendments promulgated under the authority of HSWA would be applicable on the effective date of the final rule in all states. Moreover, authorized states are required to modify

¹⁶³ EPA notes that decisions regarding whether a state rule is more stringent or broader in scope than the federal program are made when the Agency authorizes state programs.

their programs only when EPA promulgates federal regulations that are more stringent or broader in scope than the authorized state regulations. This proposed rule is considered, on the whole, to be more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt the amendments, when finalized. When a state adopts this new subpart, if elements of the state program are more stringent than this new subpart, the state has the option of retaining those more stringent elements. Likewise, when a state adopts this new subpart, the state has the option of adding elements that are more stringent or broader in scope than this new subpart.

C. Effect on State Authorization in States That Have Added Pharmaceuticals to the Universal Waste Program

The Universal Waste program allows states to add wastestreams to their own state program, even when the waste stream has not been added to the federal Universal Waste program, provided the state has adopted and been authorized for the petition process in §§ 260.20 and 260.23. Two states have added hazardous waste pharmaceuticals to their Universal Waste programs: Florida and Michigan. Because this proposed rule is considered more stringent than either the “traditional RCRA” standards or the Universal Waste program, both Florida and Michigan will be required to modify their programs to adopt an approach at least as stringent as the

amendments, if this rule is finalized. Furthermore, because the Agency has determined that it is not appropriate to add hazardous waste pharmaceuticals to the Universal Waste program, both Florida and Michigan must remove hazardous waste pharmaceuticals from their Universal Waste program when they adopt this new subpart, although they may continue to regulate non-hazardous waste pharmaceuticals under the Universal Waste program, to the extent allowed under state law. In addition, states may not add hazardous waste pharmaceuticals to their Universal Waste program in the future.

X. Adding and Reserving Part 266, Subpart O

In addition to proposing new standards for the management of hazardous waste pharmaceuticals at healthcare facilities and pharmaceutical reverse distributors, EPA is proposing to add and reserve 40 CFR part 266, subpart O. Specifically, on May 22, 2001, EPA finalized a Project XL rule in 40 CFR part 266, subpart O (66 FR 28066) for US Filter Recovery Services. However, on July 2, 2008, EPA published a rule that withdrew 40 CFR part 266, subpart O (73 FR 37858). Generally, in order to avoid the potential for confusion that might be caused by reusing a subpart, EPA reserves a subpart that has already been used and removed. In 2008, when we removed 40 CFR part 266, subpart O, we neglected to reserve it. Consequently, we are proposing to add and reserve 40 CFR part 266, subpart O.

XI. Summary of Regulatory Impact Analysis

In order to meet the Office of Management and Budget (OMB) Circular A-4 requirement that EPA analyze the costs and benefits of regulations, we conducted an economic analysis of the proposed rule. The economic analysis follows OMB guidelines and estimates the costs and benefits of the rule. The economic analysis is titled “Regulatory Impact Analysis for EPA’s Proposed Healthcare Facility-Specific Regulations for the Management of Hazardous Waste Pharmaceuticals” and is hereafter referred to as the Regulatory Impact Analysis (RIA). The RIA is summarized here while the full RIA can be found at regulations.gov under docket number EPA-HQ-RCRA-2007-0932.

This proposed rule may affect several different types of healthcare facilities, including hospitals, physicians’ offices, dentists’ offices, outpatient care centers, pharmacies, veterinary clinics, nursing care facilities, coroners’ offices, other health practitioners, other ambulatory care services, and pharmaceutical reverse distributors. Based on data from the 2007 Economic Census and a limited number of states, the RIA estimates that the rule will affect approximately 174,000 facilities. Table 12 lists the number of facilities (by NAICS code) expected to be affected by the proposed rule. The vast majority of these (83.6%) are CESQGs, followed by SQGs (13.4%), and LQGs (3.0%).

TABLE 12: PROPOSED PHARMACEUTICALS RULE FACILITIES CLASSIFIED BY NAICS CODES AND TYPE OF FACILITY		
NAICS	FACILITY TYPE	NUMBER OF FACILITIES
HEALTHCARE FACILITIES AS DEFINED BY THIS PROPOSED RULE		
44611	Pharmacies	11,617
54194	Veterinary Clinics	7,847
6211	Physicians' Offices	60,823
6212	Dentists' Offices	35,106
6213	Other Health Practitioners (e.g., chiropractors)	34,555
6214	Outpatient Care Centers	8,227
6219	Other Ambulatory Health Care Services	2,586
622	Hospitals	6,505
6231	Nursing Care Facilities	4,508
623311	Continuing Care Retirement Communities	1,641
Subset of 92219	Medical Examiners and Coroners' Offices	552
Reverse Distributors		
Various NAICS	Reverse Distributors	56
TOTAL		174,023

We estimate that there is a total of approximately 139,000 tons of RCRA hazardous waste generated by healthcare facilities annually. Approximately 36,200 tons (26%) of this total are hazardous waste pharmaceuticals.

A. Costs of the Proposed Rule

The estimated costs of the proposed rule are the incremental costs over and above the "baseline" (*i.e.*, assumptions about the way in which healthcare facilities currently dispose of their hazardous waste pharmaceuticals). The base case set of baseline assumptions reflects "full compliance" with the current RCRA hazardous waste requirements for the management of hazardous waste pharmaceuticals. A sensitivity analysis of baseline assumptions was also conducted that reflects only "partial compliance" with current regulations. To see the results for the partial compliance baseline sensitivity analysis, please see the RIA.

The estimated cost of the proposed rule, including the proposed prohibition on sewerage of hazardous waste pharmaceuticals is estimated at \$37 million annually under the full compliance baseline. However, there are also significant cost savings under the proposed rule: \$24.3 million annually under the full compliance baseline.

Therefore the net cost of the rule is \$13 million annually (\$37million cost minus \$24.3 million cost savings = \$13 million net costs). Please see the RIA for more detailed analysis and results regarding the cost of the rule and the regulatory options analyzed.

B. Benefits of the Proposed Rule

The proposed rule for the management of hazardous waste pharmaceuticals is expected to yield a range of environmental benefits as hospitals, medical clinics, and other healthcare facilities divert hazardous waste pharmaceuticals currently disposed in sewers, municipal solid waste landfills (MSWLFs), municipal waste combustors (MWCs), and medical waste autoclaves and incinerators, to hazardous waste incinerators. The rule reduces the amount of hazardous waste pharmaceuticals sewerage into waterways, provides regulatory clarity for industry and provides healthcare facilities and pharmaceutical reverse distributors with cost savings.

The largest quantified benefit is from avoided sewerage of hazardous waste pharmaceuticals. Disposal of hazardous waste pharmaceuticals through sewerage is believed to be a widespread practice of disposal. Sewerage is believed to be one of the most deleterious disposal methods because

active pharmaceutical ingredients (APIs) entering surface waters, often untreated by municipal wastewater treatment plants, pose the potential for adverse human health and environmental effects since they may be absorbed by humans and other organisms. Under the proposed rule, the Agency anticipates preventing approximately 6,400 tons of hazardous waste pharmaceuticals annually into waterways via a sewerage ban. While the Agency was not able to quantify the human health and environmental benefits of reducing or eliminating the sewerage of hazardous waste pharmaceuticals, EPA did estimate the cost savings of eliminating the wastewater treatment costs associated with sewerage such pharmaceuticals. The estimated cost savings of eliminated wastewater treatment related to the prevented sewerage of hazardous waste pharmaceuticals is estimated to be \$4.3 million annually.

The proposed rule will yield other benefits beyond the reduction in sewerage of hazardous waste pharmaceuticals. For example, under the proposed rule, healthcare facilities will no longer be required to count hazardous waste pharmaceuticals toward their RCRA generator category. This, in turn, will lead to changes in a healthcare facility's generator category,

enabling them to realize an additional cost savings. The extent to which such changes in generator category will occur under the proposed rule is uncertain, but these changes would be most likely for those healthcare facilities for which hazardous waste pharmaceuticals make up a large portion of their overall hazardous waste generation. Please see the RIA for a breakout of cost savings by regulatory requirement.

XII. Statutory and Executive Order Reviews

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

Under Executive Order 12866 (58 FR 51735; October 4, 1993), this action is a “significant regulatory action” because it is likely to raise novel legal or policy issues under section 3(f)(4). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Orders 12866 and 13563 (76 FR 3821; January 21, 2011) and any changes made in response to OMB recommendations have been documented in the docket for this action (EPA–HQ–RCRA–2007–0932).

Findings for the RIA indicate that the rule, as proposed, is projected to result in an aggregate annual cost of approximately \$37 million based on a discount rate of 7%. However, the proposed rule will also achieve an annual cost savings, which is estimated to be \$24.3 million. Therefore, the net cost of the rule is estimated at \$13 million annually. The costs, which represents annualized incremental costs relative to the full compliance baseline, is below the \$100 million threshold established under part 3(f)(1) of the Order.

In addition to calling for an assessment of regulatory costs, Executive Order 12866 also requires Federal agencies to assess benefits and, “recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.” As discussed previously, the cost savings for the rule are estimated to be \$24.3 million annually. These cost savings are considered benefits of the rule. Also, EPA estimates that the proposed rule will lead to the diversion of approximately 6,440 tons annually of hazardous waste pharmaceuticals from sewer disposal to alternate forms of disposal. This reduction in sewerage will likely reduce the concentration of

active pharmaceutical ingredients in the nation’s waterways, potentially benefiting both ecosystems and human populations. Please see the RIA for more details on the benefits of the proposed rule.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that the EPA prepared has been assigned EPA ICR number 2486.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

EPA is proposing in this rule, under a new subpart P to 40 CFR part 266, new and revised reporting and recordkeeping requirements for healthcare facilities and pharmaceutical reverse distributors managing hazardous waste pharmaceuticals. These proposed requirements, which are also identified in the ICR supporting this action, will enable EPA and state regulatory agencies to identify the universe of healthcare facilities managing hazardous waste pharmaceuticals. The healthcare facilities must keep records of any test results, waste analyses or other determinations made on hazardous waste pharmaceuticals for three years from the date of analyses. In addition, the proposed requirements include provisions for improved tracking of hazardous waste pharmaceuticals that are routed through pharmaceutical reverse distributors.

EPA will use the collected information to ensure that hazardous waste pharmaceuticals are being managed in a protective manner. The tracking requirements ensure that these wastes arrive at their intended destinations rather than diverted for illicit purposes or managed at facilities not equipped to manage these wastes. These tracking requirements will also help facilities identify shipments that do not arrive at their destination as planned, allowing generators to take corrective action that will ensure that future shipments are transported to the appropriate location. In addition, during a facility inspection, information kept in facility records will help EPA and state environmental regulatory agencies determine whether or not regulatory requirements are being followed. Information marked on containers of hazardous waste pharmaceuticals will assist handlers and transporters in ensuring proper management during storage and shipment.

EPA has carefully considered the burden imposed upon the regulated

community by the proposed regulations. EPA is confident that those activities required of respondents are necessary and, to the extent possible, has attempted to minimize the burden imposed. EPA believes strongly that if the minimum requirements specified under the proposed regulations are not met, neither the facilities nor EPA can ensure that hazardous waste pharmaceuticals are managed in a manner protective of human health and the environment.

EPA estimates that the total annual respondent burden for the new paperwork requirements in the proposed rule is approximately 54,857 hours, and the annual respondent cost for the new paperwork requirements in the rule is approximately \$3,457,478. The estimated annual hourly burden ranges from 0.1 to 3.5 hours per response for the 28,637 respondents. However, in addition to estimating the annual respondent burden associated with new paperwork requirements in the proposed rule, the Agency also estimated the annual benefits (hours and cost savings) to respondents from the new paperwork requirements in comparison to complying with the existing RCRA hazardous waste information collection requirements for hazardous waste pharmaceuticals (e.g., preparation of biennial reports, recordkeeping, etc.). Taking both the new proposed and existing RCRA requirements into account, EPA expects the proposed rule would result in a net annual paperwork burden to the 28,637 respondents of approximately 28,660 hours or \$2,301,873. The net cost to EPA of administering the rule is expected to be negligible, since the Agency is not required to review and approve any information submitted by respondents. Burden is defined at 5 CFR 1320.3(b).

Respondents/affected entities: Private entities.

Respondent’s obligation to respond: Mandatory per 40 CFR part 266, subpart P.

Estimated number of respondents: 28,637.

Frequency of response: Once.

Total estimated burden: 54,857 hours.

Total estimated cost: \$3,457,478, includes \$1,038,856 annualized capital or operation & maintenance costs.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA’s regulations in 40 CFR are listed in 40 CFR part 9. Submit your comments on the Agency’s need for this information, the accuracy of the

provided burden estimates and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to oria_submissions@omb.eop.gov, Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than October

26, 2015. The EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Small Business Analysis

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. The small entities subject to the requirements of this action are indicated in Table 13. The Agency has determined that costs of the

regulation for a facility are less than 1 percent of annual revenue.

To assess the number of small entities in the regulated universe, EPA consulted NAICS-level data from the 2007 Economic Census and tallied the number of facilities, by NAICS code, owned by entities with revenues below SBA's threshold for consideration as small. Entities in revenue categories above the SBA threshold are *not* considered small. See Table 12 for the SBA thresholds and revenues.

TABLE 13: SBA 2014 SMALL BUSINESS SIZE STANDARDS (USING 2007 NAICS CODES)			
FACILITY TYPE	SBA SIZE STANDARD (FIRM-LEVEL, ANNUAL REVENUE)	PERCENTAGE OF GENERATORS CONSIDERED "SMALL" UNDER SBA STANDARD	NUMBER OF GENERATORS THAT ARE SMALL
Pharmacies	\$27.5 million	46%	5,390
Veterinary Clinics	\$7.5 million	95%	7,416
Physicians' Offices	\$11.0 million	88%	53,577
Dentists' Offices	\$7.5 million	97%	33,932
Other Health Practitioners (e.g., chiropractors)	\$7.5 million	93%	32,036
Outpatient Care Centers (ex-kidney dialysis centers)	\$15.0 million	68%	4,787
Outpatient Care Centers (kidney dialysis centers)	\$38.5 million	14%	161
Other Ambulatory Health Care Services	\$15.0 million	66%	1,707
Hospitals	\$38.5 million	25%	1,634
Nursing Care Facilities (e.g., assisted living facilities, nursing homes, U.S. veterans domiciliary centers)	\$15.0 million	44%	1,985
Continuing Care Retirement Communities	\$27.5 million	62%	1,023
Medical Examiners and Coroners' Offices	Size standards not established	100%	552
Reverse Distributors	Various NAICS	50%	28
Total Number of Small Facilities			144,228
<u>Source:</u> U.S. Small Business Administration, Table of Small Business Size Standards Matched to North American Industry Classification System Codes, effective July 14, 2014.			

The percentage of facilities that qualify as small under SBA's thresholds were estimated for each industry affected by the proposed rule. These

percentages were applied to the number of facilities in the regulatory universe, as presented in the RIA. After estimating the number of small entities by NAICS

code, the average cost per small entity was estimated based on the model facility costs presented in the RIA. Next, the EPA determined whether the per

facility costs incurred by small entities represent more than 1% of annual revenues, which required estimating small entities' average annual revenues. For each NAICS code, the average per facility revenue of entities considered small under the SBA standard was estimated based on data from the 2007 Economic Census.

The proposed rule is expected to impact a total of 144,228 small entities (1,634 hospitals, 142,566 other healthcare facilities (*i.e.*, healthcare facilities that are not hospitals) and 28 pharmaceutical reverse distributors). The highest cost impact to small entities is estimated to be 0.013% of revenues at other healthcare facilities and 0.002% of revenues at hospitals. Because pharmaceutical reverse distributors are in various NAICS codes, the Agency was not able to obtain revenue data for pharmaceutical reverse distributors. However the estimated cost impact to small entity pharmaceutical reverse distributors is estimated at \$5,300 annually, which the Agency does not anticipate will cause significant hardship on pharmaceutical reverse distributors that are small entities. However, the Agency requests comment on the cost impacts on small entity pharmaceutical reverse distributors that process creditable hazardous waste pharmaceuticals.

In the RIA, small entity impacts are presented incremental to the full compliance baseline. The annual per facility costs incremental to both baselines are estimated to be much less than 1% of average annual revenues. Since the incremental impact to the smallest healthcare facilities in terms of revenue is less than 1% of average annual revenues, the proposed rule is not expected to cause a significant impact to a substantial number of small businesses. Please see the RIA for a detailed analysis of cost impacts on small entities.

Although this proposed rule will not have a significant economic impact on

a substantial number of small entities, EPA nonetheless has tried to reduce the impact of this rule on small entities. We continue to be interested in the potential impacts of the proposed rule on small entities and welcome comments on issues related to such impacts.

D. Unfunded Mandates Reform Act (UMRA)

This rule does not contain an unfunded mandate of \$100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. As indicated previously, the annual net cost is estimated to be \$13 million annually after cost savings (\$37 million cost minus \$24.3 million in cost savings). Thus, this proposed rule is not subject to the requirements of sections 202 or 205 of UMRA.

This proposed rule is also not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. While some hospitals and coroners' offices are publicly owned, the requirements affecting those facilities are not unique in that they are the same as those affecting all facilities in the proposed rule. Also, using data on revenues of hospitals owned by state and local governments, EPA estimated that the costs of the rule borne by state and local governments represent less than 0.001% of their revenues. Therefore, the costs incurred by small governments are not expected to be significant.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the relationship between the national government and the states, or on the distribution of power and

responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action may have tribal implications. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law.

To assess the potential tribal implications of the proposed rule, EPA compiled data on the number of tribally run healthcare facilities in the U.S. and estimated the costs of the proposed rule for these facilities. Estimates of tribally run healthcare facilities were obtained from the U.S. Department of Health and Human Services' Indian Health Service (IHS), as summarized in Table 14.¹⁶⁴ Data were not readily available on the size or hazardous waste generation amounts for the tribally run healthcare facilities identified by the IHS. To estimate the potential costs of each regulatory option, per facility costs derived in the RIA were applied to the IHS facility counts. Based on these values, Table 14 summarizes the costs that tribally run healthcare facilities are expected to incur under the proposed rule. OMB has not issued guidance on what constitutes a substantial burden on tribal governments under this executive order. The relatively low costs estimated for tribally run healthcare facilities in Table 14, however, suggest that the proposed rule will not impose a substantial burden on tribal governments. EPA welcomes comments on the proposed rule's impact on tribal governments. EPA specifically solicits additional comment on this proposed action from tribal officials.

¹⁶⁴ Indian Health Service (IHS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at <http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp>, accessed December 20, 2012.

TABLE 14: COST IMPACTS FOR HEALTHCARE FACILITIES OWNED AND OPERATED BY NATIVE AMERICAN TRIBES USING A 7 PERCENT DISCOUNT RATE (MILLIONS OF YEAR 2011\$)

FACILITY TYPE	NUMBER OF FACILITIES ¹	PROPOSED RULE
Total Annual Costs Incremental to Full Compliance Baseline		
Hospitals	16	\$0.019
Tribal Operated Facilities	16	\$0.088
Health Centers	258	
Alaska Village Clinics	164	
Health Stations	75	
TOTAL	529	\$0.107

Notes:

1. Indian Health Service (IHS), U.S. Department of Health and Human Services, IHS Year 2013 Profile, available at <http://www.ihs.gov/PublicAffairs/IHSBrochure/Profile.asp>, accessed December 20, 2012.
2. Estimate reflects annual cost impact for tribal operated facilities, health centers, Alaska village clinics, and health stations combined.

The EPA consulted with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation is provided in the docket for this proposed rule (see EPA-HQ-RCRA-2007-0932).

As required by section 7(a), the EPA's Tribal Consultation Official has certified that the requirements of the executive order have been met in a meaningful and timely manner. A copy of the certification is included in the docket for this proposed rule (see EPA-HQ-RCRA-2007-0932).

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 because it is not economically significant as defined in Executive Order 12866, and because the Agency does not believe the environmental health or safety risks

addressed by this action present a disproportionate risk to children.

To examine whether the proposed rule has a disproportionate impact on children, the RIA uses a geographic analysis of demographics near wastewater treatment plants and hazardous waste combustion facilities. Table 15 summarizes the results of this analysis. As indicated in the table, this analysis finds that children (*i.e.*, individuals under the age of 18) account for a slightly larger share of the population (28.5%) in the one-mile radius around wastewater treatment plants than they account for nationally (25.3%). Among the catchment zones of wastewater treatment plants, however, children make up a much smaller portion of the population (9.8%). Within both the one- and three-mile buffers around hazardous waste combustion facilities, children's share of the population slightly exceeds their share nationally.

These data suggest that the proposed rule will not result in a disproportionate adverse impact on children. Because the

children's share of the population near hazardous waste combustion facilities is near the national average, any increase in the combustion of hazardous waste combustion that occurs as a result of the proposed rule is unlikely to have a significant disproportionate impact on children's health. The data in Table 15 also show that the number of children living in close proximity to wastewater treatment plants, in areas likely to benefit from the rule, far exceeds the number of children who live near hazardous waste combustion facilities. This suggests that the diversion of hazardous waste pharmaceuticals from wastewater treatment plants to combustion facilities will benefit a much greater number of children than it may put at greater risk of adverse health effects. See Table 15 for the demographics of children surrounding wastewater treatment plants and hazardous waste combustion facilities. Please see the RIA for a detailed methodology of the children's health analysis.

TABLE 15: SUMMARY OF CHILDREN'S HEALTH ASSESSMENT		
GEOGRAPHIC AREA	NUMBER OF CHILDREN IN AREA	NATIONAL % OF POPULATION UNDER THE AGE OF 18
Wastewater treatment plants, one-mile radius	7.8 million (28.5%) ¹	25.3%
Wastewater treatment plants, catchment areas	4.4 million (9.8%) ¹	
Hazardous waste combustion facilities, one-mile radius	5,012 (26.1%) ¹	
Hazardous waste combustion facilities, three-mile radius	64,710 (25.6%) ¹	
GEOGRAPHIC AREA	NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS NATIONAL AVG. %	
Wastewater treatment plants, one-mile radius	8,908	
Wastewater treatment plants, catchment areas	5,171	
Hazardous waste combustion facilities, one-mile radius	13	
Hazardous waste combustion facilities, three-mile radius	11	
GEOGRAPHIC AREA	NUMBER OF FACILITIES WHERE CHILDREN'S SHARE OF THE LOCAL POPULATION EXCEEDS STATE AVG. %	
Wastewater treatment plants, one-mile radius	8,992	
Wastewater treatment plants, catchment areas	5,149	
Hazardous waste combustion facilities, one-mile radius	14	
Hazardous waste combustion facilities, three-mile radius	11	
Notes:		
1. Values in parentheses represent children's proportion of the population.		
Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.		

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use

This action is not a "significant energy action" as defined in Executive Order 13211, (66 FR 28355 (May 22, 2001)), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

The proposed rule does not directly regulate energy production or consumption. Changes in the management of hazardous waste pharmaceuticals stipulated in the proposed rule are not expected to

impact energy production or distribution. Similarly, the management requirements outlined in the proposed rule will have minimal impact on energy consumption (e.g., from transporting hazardous waste pharmaceuticals that otherwise would have been sewerred). Because the changes in energy production and consumption under the proposed rule are likely to be minimal, the proposed rule is not expected to have a significant adverse effect on energy supply, distribution, or use. In addition, no measurable adverse impacts are

expected on energy prices or foreign supplies.

I. National Technology Transfer and Advancement Act (NTTAA)

This proposed rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes the human health or environmental risk addressed by this action will not have potential disproportionately high and adverse human health or environmental effects

on minority, low-income or indigenous populations. The results of this evaluation are summarized in the following paragraphs. The evaluation is contained in the Regulatory Impact Analysis (RIA), which can be found at regulations.gov under docket number EPA-HQ-RCRA-2007-0932.

To meet the requirements of Executive Order 12898, EPA analyzed potential environmental justice impacts associated with the diversion of hazardous waste pharmaceuticals from sewer disposal to hazardous waste combustion facilities. Populations living near and downstream from wastewater treatment plants may also benefit from the elimination of sewerage of

hazardous waste pharmaceuticals. To the extent that minority and/or low-income populations near or downstream from wastewater treatment plants make up a disproportionately high portion of the overall population, the proposed rule may result in positive environmental justice impacts. See Table 16 for the results of the Environmental Justice analysis.

Overall, EPA expects that the proposed rule may positively affect U.S. environmental justice populations, although the size of the impact will vary by wastewater treatment plant. As suggested by Table 16, the reduction in sewerage expected under the proposed rule may benefit relatively large

minority and low-income populations in close proximity to or downstream from wastewater treatment plants. The diversion of hazardous waste pharmaceuticals to combustion facilities, however, may increase the environmental burden borne by environmental justice populations near these combustion facilities. Although these effects offset each other to a certain degree, the number of minority and low-income individuals near wastewater treatment facilities greatly exceeds the number near hazardous waste combustion facilities. This suggests that, on the whole, the proposed rule may benefit environmental justice populations.

TABLE 16: DEMOGRAPHICS FOR POPULATIONS NEAR WASTEWATER TREATMENT FACILITIES & COMMERCIAL HAZARDOUS WASTE COMBUSTION FACILITIES				
GEOGRAPHIC AREA	MINORITY POPULATION	LOW-INCOME POPULATION	% OF NATIONAL POPULATION	
			RACIAL & ETHNIC MINORITIES	LOW-INCOME POPULATION
Wastewater treatment plants, one-mile radius	6.2 million (22.6%) ¹	3.8 million (14.0%) ¹	24.7%	11.4%
Wastewater treatment plants, catchment areas	3.8 million (8.6%) ¹	2.2 million (4.9%) ¹		
Hazardous waste combustion facilities, one-mile radius	3,578 (18.7%) ¹	3,130 (16.3%) ¹		
Hazardous waste combustion facilities, three-mile radius	67,329 (26.6%) ¹	42,782 (16.9%) ¹		
	NO. OF FACILITIES EXCEEDING:			
GEOGRAPHIC AREA	NATIONAL AVG. MINORITY %.		NATIONAL AVG. LOW-INCOME %.	
Wastewater treatment plants, one-mile radius	3,233		7,886	
Wastewater treatment plants catchment areas	3,151		7,358	
Hazardous waste combustion facilities, one-mile radius	6		4	
Hazardous waste combustion facilities, three-mile radius	7		4	
	NO. OF FACILITIES EXCEEDING:			
GEOGRAPHIC AREA	STATE AVG. MINORITY %.		STATE AVG. LOW-INCOME %.	
Wastewater treatment plants, one-mile radius	3,596		7,949	
Wastewater treatment plants, catchment areas	3,562		7,391	
Hazardous waste combustion facilities, one-mile radius	7		13	
Hazardous waste combustion facilities, three-mile radius	8		16	
<u>Notes:</u>				
1. Values in parentheses represent the proportion of the population considered a racial or ethnic minority or below the Federal Poverty Level.				
Sources: RTI International, U.S. Synthesized Population 2005–2009 Version 2.0, August 2012; U.S. EPA Clean Watershed Needs Database; and U.S. EPA, Assessment of the Potential Costs, Benefits, & Other Impacts of the Hazardous Waste Combustion MACT Final Rule Standards, September 2005.				

List of Subjects**40 CFR Part 261**

Environmental protection, Hazardous waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 262

Environmental protection, Exports, Hazardous materials transportation, Hazardous waste, Imports, Labeling, Packaging and containers, Reporting and recordkeeping requirements.

40 CFR Part 266

Environmental protection, Energy, Hazardous Waste, Recycling, Reporting and recordkeeping requirements.

40 CFR Part 268

Environmental protection, Hazardous waste, Reporting and recordkeeping requirements.

40 CFR Part 273

Environmental protection, Hazardous materials transportation, Hazardous waste.

Dated: August 31, 2015.

Gina McCarthy,
Administrator.

For the reasons stated in the preamble, Title 40, chapter I, of the Code of Federal Regulations is proposed to be amended as follows:

PART 261—IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

■ 1. The authority citation for part 261 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, 6922, 6924(y) and 6938.

■ 2. Amend § 261.5 by adding paragraph (c)(8) to read as follows:

§ 261.5 Special requirements for hazardous waste generated by conditionally exempt small quantity generators.

* * * * *

(c) * * *

(8) Is a hazardous waste pharmaceutical managed under 40 CFR part 266, subpart P.

* * * * *

■ 3. Amend § 261.7 by adding paragraph (c) to read as follows:

§ 261.7 Residues of hazardous waste in empty containers.

* * * * *

(c) Healthcare facilities and pharmaceutical reverse distributors operating under 40 CFR part 266, subpart P are subject to § 266.507 for the management of hazardous waste pharmaceutical residues in containers, in lieu of this section.

PART 262—STANDARDS APPLICABLE TO GENERATORS OF HAZARDOUS WASTE

■ 4. The authority citation for part 262 continues to read as follows:

Authority: 42 U.S.C 6906, 6912, 6922–6925, 6937, and 6938.

■ 5. Amend § 262.10 by adding paragraphs (m) and (n) to read as follows:

§ 262.10 Purpose, scope and applicability.

* * * * *

(m) All pharmaceutical reverse distributors (as defined in § 266.500) are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

(n) Each healthcare facility (as defined in § 266.500) must determine whether it is subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals, based on the total hazardous waste it generates per calendar month (including pharmaceutical hazardous waste and non-pharmaceutical hazardous waste). Healthcare facilities that generate (or accumulate) more than 100 kg (220 pounds) of hazardous waste per calendar month, or more than 1 kg (2.2 pounds) of acute hazardous waste per calendar month, or more than 100 kg (220 pounds) per calendar month of any residue or contaminated soil, waste, or other debris, resulting from the clean-up of a spill, into or on any land or water, of any acute hazardous wastes listed in § 261.31 or § 261.33(e), are subject to 40 CFR part 266, subpart P for the management of hazardous waste pharmaceuticals in lieu of this part.

PART 266—STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES

■ 6. The authority citation for part 266 continues to read as follows:

Authority: 42 U.S.C. 1006, 2002(a), 3001–3009, 3014, 3017, 6905, 6906, 6912, 6921, 6922, 6924–6927, 6934, and 6937.

Subpart O—[Reserved]

■ 7. Add reserved subpart O:

■ 8. Add subpart P to read as follows:

Subpart P—Hazardous Waste Pharmaceuticals

Sec.

266.500 Definitions for this subpart.

266.501 Applicability.

266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).

266.505 Prohibition of sewerage hazardous waste pharmaceuticals.

266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.

266.507 Management of hazardous waste pharmaceutical residues in containers.

266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.

266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

Subpart P—Hazardous Waste Pharmaceuticals**§ 266.500 Definitions for this subpart.**

The following definitions apply to this subpart:

Evaluated hazardous waste pharmaceutical means a hazardous waste pharmaceutical that was a potentially creditable hazardous waste pharmaceutical but has been evaluated by a pharmaceutical reverse distributor to establish whether it is eligible for manufacturer's credit and will not be sent to another pharmaceutical reverse distributor for further evaluation or verification.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is listed in part 261, subpart D, or exhibits one or more characteristics identified in part 261, subpart C.

Healthcare facility means:

(1) Any person that:

(i) Provides preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or

(ii) Sells or dispenses over-the-counter or prescription pharmaceuticals.

(2) This definition includes, but is not limited to, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, coroners and medical examiners, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of over-the-counter medications; and veterinary clinics and hospitals.

Household waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, but is exempt from being a hazardous waste under § 261.4(b)(1).

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, assisted living, hospices, nursing homes, skilled nursing facilities, and the assisted living and skilled nursing care

portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, and the independent living portions of continuing care retirement communities.

Non-creditable hazardous waste pharmaceutical means a hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit.

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261, subpart D, and does not exhibit a characteristic identified in 40 CFR part 261, subpart C.

Non-pharmaceutical hazardous waste means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261, subpart D, or exhibits one or more characteristics identified in 40 CFR part 261, subpart C, but is not a pharmaceutical, as defined in this section.

Pharmaceutical means any chemical or biological product that is intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal. This definition includes, but is not limited to: dietary supplements as defined by the Federal Food, Drug and Cosmetic Act, prescription drugs, over-the-counter drugs, residues of pharmaceuticals remaining in containers, personal protective equipment contaminated with pharmaceuticals, and clean-up material from spills of pharmaceuticals.

Pharmaceutical reverse distributor means any person that receives and accumulates potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer's credit. Any person, including forward distributors and pharmaceutical manufacturers, that processes pharmaceuticals for the facilitation or verification of manufacturer's credit is considered a pharmaceutical reverse distributor.

Potentially creditable hazardous waste pharmaceutical means:

(1) A hazardous waste pharmaceutical that has the potential to receive manufacturer's credit and is:

- (i) Unused or un-administered; and
- (ii) Unexpired or less than one year past expiration date.

(2) The term does not include "evaluated hazardous waste pharmaceuticals," residues of pharmaceuticals remaining in

containers, contaminated personal protective equipment, and clean-up material from the spills of pharmaceuticals.

§ 266.501 Applicability.

(a) A healthcare facility that is a conditionally exempt small quantity generator remains subject to § 261.5 and is *not* subject to this subpart, except for §§ 266.504, 266.505, and 266.507(a) and (b).

(b) A healthcare facility that is a conditionally exempt small quantity generator has the option of complying with this subpart for the management of its hazardous waste pharmaceuticals, as an alternative to complying with the conditional exemption of § 261.5.

(c) A healthcare facility or pharmaceutical reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in subsection (a), a healthcare facility is subject to:

(1) Sections 266.502 and 266.504 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a pharmaceutical reverse distributor.

(2) Sections 266.503 through 266.507 and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are destined for a pharmaceutical reverse distributor.

(e) A pharmaceutical reverse distributor is subject to §§ 266.505 through 266.510 of this subpart with respect to the management of hazardous waste pharmaceuticals.

(f) This subpart does not apply to the management of hazardous waste pharmaceuticals that are generated or managed by entities other than healthcare facilities and pharmaceutical reverse distributors.

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

(a) *Notification and withdrawal from this subpart for healthcare facilities managing non-creditable hazardous waste pharmaceuticals*—(1)

Notification. A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous

Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA Identification Number.

(i) A healthcare facility that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification form (EPA form 8700–12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) *Withdrawal.* A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a conditionally exempt small quantity generator under § 261.5, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA form 8700–12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 11 (Description of Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA Identification Number.

(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 261.5(b).

(ii) A healthcare facility must keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.

(b) *Training of employees managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all employees that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar

with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility that generates a solid waste that is a pharmaceutical must determine whether the solid waste pharmaceutical is a hazardous waste pharmaceutical (*i.e.*, it exhibits a characteristic identified in 40 CFR part 261, subpart C or is listed in 40 CFR part 261, subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its solid waste pharmaceuticals as hazardous waste pharmaceuticals under this subpart even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive hazardous waste pharmaceuticals, or that mixes or commingles incompatible hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

- (i) Generate extreme heat or pressure, fire or explosion, or violent reaction;
- (ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;
- (iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;
- (iv) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate hazardous waste pharmaceuticals and non-hazardous pharmaceutical waste in the same container, except that hazardous waste pharmaceuticals prohibited from being combusted because of the dilution

prohibition of § 268.3(c) must be accumulated in separate containers.

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on-site for one year or less without a permit or having interim status. A healthcare facility may accumulate for more than one year without a permit or having interim status, only if the requirements of paragraph (f)(3) of this section are met.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceutical being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste; or

(iv) Any other method which clearly demonstrates the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating from the date it first became a waste.

(3) A healthcare facility may request from the EPA Regional Administrator an extension beyond the one year accumulation time limit for non-creditable hazardous waste pharmaceuticals involved in litigation, a recall, or unforeseen circumstances beyond the control of the healthcare facility.

(i) A request must be sent to the EPA Regional Administrator in writing (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of

the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time extension granted is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The hazardous waste pharmaceuticals generated by a healthcare facility are subject to the Land Disposal Restrictions of 40 CFR part 268. A healthcare facility that generates hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (codes).

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of delivery of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; and

(4) Transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a).

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals—(1) Biennial report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception report by healthcare facilities for a missing copy of the manifest.* (i) For shipments from a

healthcare facility to a designated facility: If a healthcare facility does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(ii) For shipments rejected by the designated facility and shipped to an alternate facility: If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the handwritten signature of the owner or operator of the alternate facility within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(A) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the EPA Regional Administrator for the Region in which the healthcare facility is located, and

(B) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(3) *Additional reports.* The EPA Regional Administrator may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.* (1) A healthcare facility must keep a copy of each manifest signed in accordance with

§ 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) for at least three years from the date of the test, analysis, or other determination.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(k) *Response to releases of non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility must immediately contain all releases of non-creditable hazardous waste pharmaceuticals and other residues from non-creditable hazardous waste pharmaceuticals.

(2) A healthcare facility must determine whether any material resulting from the release is a non-creditable hazardous waste pharmaceutical, and if so, must manage the non-creditable hazardous waste pharmaceutical residues and spill clean-up materials in accordance with the requirements of this subpart.

(l) *Long-term care facilities that manage non-creditable hazardous waste pharmaceuticals.* A healthcare facility that is a long-term care facility and that has individuals that administer their own pharmaceuticals must collect any unused non-creditable hazardous waste pharmaceuticals from those self-administering individuals and manage them in accordance with this subpart.

(m) *Accepting creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a CESQG.* A healthcare facility may accept creditable and non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a conditionally exempt small quantity generator under § 261.5, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the conditionally exempt small quantity

generator healthcare facility that is sending the hazardous waste pharmaceuticals off-site or has a contractual relationship whereby the receiving healthcare facility supplies pharmaceuticals to the conditionally exempt small quantity generator healthcare facility,

(2) Is operating under this subpart for the management of its hazardous waste pharmaceuticals,

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off-site in compliance with this subpart, and

(4) Keeps records of the hazardous waste pharmaceutical shipments it receives from off-site for 3 years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for creditable hazardous waste pharmaceuticals at the healthcare facility.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable solid waste pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.*, it listed in 40 CFR part 261, subpart D or exhibits a characteristic identified in 40 CFR part 261, subpart C). A healthcare facility may choose to manage its potentially creditable solid waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under § 266.509 even if the solid waste pharmaceuticals do not exhibit a characteristic identified in 40 CFR part 261, subpart C and are not listed in 40 CFR part 261, subpart D.

(b) Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor.

(c) *Biennial Report by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(d) *Recordkeeping.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for 3 years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

§ 266.504 Healthcare facilities that are conditionally exempt small quantity generators (CESQGs).

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a conditionally exempt small quantity generator may send its potentially creditable hazardous waste pharmaceuticals to a pharmaceuticals reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a CESQG.* A healthcare facility that is a conditionally exempt small quantity generator may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility meets the conditions in § 266.502(m) of this subpart.

(c) *Long-term care facilities that are CESQGs.* A long-term care facility that is a conditionally exempt small quantity generator may dispose of its hazardous waste pharmaceuticals in a collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

§ 266.505 Prohibition of sewerage hazardous waste pharmaceuticals.

All healthcare facilities and pharmaceutical reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. The exclusion in § 261.4(a)(1)(ii) for mixtures of domestic sewage and other wastes that pass through a sewer system to a publicly-owned treatment works does not apply to a hazardous waste pharmaceutical.

§ 266.506 Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances.

(a) The following are exempt from 40 CFR parts 260 through 273, provided the conditions of paragraph (b) of this section are met:

(1) A hazardous waste pharmaceutical that is also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) An authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that collects controlled substances collected from an ultimate user (as defined by the Drug Enforcement Administration) and co-mingles them with hazardous waste pharmaceuticals that are exempt as a household waste under § 261.4(b)(1).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances, and combusted at one of the following:

(1) A permitted large municipal waste combustor (LMWC), subject to 40 CFR part 62, subpart FFF for existing LMWCs, or 40 CFR part 60, subparts Ea and Eb for new LMWCs, or

(2) A permitted small municipal waste combustor (SMWC), subject to 40 CFR part 62, subpart JJJ for existing SMWCs, or 40 CFR part 60, subparts AAAA and BBBB for new SMWCs, or

(3) A unit that has a permit or interim status to burn hazardous waste and is covered by 40 CFR part 63, subpart EEE. A unit that is exempt from 40 CFR part 63, subpart EEE as specified in § 63.1200(b) of this chapter is not covered by subpart EEE.

§ 266.507 Management of hazardous waste pharmaceutical residues in containers.

(a) *Dispensing and unit-dose containers.* A dispensing bottle, vial, or ampule (not to exceed 1 liter or 1000 pills); or a unit-dose container, (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided:

(1) All pharmaceuticals have been removed from the dispensing bottle, vial or ampule; or the unit-dose container, (e.g., unit-dose packet, cup, wrapper, blister pack, or delivery device) using the practices commonly employed to remove materials from that type of container, and

(2) Any dispensing bottle or unit-dose container that is an original manufacturer's product package is

destroyed prior to disposal in such a manner as would prevent further use of the container.

(b) *Dispensed syringes.* The residues remaining in a syringe are not regulated as hazardous waste provided:

(1) The syringe has been used to administer the pharmaceutical to a patient, and

(2) The syringe is placed in a sharps container that is managed in accordance with all applicable federal, state, and local medical waste requirements.

(c) *Other containers, including delivery devices.* The residues remaining in all other types of unused or used containers that once held pharmaceuticals must be managed as hazardous waste pharmaceuticals, if the residues are listed in 40 CFR part 261, subpart D or exhibit a characteristic identified in 40 CFR part 261, subpart C. This includes, but is not limited to, the residues in intravenous (IV) bags and tubing, inhalers, aerosols, nebulizers, tubes of ointment, gels or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a pharmaceutical reverse distributor.

(a) A healthcare facility or pharmaceutical reverse distributor that ships either non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, respectively, off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility), must comply with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart E.

(iii) *Marking.* (A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172, subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety

authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Pharmaceutical Reverse Distributor's Name and Address__.

Healthcare Facility's or Pharmaceutical Reverse Distributor's EPA Identification Number__.

Manifest Tracking Number__.

(iv) *Placarding*. Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172, subpart F.

(v) *Shipping papers*. Prepare shipping papers in accordance with 49 CFR part 172, subpart C.

(2) The manifest requirements of 40 CFR part 262, subpart B, except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list hazardous waste codes in box 13 of EPA Form 8700-22.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the words "hazardous waste pharmaceuticals" in Box 14 (the special handling instructions and additional information) of EPA Form 8700-22.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals*. A healthcare facility or pharmaceutical reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart E.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals*. Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262, subpart F. A healthcare facility or pharmaceutical reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a pharmaceutical reverse distributor to a pharmaceutical reverse distributor.

(a) A healthcare facility or a pharmaceutical reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a pharmaceutical reverse distributor must:

(1) Provide advance notice (paper or electronic) to the pharmaceutical

reverse distributor of the intent to ship potentially creditable hazardous waste pharmaceuticals to the receiving pharmaceutical reverse distributor before each shipment of potentially creditable hazardous waste pharmaceuticals is sent, and

(2) Comply with the pre-transport requirements of § 266.508(a)(1)(i) through (v).

(b) Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving pharmaceutical reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or pharmaceutical reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived.

(c) If a healthcare facility or pharmaceutical reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor and does not receive delivery confirmation within seven calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or pharmaceutical reverse distributor that initiated the shipment must contact the shipper and the intended recipient (*i.e.*, the pharmaceutical reverse distributor) promptly to report that the confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals*. (1) A healthcare facility or pharmaceutical reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the following requirements in addition to paragraphs (a) through (c) of this section:

(i) Comply with the requirements applicable to a primary exporter at 40 CFR 262.53, 262.56(a)(1) through (4), (a)(6), and (b) and 262.57;

(ii) Export such potentially creditable hazardous waste pharmaceuticals only upon consent of the receiving country and in conformance with the EPA Acknowledgement of Consent as defined in 40 CFR part 262, subpart E; and

(iii) Provide a copy of the EPA Acknowledgement of Consent for the shipment to the transporter transporting the shipment for export.

(2) A transporter of potentially creditable hazardous waste pharmaceuticals to a foreign destination other than those OECD countries specified 40 CFR 262.58(a)(1) (in which case the transporter is subject to the

requirements of 40 CFR part 262, subpart H) may not accept a shipment if the transporter knows the shipment does not conform to the EPA Acknowledgment of Consent. In addition the transporter must ensure that:

(i) A copy of the EPA Acknowledgement of Consent accompanies the shipment; and

(ii) The shipment is delivered to the facility designated by the person initiating the shipment.

(e) *Importing potentially creditable hazardous waste pharmaceuticals*. Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262, subpart F.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at pharmaceutical reverse distributors.

A pharmaceutical reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off-site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on-site without a permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals*.

(1) *Notification*. A pharmaceutical reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor operating under this subpart.

(i) A pharmaceutical reverse distributor that already has an EPA identification number must re-notify the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A pharmaceutical reverse distributor that does not have an EPA identification number must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA form 8700-12), that it is a pharmaceutical reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(2) *Inventory by the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must maintain an inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on-site.

(i) A pharmaceutical reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical upon arrival at the pharmaceutical reverse distributor.

(ii) The inventory must include the identity (*e.g.*, name or national drug code (NDC)) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(3) *Security at the pharmaceutical reverse distributor facility.* A pharmaceutical reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize unauthorized entry include, but are not limited to:

(A) 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) Means to control entry, such as keycard access.

(ii) If the pharmaceutical reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration regulations, the facility is not required to provide separate security measures pursuant to this section.

(4) *Maximum accumulation time for hazardous waste pharmaceuticals at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for 90 calendar days or less. The 90 days start when the potentially creditable hazardous waste pharmaceutical arrives at the pharmaceutical reverse distributor and applies to all hazardous waste pharmaceuticals accumulated on-site, regardless of whether they are destined for another pharmaceutical reverse distributor (*i.e.*, potentially creditable hazardous waste pharmaceuticals), or a permitted or interim status treatment, storage or disposal facility (*i.e.*, evaluated hazardous waste pharmaceuticals).

(5) *Extension of 90-day accumulation time limit at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor may request an extension of its 90-day accumulation time limit for hazardous waste pharmaceuticals from the EPA Regional Administrator due to unforeseen circumstances beyond the control of the pharmaceutical reverse distributor, or if the potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are involved in litigation or a recall.

(i) A written request must be sent to the EPA Regional Administrator (paper or electronic). The request for an extension must include an explanation of the reason an extension is requested, the approximate volume or weight of the hazardous waste pharmaceuticals that will be accumulated more than 90 days, and the amount of additional time requested.

(ii) The amount of time granted for an extension is at the discretion of the EPA Regional Administrator on a case-by-case basis.

(6) *Contingency plan and emergency procedures at a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must prepare a contingency plan and comply with the other requirements of 40 CFR part 265, subpart D.

(7) *Closure of a pharmaceutical reverse distributor.* When closing an area where a pharmaceutical reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the pharmaceutical reverse distributor must control, minimize, or eliminate to the extent necessary to protect human health and the environment, post-closure escape of hazardous waste, leachate, contaminated run-off, or hazardous waste decomposition products to the ground or surface waters or to the atmosphere.

(8) *Reporting by a pharmaceutical reverse distributor—(i) Unauthorized waste report.* A pharmaceutical reverse distributor must submit an unauthorized hazardous waste report if the pharmaceutical reverse distributor receives hazardous waste from off-site that it is not authorized to receive (*e.g.*, non-creditable hazardous waste pharmaceuticals, non-pharmaceutical hazardous waste). The pharmaceutical reverse distributor must prepare and submit an unauthorized waste report to the EPA Regional Administrator within 15 days after receiving the unauthorized hazardous waste and the

pharmaceutical reverse distributor must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized hazardous waste. The pharmaceutical reverse distributor must manage the unauthorized hazardous waste in accordance with all applicable regulations for generators of non-pharmaceutical hazardous waste. The unauthorized waste report must be signed by the owner or operator of the pharmaceutical reverse distributor, or his authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the pharmaceutical reverse distributor;

(B) The date the pharmaceutical reverse distributor received the hazardous waste;

(C) The EPA identification number, name and address of the healthcare facility that shipped the hazardous waste, if available;

(D) A description and the quantity of each unauthorized hazardous waste the pharmaceutical reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized hazardous waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The EPA Regional Administrator may require pharmaceutical reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(9) *Recordkeeping by pharmaceutical reverse distributors.* A pharmaceutical reverse distributor must keep the following records (paper or electronic):

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the advance notification, delivery confirmation, the shipping papers or bill of lading for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date it receives the shipment;

(iii) A copy of its inventory for as long as the facility is subject to this subpart; and

(iv) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

(10) A pharmaceutical reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 21 calendar days of arriving at the pharmaceutical reverse distributor to establish whether it is destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit or for a permitted or interim status treatment, storage or disposal facility. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another pharmaceutical reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceuticals that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(11) A pharmaceutical reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer's credit within 21 calendar days of arriving at the facility and must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section. This 21 calendar days is part of the 90 calendar days allowed for on-site accumulation.

(b) *Additional standards for pharmaceutical reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another pharmaceutical reverse distributor for further evaluation or verification of manufacturer's credit:

(1) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another pharmaceutical reverse distributor within 90 days from when the potentially creditable hazardous waste

pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another pharmaceutical reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a pharmaceutical reverse distributor that is a pharmaceutical manufacturer within 90 days from when the potentially creditable hazardous waste pharmaceuticals arrived or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A pharmaceutical reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another pharmaceutical reverse distributor in accordance with § 266.509.

(4) *Recordkeeping.* A pharmaceutical reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another pharmaceutical reverse distributor, for at least three years from the date of shipment:

(i) A copy of the advance notification provided to the pharmaceutical reverse distributor;

(ii) The confirmation of delivery; and

(iii) The shipping papers or bill of lading.

(c) *Additional standards for pharmaceutical reverse distributors managing evaluated hazardous waste pharmaceuticals.* A pharmaceutical reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the pharmaceutical reverse distributor.* A pharmaceutical reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Weekly inspections of on-site accumulation area.* A pharmaceutical reverse distributor must inspect its on-site accumulation area at least weekly, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a pharmaceutical reverse distributor.* Personnel at a pharmaceutical reverse distributor that handle evaluated

hazardous waste pharmaceuticals are subject to the training requirements of § 265.16.

(4) *Labeling and management of containers at on-site accumulation area.*

A pharmaceutical reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) A pharmaceutical reverse distributor that manages ignitable or reactive evaluated hazardous waste pharmaceuticals, or that mixes or commingles incompatible evaluated hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (e.g., arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the pharmaceutical reverse distributor.

(5) *Hazardous waste numbers.* Containers of evaluated hazardous waste pharmaceuticals must be marked with the applicable hazardous waste number(s) (i.e., hazardous waste code(s)) prior to transport off-site.

(6) *Shipments.* A pharmaceutical reverse distributor must ship evaluated hazardous waste pharmaceuticals that

are destined for a permitted or interim status treatment, storage or disposal facility, in accordance with § 266.508(a).

(7) *Procedures for a pharmaceutical reverse distributor for managing rejected shipments.* A pharmaceutical reverse distributor who sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned hazardous waste pharmaceuticals on-site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with paragraph (a) of this section. Upon receipt of the returned shipment, the pharmaceutical reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of delivery of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the pharmaceutical reverse distributor; and

(iv) Transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the shipping standards of § 266.508(b).

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the Land Disposal Restrictions of 40 CFR part 268. A pharmaceutical reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) *Biennial report by a pharmaceutical reverse distributor.* A pharmaceutical reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the EPA Regional Administrator by March 1 of each even numbered year in accordance with § 262.41, except § 262.41(a)(7).

(ii) *Exception reporting by a pharmaceutical reverse distributor for a missing copy of the manifest.* (A) For shipments from a pharmaceutical reverse distributor to a designated facility:

(1) If a pharmaceutical reverse distributor does not receive a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the pharmaceutical reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(2) A pharmaceutical reverse distributor must submit an exception report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(i) A legible copy of the manifest for which the pharmaceutical reverse distributor does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) For shipments rejected by the designated facility and shipped to an alternate facility:

(1) A pharmaceutical reverse distributor that does not receive a copy of the manifest with the handwritten signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35 day timeframe begins the date the waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

(2) A pharmaceutical reverse distributor must submit an Exception Report to the EPA Regional Administrator for the Region in which the pharmaceutical reverse distributor is located if it has not received a copy of the manifest with the handwritten signature of the owner or operator of the

alternate facility within 45 days of the date the hazardous waste was accepted by the initial transporter. The 45-day timeframe begins the date the hazardous waste is accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility. The Exception Report must include:

(i) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(ii) A cover letter signed by the pharmaceutical reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(10) *Recordkeeping by a pharmaceutical reverse distributor for evaluated hazardous waste pharmaceuticals.* (i) A pharmaceutical reverse distributor must keep a log (written or electronic) of the weekly inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

(ii) A pharmaceutical reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(iii) A pharmaceutical reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A pharmaceutical reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A pharmaceutical reverse distributor must keep records to document personnel training, in accordance with § 265.16.

(d) *When a pharmaceutical reverse distributor must have a permit.* A pharmaceutical reverse distributor is an operator of a hazardous waste treatment, storage or disposal facility and is subject to the requirements of 40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270, if the pharmaceutical reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off-site; or

(3) Treats or disposes of hazardous waste on-site.

PART 268—LAND DISPOSAL RESTRICTIONS

■ 9. The authority citation for part 268 continues to read as follows:

Authority: 42 U.S.C. 6905, 6912(a), 6921, and 6924.

■ 10. Amend Section 268.7 by revising the section heading and the paragraph (a) subject heading to read as follows:

§ 268.7 Testing, tracking, and recordkeeping requirements for generators, pharmaceutical reverse distributors, treaters, and disposal facilities.

(a) *Requirements for generators and pharmaceutical reverse distributors:*

* * *
* * * * *

■ 11. Amend § 268.50 by adding paragraphs (a)(4) and (5) to read as follows:

§ 268.50 Prohibitions on storage of restricted wastes.

(a) * * *

(4) A healthcare facility accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the healthcare facility complies with the requirements in § 266.502 of this chapter.

(5) A pharmaceutical reverse distributor accumulates such wastes in containers on-site solely for the purpose of the accumulation of such quantities of hazardous waste pharmaceuticals as necessary to facilitate proper recovery, treatment, or disposal and the pharmaceutical reverse distributor complies with § 266.510 of this chapter.
* * * * *

PART 273—STANDARDS FOR UNIVERSAL WASTE MANAGEMENT

■ 12. The authority citation for part 273 continues to read as follows:

Authority: 42 U.S.C. 6922, 6923, 6924, 6925, 6930, and 6937.

■ 13. Amend § 273.80 by revising paragraph (a) and adding paragraph (d) to read as follows:

§ 273.80 General.

(a) Except as provided in paragraph (d), any person seeking to add a hazardous waste or category of hazardous waste to this part may petition for a regulatory amendment under this subpart and 40 CFR 260.20 and 260.23.

* * * * *

(d) Pharmaceutical hazardous waste is regulated by 40 CFR part 266, subpart P and may not be added as a category of hazardous waste for management under this part.

[FR Doc. 2015-23167 Filed 9-24-15; 8:45 am]

BILLING CODE 6560-50-P



Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-01-Hospital

DATE: October 30, 2015

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Revised Hospital Guidance for Pharmaceutical Services and Expanded Guidance
Related to Compounding of Medications

Memorandum Summary

Hospital Appendix A Updated: The Centers for Medicare & Medicaid Services (CMS) has updated the State Operations Manual (SOM) Appendix A with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP). The update includes the following features:

- **Pharmaceutical Services:** Revisions were made to portions of the pharmaceutical services CoP to bring them into alignment with current accepted standards of practice. To improve clarity, the revised guidance addresses: accepted professional pharmacy principles, including United States Pharmacopeia (USP) standards; compounding of medications, particularly compounded sterile preparations (CSPs); determining beyond-use dates (BUDs); safe and appropriate storage and use of medications; and, policies and procedures related to high-alert medications and minimizing drug errors.
- **Additional Tag:** We added a new standard-level tag to allow surveyors to cite to the regulatory language found in the condition stem statement at either the standard- or condition-level, as appropriate, in the Automated Survey Processing Environment (ASPEN).
- **Preparing CSPs Outside of the Pharmacy:** We are updating our guidance for the nursing service regulatory requirements concerning medication administration to clarify that hospitals must ensure staff adherence to accepted standards of practice in those limited instances when CSPs may be prepared outside of the pharmacy.

Background

Injections of contaminated compounded medications produced by a compounding pharmacy caused a nationwide meningitis outbreak in 2012. In addition to the compounding pharmacy-related outbreak of meningitis, a recent Institute for Safe Medication Practices (ISMP) article suggests that there are widespread problems with sterile compounding practices in acute care facility pharmacies: <http://www.ismp.org/newsletters/acutecare/issues/20150115.pdf>

The meningitis outbreak raised concerns about compounding pharmacies in general and prompted an investigation by the Office of Inspector General (OIG) regarding the use of compounding pharmacies by hospitals, as well as a follow-up report on oversight of hospital compounding by CMS and accrediting organizations. The latter OIG report (OEI-01-13-00400), released in January 2015, recommended that CMS should:

- Ensure that hospital surveyors receive training on standards from nationally recognized organizations related to safe compounding practices; and,
- Amend its interpretive guidelines to address hospitals' contracts with standalone compounding pharmacies.

The CMS concurred with both recommendations. Previously we issued revised guidance for critical access hospitals (CAHs), including expanded information on compounding. (See S&C policy memorandum 15-19, January 16, 2015). With this policy memorandum we are making similar revisions in Appendix A to the guidance for the Hospital Pharmaceutical Services CoP at 42 CFR 482.25, as well as for portions of the Nursing Services CoP at 42 CFR 482.23, related to medication administration. At a future date, we will also be providing targeted surveyor training related to compounding.

Additionally, in the course of revising and expanding our guidance concerning compounding, we have also reorganized and updated guidance for other parts of the Pharmaceutical Services CoP as well as the Nursing Services CoP.

Highlights of the revisions to Appendix A include:

Pharmaceutical Services:

- We reorganized the guidance by renumbering the condition-level tag as A-0489, creating a standard-level tag at A-0490 for a portion of the condition “stem” statement of the regulation, and including another portion of the condition stem statement in the tag at A-0491, Governing Pharmacy Management and Administration. We also updated and moved much of the guidance currently found in the condition-level tag to these or other standard-level tags, to reduce the potential for confusion about whether the guidance applies only in the case of condition-level citations.

The guidance is now placed to more clearly indicate what must be evaluated when assessing compliance with the condition and standards. Following normal survey procedure, citations issued at the standard-level may, depending on the manner and degree of noncompliance identified, also result in a condition-level citation.

- We have clarified that a hospital must have pharmaceutical services administered in accordance with accepted professional principles, such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF), and have provided additional information about USP standards.

- Similar to the CAH guidance released in January 2015, we have expanded our hospital guidance on the requirements for compounding of medications, particular for CSPs. We have also included discussion of U.S. Food and Drug Administration (FDA)-registered outsourcing facilities, and the implications for assessing compliance when hospitals use these facilities versus using other outside compounding pharmacies as a source for their CSPs. Under the current CoP, hospitals cannot be required to use only registered outsourcing facilities when obtaining compounded medications from an external source. However, if they do so, they will find it easier to demonstrate compliance than would be the case if they use a compounding pharmacy that is not registered with the FDA.
- We also are providing additional guidance on recommended best practice resources, summaries and assessment tools from organizations such as, the American Society of Health System Pharmacists (ASHP), ISMP, and USP in “blue boxes.” Information in blue boxes does not represent regulatory requirements and surveyors must not cite hospitals solely because they do not adhere to practices described in a “blue box.”

Nursing Services: We have updated our guidance for §§482.23(c)(1), (c)(1)(i) & (c)(2), concerning preparation and administration of drugs, to clarify accepted standards of practice required to prevent healthcare-associated infections in those limited circumstances when CSPs may be prepared outside of the pharmacy. We have also included discussion regarding medication beyond-use-dates (BUD).

An advance copy of revised SOM Appendix A is attached. It may differ slightly from the final version that will be published at a later date.

Contact: Questions concerning this memorandum may be addressed to hospitalscg@cms.hhs.gov

Training: The information contained in this letter should be shared with all survey and certification staff, their managers, and the State/RO training coordinators.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/

Thomas E. Hamilton

Attachment – Advanced Copy SOM Appendix A

cc: Survey and Certification Regional Office Management

CMS Manual System

Pub. 100-07 State Operations Provider Certification

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal- ADVANCE
COPY

Date: XXXX

SUBJECT: Revisions to State Operations Manual (SOM), Appendix A -Survey Protocol, Regulations and Interpretive Guidelines for Hospitals

I. SUMMARY OF CHANGES: We are clarifying our interpretive guidance in Appendix A for existing regulations in 42 CFR Part 482, concerning preparation and administration of drugs as well as pharmacy requirements and accepted standards of practice for drug compounding. We are taking this opportunity to make clarifications and updates to existing guidance.

**NEW/REVISED MATERIAL - EFFECTIVE DATE*: Upon Issuance
IMPLEMENTATION DATE: Upon Issuance**

The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

**II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)**

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	Appendix A/A-0405/§482.23(c) Standard: Preparation and Administration of Drugs
R	Appendix A/A-0489/§482.25 Condition of Participation: Pharmaceutical Services
N	Appendix A/A-0490/§482.25 Standard level tag for Condition for Coverage: Pharmaceutical Services
R	Appendix A/A-0491/§482.25(a) Standard: Pharmacy Management and Administration
R	Appendix A/A-0492/§482.25...The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision...& §482.25(a)(1)- A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.
R	Appendix A/A-0500/§482.25(b) Standard: Delivery of Services

R	Appendix A/A-0501/§482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.
R	Appendix A/A-0502/§482.25(b)(2)(i)- All drugs and biologicals must be kept in a secure area, and locked when appropriate.
R	Appendix A/A-0505/§482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.
R	Appendix A/A0507/§482.25(b)(5) - Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.
R	Appendix A/A0510/§482.25(b)(8) - Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2015 operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

A-0405
(Rev.)

§482.23(c) Standard: Preparation and Administration of Drugs.

(1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under §482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under §482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations....

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

Interpretive Guidelines §§482.23(c)(1), (c)(1)(i) and (c)(2)

According to the Institute of Medicine of the National Academies, medication errors are among the most common medical errors, harming at least 1.5 million people each year.¹ It has been estimated that drug-related adverse outcomes were noted in nearly 1.9 million inpatient hospital stays (4.7 percent of all stays), and 838,000 treat-and-release ED visits (0.8 percent of all visits).² Although technological advances in electronic order entry, medication administration, and electronic medical records hold a great deal of promise for decreasing medication errors, there are a multitude of human and environmental factors that will impact their success. The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety.

The regulations at §482.23(c) and §482.23(c)(1) promote safety in the preparation and administration of drugs and biologicals to hospital patients by requiring preparation and administration in accordance with:

- Federal and State law;
- Accepted standards of practice;

¹Institute of Medicine. Preventing Medication Errors. Washington DC: The National Academies Press, 2007.

²Lucado, Jennifer, et al, *Medication-Related Adverse Outcomes in U.S. Hospitals and Emergency Departments*. Statistical Brief #109, April, 2011. Healthcare Cost and Utilization Project, Agency For Healthcare Research and Quality, Rockville, MD.

- Orders of the practitioner(s) responsible for the patient's care, as specified under §482.12(c) or of another practitioner as permitted under State law, hospital policy and medical staff bylaws, rules and regulations; and
- Medical staff-approved policies and procedures.

Federal and State Law

Federal law regulates the approval and classification of drugs and biologicals. Individual States establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals, including which medications they may prescribe and administer, including controlled substances.

Accepted Standards of Practice

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration. Examples of such organizations include, but are not limited to:

- *American Society of Health-System Pharmacists* (<http://www.ashp.org/default.aspx>)
- Infusion Nurses Society (<http://www.insl.org>)
- Institute for Safe Medication Practices (www.ismp.org)
- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org)
- U.S Pharmacopeia (www.usp.org)

Orders of an authorized practitioner

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. (See §482.23(c)(1) (ii) concerning standing orders.) Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with §482.12(c). However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules and regulations. This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least the following:

- Name of the patient;

- Age and weight of the patient, to facilitate dose calculation when applicable. Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or g for newborns). If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners. For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric);
- Date and time of the order;
- Drug name;
- Dose, frequency, and route;
- Dose calculation requirements, when applicable
- Exact strength or concentration, when applicable;
- Quantity and/or duration, when applicable;
- Specific instructions for use, when applicable; and
- Name of the prescriber.

Medical Staff Approved Policies and Procedures

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures. The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

Personnel authorized to administer medication

§482.23(c)(2) requires that all drugs and biologicals are administered by, or under the supervision of, nursing or other personnel, in accordance with Federal or State law and approved medical staff policies and procedures. State law requirements include licensure requirements. Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel administering drugs and biologicals.

Medication administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication administration may include but are not limited to the following:

- Safe handling and preparation of authorized medications;
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications;

- Equipment, devices, special procedures, and/or techniques required for medication administration;

Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

Basic safe practices for medication administration

The hospital’s policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the “five rights” of medication administration practice):

- **Right patient:** the patient’s identity— acceptable patient identifiers include, but are not limited to: the patient’s full name; an identification number assigned by the hospital; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital’s policy. The patient’s identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.
- **Right medication:** the correct medication, to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it;
- **Right dose:** the correct dose, to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low);
- **Right route:** the correct route, to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient; and
- **Right time:** the appropriate time, to ensure adherence to the prescribed frequency and time of administration.

Note: the “5 rights” focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the “5 rights” of medication administration, for example when there has been a prescribing or a dispensing error. Hospitals are also expected to comply with requirements under the Pharmaceutical Services CoP at §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at §482.21, using a comprehensive systems approach to all components of the medication process.

For Information – Not Required/Not to be Cited

Recent literature* identifies up to nine “rights” of medication administration including:

- Right patient
- Right drug
- Right route
- Right time
- Right dose
- Right documentation
- Right action (appropriate reason)
- Right form
- Right response

However, other sources refer to 8 or 10 “rights, and some of these topics, such as right action, appear to involve prescribing and/or dispensing. Accordingly, there does not (yet) appear to be consensus about expanding beyond the 5 “rights.”

*Reference: Elliott, M. and Lis, Y. (2010). The Nine Rights of Medication Administration: An Overview. British Journal of Nursing, Vol. 19, 5, 300-305.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

Hospitals must also ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration. Adherence to these standards is assessed under the infection control CoP at 42 CFR 482.42, and details about the required practices are found in the Hospital Infection Control Worksheet.

Compounded sterile preparations (CSPs) may also be a source of healthcare-associated infection if proper precautions are not followed. The applicable standards of practice for safe sterile compounding are, at a minimum, the standards published in The United States Pharmacopeia National Formulary Chapter <797> (“Pharmaceutical Compounding – Sterile Preparations”) and other relevant USP/NF Chapters (USP <797>). (See the guidance for §482.25(b)(1) for more information on the role of USP/NF standards and for discussion of the term “compounding.”) Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for CSPs, whether they are the type of CSP that must be compounded in an aseptic pharmacy location that meets USP <797> standards for low, medium or high-level risk CSPs or are “immediate-use CSPs” prepared outside of the pharmacy.

Nurses commonly prepare sterile medications that are categorized by USP <797> as “immediate-use CSPs,” which are needed for immediate or emergency use for a particular

patient and are not to be stored for anticipated needs. The following USP <797> standards apply when preparing an immediate-use CSP:

- Preparation of an immediate-use CSP must only involve “simple transfer of not more than three commercially manufactured...sterile nonhazardous products from the manufacturer’s original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/device;”*
- “Administration begins not later than one hour following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded);”*
- Meticulous aseptic technique must be followed during all phases of preparation. If the CSP is not administered to the patient as soon as it is ready, “the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces...,” contamination and/or confusion with other CSPs; and*
- “Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer...,” the CSP must be labeled with at least:*
 - Patient identification information;*
 - The names and amounts of all ingredients;*
 - The name or initials of the person who prepared it; and*
 - The exact one hour “beyond use date” (see below).*

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the U.S. Food and Drug Administration’s (FDA) approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer’s approved labeling.

A drug or biological is also outdated after its “beyond-use date” (BUD), which may be reached before the expiration date, but never later. The BUD is the date and time after which the medication must not be used, stored or transported. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer. The policies and

procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the USP/NF (USP).³

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled “Determining Beyond-Use Dates,” which addresses sterile compounding, notes that “the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies.” It provides an example of testing considered more appropriate for certain types of CSPs such as “CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity....” It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred approach, while the latter results in a “theoretical BUD,” which has an inherent likelihood of inaccuracy or error.

Timing of Medication Administration

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them. The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration. Consequently, the application of a uniform required window of time before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately. This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration. The policies and procedures must address at least the following:

- Medications **not eligible** for scheduled dosing times;
- Medications **eligible for** scheduled dosing times;
- Administration of eligible medications outside of their scheduled dosing times and windows; and
- Evaluation of medication administration timing policies, including adherence to them.

Medications or categories of medication not eligible for scheduled dosing times

³ All references to “USP” herein are from: *United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement. Rockville, MD: United States Pharmacopeial Convention, 2014.*

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications. These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors. Examples of medications that hospitals may choose to identify as not eligible for scheduled dosing times may include, but are not limited to:

- Stat doses (immediate);
- First time or loading doses (initial large dose of a drug given to bring blood, tissue or fluid levels to an effective concentration quickly);
- One-time doses; doses specifically timed for procedures;
- Time-sequenced doses; doses timed for serum drug levels;
- Investigational drugs; or
- Drugs prescribed on an as needed basis (prn doses).

The policies and procedures must ensure timely administration of such medications. In addition they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

Medications eligible for scheduled dosing times

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc. The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications. For example, medications prescribed for BID (twice a day) administration might, under a given hospital's policies and procedures, be scheduled to be administered at 8am and 8pm. Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm. Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital's pharmacy that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration. For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address: first dose medications, including parameters within which nursing staff are allowed to use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times; retiming of missed or omitted doses; medications that will not follow scheduled dosing times; and patient units that are not subject to following the scheduled dosing times.

Time-critical scheduled medications

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect. Accordingly, scheduled medications identified under the hospital's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time-critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients. Therefore, hospital policies and procedures must address the process for determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical. Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics;
- Anticoagulants;
- Insulin;
- Anticonvulsants;
- Immunosuppressive agents;
- Pain medication (non-IV);
- Medications prescribed for administration within a specified period of time of the medication order;
- Medications that must be administered apart from other medications for optimal therapeutic effect; or
- Medications prescribed more frequently than every 4 hours.

Non-time-critical scheduled medications

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm. For such medications greater flexibility in the timing of their administration is permissible. Specifically:

- Medications prescribed for daily, weekly or monthly administration may be within 2 hours before or after the scheduled dosing time, for a total window that does not exceed 4 hours.
- Medications prescribed more frequently than daily but no more frequently than every 4 hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed 2 hours.

Missed or late administration of medications

The hospital's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time. This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration. Likewise, policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff are allowed to use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at §482.25(b)(6). See interpretive guidance at §482.25(b)(6) for more details on internal reporting requirements

Evaluation of medication administration timing policies

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Consistent with the QAPI requirements at 42 CFR 482.21(c)(2), medication errors related to the timing of medication administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

Assessment/Monitoring of Patients Receiving Medications

Observing the effects medications have on the patient is part of the multi-faceted medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action. Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels;
- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of

errors are often harmful, sometimes fatal, to patients. (See also the discussion of high-risk medications (typically referred to as “high-alert” medications) in the guidance for §482.25(a)(1))

For Information – Not Required/Not to be Cited

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. The current list may be found at: <http://www.ismp.org/Tools/highAlertMedicationLists.asp>

In addition, certain factors place some patients at greater risk for adverse effects of medication. Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients’ medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for §482.23(c)(5) and §482.25(b)(6), concerning reporting of adverse medication-related events.)

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring is essential in all hospital settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion of the requirements for intravenous medications at §482.23(c)(4)).

As part of the monitoring process, staff are expected to include the patient’s reports of his/her experience of the medication’s effects. Further, when monitoring requires awakening the patient in order to assess effects of the medications, the patient and/or the patient’s representative must

be educated about this aspect of the monitoring process. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication.

Documentation

Note that documentation of medication administration is addressed in the Medical Records CoP, at §482.24(c), which specifies the required content of the medical record. Within this regulation §482.24(c)(vi) requires that the record contain: "All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition." Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate, but may result in medication errors. Proper documentation of medication administration actions taken and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §482.24(c) concerning documentation in the medical record. Deficiencies in documentation would be cited under the applicable Medical Records regulation.

Survey Procedures §§482.23(c)(1), (c)(1)(i), and (c)(2)

Verify that there is an effective method for the administration of drugs. Use the following indicators for assessing drug administration:

- Verify that there are policies and procedures approved by the medical staff and governing body concerning ordering of drugs and biologicals by practitioners.
- Verify that there are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
 - Verify nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice.
 - Are personnel other than nursing personnel administering drugs or biologicals? If yes, determine if those personnel are administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules and regulations. Use the above procedures to determine compliance.
- Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.

- Verify that the hospital has, consistent with its policies, identified medications: which are:
 - not eligible for scheduled dosing times;
 - Eligible for scheduled dosing times and are time-critical; and
 - Eligible for scheduled dosing times and are not time-critical.
- Verify the hospital has established total windows of time that do not exceed the following:
 - 1 hour for time-critical scheduled medications
 - 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours; and
 - 4 hours for medications prescribed for daily or longer administration intervals.
- Verify that the hospital's policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation- specific?
- Review a sample of medical records to determine whether medication administration conformed to an authorized practitioner's order, i.e., that there is an order from an authorized practitioner, or an applicable standing order, and that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures. Check that the practitioner's order was still in force at the time the drug was administered.
- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed
 - Is the patient's identity confirmed prior to medication administration?
 - Are procedures to assure the correct medication, dose, and route followed?
 - *If immediate-use CSPs are prepared outside of the pharmacy, are practices consistent with USP <797>?*
 - Are drugs administered in accordance with the hospital's established policies and procedures for *safe and* timely medication administration?
 - Does the nurse remain with the patient until oral medication is taken?
- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?

- Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
- Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
 - Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
 - Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?

A-0489
(Rev.)

§482.25 Condition of Participation: Pharmaceutical Services.

The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

Interpretive Guidelines §482.25

A hospital must provide pharmaceutical services that meet the needs of its patients. The services must include either a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised. The hospital's medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors, but may delegate this function to the pharmaceutical service.

The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.

A-0490
(Rev.)

Standard-level Tag for

§482.25 Condition of Participation: Pharmaceutical Services.

The hospital must have pharmaceutical services that meet the needs of the patients....

Interpretive Guidelines §482.25

What is included in pharmaceutical services?

Pharmaceutical services encompass the functions of procuring, storing, compounding, re-packaging, and dispensing all medications, biologicals, chemicals and medication-related devices within the hospital. They also include providing medication-related information to care professionals within the hospital, as well as direct provision of medication-related care.

Meeting patient needs

Hospitals must provide pharmaceutical services that meet the needs of their patients. The scope and complexity of pharmaceutical services available in the hospital must be consistent with the volume and types of patients the hospital serves. Except in unusual circumstances, the pharmaceutical service is expected to make available in a timely manner the volume and types of medications typically needed. These would be those medications typically prescribed by the hospital's practitioners for hospital patients receiving inpatient services, surgical services, diagnostic services involving medications as a component of testing, and outpatient drug therapies administered while the patient is in the hospital.

Not every hospital is expected to offer the same level of pharmaceutical services. For example:

- *It would not be uncommon for a psychiatric hospital to maintain a relatively limited pharmaceutical service, due to minimal need for compounding, and/or dispensing multiple types and forms of medications and biologicals.*
- *On the other hand, a short-term acute care hospital with a busy oncology outpatient service and other complex medical and surgical departments would be expected to provide a wider range of pharmaceutical services that are ready to be furnished when needed.*

Survey Procedures §482.25

- *Ask the hospital for evidence of the scope and complexity of its pharmaceutical services.*
- *Ask how the hospital has determined that the services meet the needs of its patients.*

- *Ask unit nursing staff if prescribed medications are routinely available and timely. If there are reports of frequent delays or other problems, probe further with the director of pharmaceutical services.*

A-0491

(Rev.)

[\$482.25 Condition of Participation: Pharmaceutical Services

.....The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital’s organized pharmaceutical service.]

§482.25(a) Standard: Pharmacy Management and Administration

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

Interpretive Guidelines §482.25(a)

Pharmaceutical services must be administered in accordance with accepted professional principles. Accepted professional principles includes compliance with applicable Federal and State laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations, *such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF).*

The hospital’s pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.

Hospitals may choose how to set up the pharmaceutical services utilizing various methods including, but not limited to:

- *a unit dose system (i.e.; single unit package, dispensed in most ready to administer form possible),*
- *individual prescription (i.e.; instruction for a single patient, written by a medical practitioner for a medication or treatment),*
- *floor stock system (i.e.; storage of pharmaceutical and over-the-counter drugs on the patient care unit), or*
- *a combination of these systems, as long as they are properly stored.*

However, hospitals with only a drug storage area must only use drugs that are pre-packaged and need no further preparation beyond that required at the point of care.

The *hospital must* develop, implement and periodically review and revise *as needed* policies and procedures governing provision of pharmaceutical services. *The regulation makes the hospital's medical staff responsible for the policies and procedures, but also permits the medical staff to delegate this function to the hospital's pharmaceutical services. The policies and procedures must reflect accepted professional pharmacy principles, and the pharmacy director must be able to identify the source(s) used when developing and adopting the policies and procedures. There must also be a process to train staff on the applicable policies and procedures and to monitor their adherence.*

Policies and Procedures for Minimizing Drug Errors

Medication errors are a substantial source of morbidity and mortality risk in the hospitalized setting. Therefore, hospitals must take steps to prevent, identify, and minimize these errors. These steps must be based on accepted professional principles. This includes not only ensuring that the pharmacy processes conform to of accepted standards of pharmacy practice but also proactively identifying and reviewing Adverse Drug Events (ADE) that occur. Pharmacies also need to be aware of external alerts to real or potential pharmacy-related problems in hospitals.

The *pharmaceutical services* policies and procedures *must be designed* to minimize drug errors and are expected to address:

- *High-alert medications - are considered inherently high risk for adverse drug events. High alert drugs may include controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications, look-alike/sound-alike medications and those new to the market or new to the hospital. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal, to patients. Examples of ways to minimize high alert medication errors include, but are not limited to, the following: dosing limits, administration guidelines, packaging, labeling and storage.*
- *Investigational medications - hospitals that conduct research involving investigational medications must have a policy and procedure in place to ensure that investigational medications are safely controlled and administered. Procedures for the use of investigational medications include, but are not limited to, the following: A written process for reviewing, approving, supervising and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.*
- *Adherence to professional standards of practice for all compounding, packaging dispensing and drug disposal activities;*
- *Standardizing medication-related devices and equipment where feasible. For example, limit the types of general-purpose infusion pumps to one or two;*
- *Availability of up-to-date medication information and pharmacy expertise on-call when pharmacy does not operate 24 hours a day;*

- *Standardization of prescribing and communication practices to include:*
 - *Avoidance of dangerous abbreviations;*
 - *All elements of the order – dose, strength, units (metric), route, frequency, and rate;*
 - *Alert systems for look-like and sound-alike drug names;*
 - *Use of facility approved pre-printed order sheets whenever possible.*
- *Prohibition of orders to “resume previous orders;”*
- *Availability of patient-specific information to all individuals involved in provision of pharmaceutical services. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate;*
- *Identification of when weight-based dosing for pediatric populations is required; and*
- *A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions);*
- *Monitoring drug alerts and/or recalls. The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice and National Coordinating Council for Medication Error Reporting and Prevention. Governmental agencies may include: Food and Drug Administration, Med Watch Program; and*
- *The hospital’s pharmacy services must be integrated into its hospital-wide QAPI program and therefore, it is important to flag new types of mistakes and continually improve and refine policies and procedures as a result of analyses of errors and adverse events.*

Survey Procedures §482.25(a)

- *Is the hospital’s organized pharmaceutical services responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?*
- *If the hospital has a drug storage area instead of a pharmacy, does it use only drugs that are pre-packaged and need no further preparation beyond that required at the point of care?*
- *Is there evidence that the hospital’s medical staff has either adopted pharmaceutical services policies and procedures, or has delegated this task to the pharmaceutical services?*

- *Can the pharmacy director provide evidence that the policies and procedures are consistent with accepted professional principles?*
- *Can the pharmacy director provide evidence that policies and procedures address key areas to prevent medication errors?*
- *Is there evidence of training staff on applicable pharmaceutical policies and procedures?*
- *Is there a process in place to monitor adherence to policies and procedures?*

A-0492

(Rev.)

[\$482.25 Condition of Participation: Pharmaceutical Services

The hospital.... must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision....

§482.25(a)(1) - A full-time, part-time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services.

Interpretive Guidelines §482.25 and §482.25(a)(1)

Pharmaceutical services offered throughout the hospital must be under the direction of a pharmacist, who may be full-time, part-time, or consulting. This is required even in the case of a hospital that has a drug storage area instead of a pharmacy. The director must have documented training or expertise in hospital pharmacy practice and management. The hospital must have written criteria for the qualifications of the pharmacy director in accordance with the scope of services provided.

The extent of pharmaceutical services provided by the hospital determines whether a part-time director of the services is sufficient. Depending on the volume and complexity of the hospital's services, oversight may not require full-time on-site management at the hospital's pharmacy, but may be accomplished through regularly scheduled visits, and/or use of telecommunications in accordance with federal and state law and accepted professional principles. If the hospital does not have a full-time pharmacist, it must be able to provide evidence of how a part-time or consulting pharmacist is able to perform all functions relating to developing, supervising and coordinating all pharmacy services activities.

In general, hospital pharmacies are staffed with registered pharmacists and pharmacy technicians who perform various functions, including, but not limited to, compounding, labeling, and dispensing of various drugs and biologicals.

There may be instances of small hospitals that do not have a pharmacy but utilize a drug storage area for dispensing pre-packaged drugs only. If the hospital has a drug storage area in lieu of a

pharmacy, the day-to-day operations of pharmaceutical services must be under the supervision of an individual who, if not a pharmacist, nevertheless has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.). The hospital must establish in writing the qualifications of the drug storage area supervisor.

Likewise, if a hospital has remote locations or satellites that rely on the pharmacy of the main campus and maintain only drug storage area(s) on-site, there must be competent day-to-day supervision of those storage area(s), under the overall direction of the pharmacist who manages the hospital's pharmaceutical services.

The job description or the written agreement for the responsibilities of the pharmacist director should be clearly defined and include development, supervision and coordination of all the activities of pharmacy services, including active leadership of those committees responsible for establishing medication-related policies and procedures.

Survey Procedures §482.25 and §482.25(a)(1)

- *Does the hospital have a pharmacist who has been appointed to direct the pharmaceutical services?*
 - *Are there written criteria for the qualifications of the pharmacist director?*
 - *Is there evidence in the pharmacist's file that he/she satisfies the criteria?*
- *If the hospital has a drug storage area in lieu of a pharmacy, is there evidence the storage area is under competent supervision?*
- *Review the pharmaceutical services Director's file to verify that he or she meets the qualifications established by the medical staff and has been granted privileges as a pharmacist.*
- *If the Director is a part-time employee or consultant, ask him/her how much time/week is spent on developing, supervising and coordinating pharmaceutical services.*
- Review the implementation of the pharmacy *director's* responsibilities by:
 - Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services;
 - Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services;

Determining whether the pharmacy *director/manager* routinely evaluates the performance and competency of pharmacy personnel?

- *Ask the pharmacy director to describe how policies and procedures related to pharmaceutical services are developed, approved, and implemented. What is his/her role in this process?*
- *Is there any evidence of problems within the pharmaceutical services that suggest lack of supervision?*

A-0500
(Rev.)

§482.25(b) Standard: Delivery of Services

In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law.

Interpretive Guidelines §482.25(b)

Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines. The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

Other sources of additional guidelines could include, but are not limited to: American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Pharmacists Association, United States Pharmacopeia, etc.

Note re: US Pharmacopeia/National Formulary (USP/NF)

According to the Federal Food, Drug and Cosmetic Act (FCDA), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (<http://www.usp.org/>) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern Food, Drug and Cosmetic Act (FDCA) beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of FDCA. (See, for example, §501(b) of the FDCA regarding compendial standards for strength, quality and purity, §502(g) for compendial standards for packaging and labeling). Under the FDCA, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

The hospital must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner. Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following:

- *Implementing systems such as dose limits, pre-printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications;*
- *Reviewing all medication orders (except in emergency situations) for appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order;*

This review should include:

- *Therapeutic appropriateness of a patient's medication regimen;*
 - *Therapeutic duplication in the patient's medication regimen;*
 - *Appropriateness of the drug, dose, frequency, and route of administration;*
 - *Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions;*
 - *Real or potential allergies or sensitivities; and*
 - *Other contraindications.*
- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons;
 - *Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy; and*
 - *Having a system in place to reconcile medications that are not administered (e.g., left in the patient's medication drawer) when the pharmacy inventories patient medications or restocks patient medications.* For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

Monitoring the Effects of Medications

The pharmaceutical service may be responsible for monitoring the effects of medication(s) specified per hospital policy to assure medication therapy is appropriate and minimizes the occurrence of adverse events. Typically this occurs with anticoagulant therapy and antibiotics

prescribed for the pharmacy to establish or adjust the dosage (i.e.; “pharmacy to dose” order). In such cases, the pharmacy’s monitoring process includes:

- *Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects;*
- *Physical signs and clinical symptoms relevant to the patient’s medication therapy;*
- *Assessing the patient’s own perceptions about side effects, and, when appropriate, perceived efficacy.*

(See also the Nursing CoP discussion regarding monitoring of patients at §482.23(c)(4)).

Survey Procedures §482.25(b)

- *Are medication orders routinely reviewed by the pharmacy before the first dose? What evidence can the hospital present that such reviews take place?*
- *Are questions regarding **medication** orders resolved with the prescriber and a written notation of these discussions documented in the patient’s medical record or pharmacy copy of the prescriber’s order?*
- *Does the hospital pharmacy have a system for monitoring the effects of medication therapies for cases specified per hospital policy?*
- *Does the hospital retrieve and remove medications available or patient use when the hospital has been informed of a drug recall?*

A-0501

(Rev.)

§482.25(b)(1) - All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.

Interpretive Guidelines §482.25(b)(1)

All *pharmaceutical services involving* compounding, packaging, *or* dispensing of drugs and biologicals, *must be* conducted *by or* under the supervision of a pharmacist and performed consistent with State and Federal laws. *The hospital must adopt and implement written policies and procedures to ensure all* medications *are* prepared *by authorized personnel.*

Compounded Preparations

Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered “compounded” preparations. Some may be compounded in the hospital pharmacy

and/or the hospital may obtain some or all from external sources. The external sources could include:

- *manufacturers,*
- *registered outsourcing facilities, and/or*
- *compounding pharmacies.*

Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially devastating or even lethal consequences for the patients who receive them.

Use of Registered Outsourcing Facilities

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA. Facilities that elect to register as outsourcing facilities, per section 503B:

- *Must comply with the FDA’s Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm> ;*
- *Will be inspected by FDA according to a risk-based schedule; and*
- *Must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.*

In a January 2014 letter to purchasers of compounded medications (available at <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm380596.htm>), the Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that, “[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling.”

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at:

<http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm>

Note that these registered outsourcing facilities are also popularly referred to as “503B pharmacies.”

Use of Compounding Pharmacies

Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as “503A pharmacies” and generally are subject to oversight only by their State pharmacy board. If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable State or Federal laws or regulations. For example, does the contract with the vendor include provisions:

- Ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data?*
- Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?*

For Information – Not Required/Not to be Cited

ASHP Research and Education Foundation™ “Outsourcing Sterile Products Preparation: Contractor Assessment Tool”

The ASHP Research and Education Foundation™ offers a tool that hospitals may find useful for assessing vendors that provide compounded sterile preparations. The tool can be found at:

<http://www.ashpfoundation.org/MainMenuCategories/PracticeTools/SterileProductsTool.aspx> and click on “Start using Sterile Products Outsourcing Tool now.”

Medications Compounded by the Hospital's Pharmacy

Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation). In addition, all compounding of medications used or dispensed by the hospital must be performed consistent with standards of practice equivalent to or more stringent than those described in the compounding-related chapters in the United States Pharmacopeia and the National Formulary (USP) published by the U.S. Pharmacopeial Convention, which are recognized as authoritative guidance regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):

“The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner’s prescription, medication order or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice. Compounding includes the following:

- Preparation of drug dosage forms for both human and animal patients*
- Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns*
- Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients*
- Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis*
- Preparation of drugs and devices for prescriber’s office use where permitted by federal and state law.”*

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

USP <797> outlines minimum standards of practice to be followed by all health care personnel in any setting when preparing, storing and transporting “compounded sterile preparations” (CSPs). Its stated objective is “to describe conditions and practices to prevent harm, including death, to patients that could result from...microbial contamination...excessive bacterial endotoxins...variability of intended strength of correct ingredients...unintended chemical and physical contaminants...and ingredients of inappropriate quality....” Contaminated CSPs are especially hazardous if administered into body cavities, the central nervous system, vascular system, eyes, joints, and/or used as baths for live organs and tissues. “All compounded dosage forms that must be sterile when they are administered to patients” are considered by USP <797> to be CSPs, including but not limited to:

- *“Aqueous bronchial and nasal inhalations;*
- *Baths and soaks for live organs and tissues;*
- *Injections [and infusions];*
- *Irrigations for wounds and body cavities;*
- *Ophthalmic drops and ointments;*
- *Tissue implants.”*

USP <797> specifies differing standards for the physical layout and structure of the locations in which compounding takes place as well as processes, precautions and quality assurance practices to be implemented during the preparation, transport and storage of CSPs. The standards differ in part based on the level of risk of microbial contamination of the CSP, and the risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored before use. The risk categories and accompanying standards are based on specific criteria, including but not limited to, factors such as:

- *The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs are exposed.*
- *The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.*
- *Whether compounding personnel are appropriately garbed and gloved.*
- *Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.*

The goal of the USP <797> standards is to prevent and/or minimize the risk of microbial contamination of CSPs, whether by direct contact, exposure to particles in air generated by personnel or objects, or other mechanisms. A major concern is preventing contamination of “critical sites,” which include “any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed or at risk of direct contact with air...moisture...or touch contamination.”

USP <797> describes two basic structural designs for the physical layout and environmental controls intended to minimize airborne contamination of critical sites during preparation of CSPs. The risk level of the CSPs a facility can produce depends, in part, on which USP <797> environmental quality and control/facility design standards the hospital (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see §482.23(c) for a discussion of “immediate-use” CSPs):

- *Some facilities may only prepare low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient, and administration must commence within the lesser of 12 hours of preparation or as recommended in the manufacturer’s package insert. Such a facility would have a designated, demarcated room or space that is the “segregated compounding area (SCA),” which contains a device that provides unidirectional airflow of International Standards Organization (ISO) Class 5 air quality (quality class ranges from class 0, the most stringent, to class 9, the most relaxed). The SCA may not be in an area with unsealed openings/potential openings to high traffic locations, the outdoors and other proscribed environmental conditions, and the SCA area may not contain any materials or be the site of any activities unrelated to preparing low-risk CSPs.*
- *If a facility is preparing high- or medium-level risk CSPs or low-risk CSPs with a beyond-use date of greater than 12 hours, it must meet additional environmental design and monitoring/testing standards in the buffer and ante-areas.*
- *USP<797> contains separate standards for the safe compounding of hazardous medications (defined as “...if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs...”), radiopharmaceuticals and allergen extracts.*

In addition, USP <797> includes standards for various processes, precautions and quality assurance practices required and recommended for the safe preparation of all risk levels of CSPs. These address issues such as:

- *The responsibilities of compounding personnel and their supervisors to implement and maintain proper procedures and quality assurance checks.*
- *Issues specific to “immediate use” CSPs; single- and multiple-dose containers; CSPs containing hazardous drugs; radiopharmaceuticals; allergen extracts; and automated compounding devices used for parenteral nutrition compounding.*
- *Methods for sterilization, depyrogenation and for verifying compounding accuracy and sterility.*
- *Specifications for environmental quality and control, including but not limited to:*
- *Specifications and related personnel training, including competency assessment and evaluation of skill in aseptically preparing CSPs using visual observation as well as bacterial sampling of glove fingertips and “media-fill testing” at specified intervals.*

- *Evaluation and monitoring/testing of the environment in which compounding takes place and, if applicable, the adjacent “ante-” and “buffer” areas, including facility layout, design, environmental controls, restricted access, air quality standards and testing, surface characteristics, furnishings, cleaning and disinfection procedures, and standards for personnel health, attire/cosmetics, cleansing/garbing/gloving, aseptic work practices, etc.*
- *Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared.*
- *Quality control related to ingredients, devices and equipment used in relation to CSPs.*
- *Quality checks to be performed before CSPs are dispensed or administered.*
- *Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs.*
- *Protecting dispensed and distributed CSPs.*
- *Patient education issues.*
- *Monitoring for and reporting adverse patient events related to CSPs.*
- *Requirements for a formal quality assurance program to be maintained by providers of CSPs.*

For Information – Not Required/Not to be Cited

USP <797> Appendices I and III-V contain summaries and assessment tools that hospitals may find helpful. However, there is no requirement to use specific forms or materials as long as the hospital and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding. These USP <797> materials are referenced here only as examples:

- *“Appendix I: Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required...and Recommended in USP Chapter <797>”*
- *“Appendix III: “Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel”*
- *“Appendix IV: “Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel”*
- *“Appendix V: “Sample Form for Assessing Cleaning and Disinfection Procedures”*

Packaging and Labeling of Medications

Safe medication use includes proper packaging and labeling to reduce the risk of error. For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a beyond-use date (BUD). It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

For Information Only

Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although hospitals are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal laws.

Dispensing of Medications

Medications ***must*** be dispensed ***by the hospital*** in a manner that is safe and meets the needs of the patient:

- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient;
- Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.
- Whenever possible, medications are dispensed in the most ready to administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy;
- The hospital consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system;

- All concerns, issues or questions are clarified with the individual prescriber before dispensing; *and*
- *Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.*

Medications must be available for administration to patients when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.

- *Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can only be accessed by authorized personnel.*
- *Policies and procedures must address who can access medications during after-hours.*

For Information Only – Not Required/Not to be Cited

When utilizing automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following:

(See: <http://www.ismp.org/Newsletters/acutecare/articles/20090212.asp> and http://www.ismp.org/Tools/guidelines/ADC_Guidelines_Final.pdf)

Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.

- *Utilize biometric user identification or, at a minimum, change user passwords quarterly.*
- *Link the ADC to the pharmacy computer to allow for patient “profiling,” so that a pharmacist can review each medication order and screen it for safety before the drug is dispensed or accessed by the nurse or other healthcare professional.*
- *Limiting the availability of overrides to the ADC system.*
- *Limiting access to drugs based on the patients profile so to decrease medication selection errors.*
- *Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.*

- *Document the destruction of medication waste at the time of removal of the medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/reconcile the documented medication waste.*
- *Return all medications to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.*

Survey Procedures §482.25(b)(1)

- Determine that only pharmacists or *pharmacist*-supervised personnel compound, *package* and dispense drugs or biologicals in accordance with State and Federal laws and regulations and accepted *standards of practice* by:
 - Interviewing pharmacy and hospital staff to determine *who prepares and dispenses* drugs and biologicals;
 - Observing on site *preparation and* dispensing operations;
 - Inspecting drug storage areas.
- *Can the hospital demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>?*
 - *Can the pharmacy director provide evidence that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>?*
 - *If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities? If not, can the hospital demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding? For example, does the contract include provisions ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data?*
- *Can the pharmacy director explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources? Can he or she demonstrate that the assigned risk levels are consistent with USP <797> or equivalent/more stringent standards?*

- *If any CSPs are produced in the hospital:*
 - *Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the hospital's policies and procedures?*
 - *Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?*
 - *Ask the pharmacy director to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with USP <797> or equivalent/more stringent standards for the risk level(s) of CSPs being produced for/dispensed to hospital patients:*
 - *Verification of compounding accuracy and sterility.*
 - *Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;*
 - *Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.*
 - *Review the hospital's procedures for maintaining the quality of CSPs during storage, transport and dispensing. Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed? How does the hospital ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?*
 - *Can the hospital document that it is systematically monitoring and tracking adherence to all of the quality assurance and personnel training and competency standards described above? Have any problems or risks been identified? If so, did the hospital take effective action to protect patients, if relevant, and to effectively remedy the problem/risk?*

A-0502
(Rev.)

§482.25(b)(2)(i) - All drugs and biologicals must be kept in a secure area, and locked when appropriate.

Interpretive Guidelines §482.25(b)(2)(i)

A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Drugs and biologicals must not be stored in areas that are readily accessible to unauthorized persons. For example, if medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, ambulatory infusion), they are considered secure. Areas restricted to authorized personnel only would generally be considered “secure areas.” If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital is expected to evaluate its current medication control policies and procedures, and implement the necessary systems and processes to ensure that the problem is corrected, and that patient health and safety are maintained. (71 FR 68689)

All controlled substances must be locked. Hospitals are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, **both** controlled and non-controlled substances are expected to be locked.

Generally labor and delivery suites and critical care units are staffed and actively providing patient care around the clock, and, therefore, considered secure. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients and visitors.

The operating room suite is considered secure when the suite is staffed and staff are actively providing patient care. When the suite is not in use (e.g., weekends, holidays and after hours), it would not be considered secure. A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual operating room is not in use, the hospital is expected to lock non-mobile carts, and ensure mobile carts are in a locked room. (71 FR 68689)

This regulation gives hospitals the flexibility to integrate patient self-administration of non-controlled drugs and biologicals into their practices as appropriate. When a hospital allows a patient to self-administer selected drugs and biologicals, the hospital authorizes the patient to have access to these medications. This regulation is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers. It supports the current practice of placing selected nonprescription medications at the bedside for the patient’s use, such as lotions and creams, and rewetting eye

drops. Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures (*see self-administration discussion at §§482.23(c)(6)(i) and 482.23(c)(6)(ii)*). This regulation supports hospital development, in collaboration with the medical staff and the nursing and pharmacy departments, of formal patient medication self-administration programs for select populations of patients, including hospital policies and procedures necessary to ensure patient safety and security of medications. The policies and procedures are expected to include measures to ensure the security of bedside drugs and biologicals. They are also expected to address both the competence of the patient to self-administer drugs and biologicals as well as patient education regarding self-administration of drugs and biologicals. (71 FR 68689)

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as “carts”) must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. (71 FR 68689)

Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.

Survey Procedures §482.25(b)(2)(i)

- Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate.
- Review hospital policies and procedures governing patient self-administration of drugs and biologicals.
- Observe whether medications in various areas of the hospital are stored in a secure area, and locked when appropriate. *Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored?*
- Determine that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc.
- Interview staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.
- *If patient self-administration of drugs and biologicals is permitted, interview* patients and staff to determine whether policies and procedures are implemented and effective.

A-0505
(Rev.)

§482.25(b)(3) - Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

Interpretive Guidelines §482.25(b)(3)

The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. *This would include drugs that are the subject of a manufacturer's recall.*

A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer. The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).⁴

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled "Determining Beyond-Use Dates," which addresses sterile compounding, notes that "the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies." It provides an example of testing considered more appropriate for certain types of compounded sterile preparations (CSPs) such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity...." It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the

⁴ All references to "USP" herein are from: United States Pharmacopeial Convention. *USP on Compounding: A Guide for the Compounding Practitioner. Current with USP 37-NF32 through First Supplement.* Rockville, MD: United States Pharmacopeial Convention, 2014.

preferred approach, while the latter results in a “theoretical BUD,” which has an inherent likelihood of inaccuracy or error.

For individual drug containers: each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. In addition, where applicable, each patient’s individual drug container is expected to be labeled with the patient’s full name and quantity of the drug dispensed.

If the unit dose system is utilized, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

Survey Procedures §482.25(b)(3)

- Spot-check the labels of individual drug containers to verify that they conform to *Federal and State laws*, and/or contain the following minimal information:
 - Each patient’s individual drug container bears his/her full name, and strength and quantity of the drug dispensed. Appropriate accessory and cautionary statements are included as well as the expiration date *and/or, if applicable, a BUD*.
 - Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, expiration date.
- If the unit dose system is utilized, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, expiration date *and/or, if applicable, a BUD*.
- Inspect patient-specific and floor stock medications to identify expired, mislabeled or unusable medications.
- *Review the pharmacy policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).*
 - *Can the hospital demonstrate that the policies and procedures are consistent with or more stringent than the applicable USP standards?*
 - *Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer’s instructions are not available have the expertise and technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies?*

- *Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs. Is there evidence that the BUDs are determined consistent with the hospital's policies and procedures?*

A-0507

(Rev.)

§482.25(b)(5) - Drugs and biologicals not specifically prescribed as to time or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.

Interpretive Guidelines §482.25(b)(5)

In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses. The hospital must implement, monitor, and enforce this automatic stop system.

It is important to note that hospitals with an electronic health record (EHR) system may have time and dose parameters automatically built into computerized provider order entry (CPOE) screens. These may be part of the hospital's plan for addressing automatic stop orders.

Survey Procedures §482.25(b)(5)

- Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients' medical records to determine compliance with stop-order policy.
- *Ask unit staff what happens in the case of drugs with no stop date or prescribed number of doses. Are they aware of the automatic stop policy? Can they describe how it is enforced?*

A-0510

(Rev.)

§482.25(b)(8) - Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

Interpretive Guidelines §482.25(b)(8)

The pharmacy must be a resource for medication-related information to the hospital's health-care practitioners and other health care personnel to optimize therapeutic outcomes and

minimize adverse drug events. Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration. The pharmacy may also assist other health care professionals with the following medication-related functions:

- *Collection and organization of patient-specific information (height, weight, allergies);*
- *Identification of the presence of medication-therapy problems, both potential and actual, such as drug-drug interactions, excessive doses;*
- *Identification and specification of pharmaco-therapeutic goals;*
- *Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health-care professionals;*
- *Monitoring the effects of the pharmacotherapeutic regimen – could include adjusting doses based on lab values (i.e.: Coumadin dosing); or*
- *Redesigning the regimen and monitoring plan as indicated.*

For example, practitioners may write an order for “pharmacy to dose” an antibiotic. The pharmacist would then take patient-specific information, review the patient’s current medication therapies for any problems, and then calculate the dose required to meet therapeutic goals.

Increasingly, as hospitals move to computerized physician-order entry (CPOE) of medication orders, much of this consultation function (e.g.; dosage, path of administration, drug-drug interactions and other contraindications, etc.) is built in to the electronic health record (EHR) system. However, the pharmacy service remains responsible for the provision of accurate, up-to-date information to meet the needs of the hospital’s practitioners, nursing staff and patients.

The *hospital must also have immediately available sufficient up-to-date reference material on drug therapy, whether in electronic or hard copy format. A pharmacist also should be readily available by telephone or other means to respond to questions from practitioners and nursing personnel.*

Survey Procedures §482.25(b)(8)

- *Is drug information readily available to nurses and practitioners, whether in hard copy or electronic format?*
- *If drug information is built in to the hospital’s EHR system, ask the pharmacy director how the hospital ensures that the information is accurate and up-to-date.*
- *Ask practitioners whether needed reference information is available to them when*

prescribing drugs.

- *Ask nursing staff whether needed reference information is available to them when administering drugs or biologicals and when monitoring patients for effects of medication therapies.*

Draft CDC Guideline for Prescribing Opioids for Chronic Pain, 2016: Summary of Constituent Comments and CDC Response

Overview

CDC hosted two constituent engagement webinars on September 16 and 17, 2015 for comment on the Draft CDC Guideline for Prescribing Opioids for Chronic Pain, 2016. Approximately 765 people participated in the live webinars and over 1200 verbal and written comments were received during the webinars or via email until September 18, 2015. Constituents were able to hear about the scope, audience, and development process, and review the draft recommendation statements on the webinars. A summary of the problem, intended purpose and use, clinical practices addressed, and guideline development process was posted on the CDC Injury Center website at <http://www.cdc.gov/drugoverdose/prescribing/guideline.html>. Comments were received from physicians and other health care providers, pharmacists, professional organizations, pain advocacy organizations, state and local health departments, and patients.

CDC subject matter experts carefully reviewed each comment individually and considered modifications to the guideline document in response. Comments were categorized into themes which are presented below, with example comments highlighting each theme. Comments were diverse and have been organized by recommendation statement and consistent themes that emerged. This summary captures the larger constructive themes of the constituent's written comments, and is not inclusive of all the individual comments received. Similarly, this summary captures the more substantive edits made to the guideline in response to constituent engagement and is not inclusive of all the edits made. The summary reflects edits made after all constituent comments were reviewed and feedback from CDC clearance reviewers on the revision was received. CDC thanks participating constituents for providing comments that will improve the quality, credibility, and implementability of the recommendations for opioid prescribing.

Comments about Specific Recommendations

Determining when to initiate or continue opioids for chronic pain outside end-of-life care

- 1. Non-pharmacologic therapy and non-opioid pharmacologic therapy are preferred for chronic pain. Providers should only consider adding opioid therapy if expected benefits for both pain and function are anticipated to outweigh risks.**

Theme 1a: Reduced access

Questions about whether this will limit or reduce access to opioids for people for whom they are needed and effective.

- *...The only treatment left for me is pain medication. Please don't tie [physician's] hands for this treatment as it's all I have left.*
- *There is no way I could live without my medicine for pain...I've tried many times to get off of it, but no other medication works as well to give me quality of life.*
- *Opioids may not be the "preferred" treatment for chronic pain conditions, but for some of us, opioids are the only effective treatment currently available.*
- *Chronic pain patients don't deserve this. If painkillers get taken away from us suicide rates will [go] up.*

Theme 1b: Details on non-pharmacologic therapies

List non-pharmacological therapies and provide information on efficacy and evidence of these therapies.

- *Do you plan list common non opioid and non-pharma therapies?*

- *What do you mean by non-pharmacological therapy?*
- *Specific non-pharmacologic therapies that have shown benefit for chronic pain could be suggested.*
- *List non-opioid pharma therapy and maybe efficacy of these agents if available.*
- *Include in the recommendation to include behavioral health in the treatment of complex pain.*

Theme 1c: Limitations to non-pharmacologic/non-opioid pharmacologic therapy

Addresses barriers to non-pharmacologic therapy (e.g., cost, insurance reimbursement, and access) or limitations of non-opioid pharmacologic therapy (e.g., inability to take NSAIDs).

- *Non-pharmacological therapies are not accessible to all—many are not paid for by insurers.*
- *Insurance companies often do not pay for other than pharmacological therapies.*
- *Reimbursement needs to be addressed.*
- *I would suggest that insurance companies or payers be encouraged to pay for non-pharmacological therapy and include psychological/behavioral strategies.*
- *Many patients cannot take NSAIDs due to gastric issues or being on blood thinners, etc.*
- *It often takes weeks, if not months, for non-pharmacological therapy (and especially non-opioid therapy) to reduce pain to the point where a patient who might need opioids does not any more.*
- *Inappropriately endorses all non-opioid analgesics over opioids. For example, you would not recommend prescribing an NSAID to a patient with renal insufficiency, and hemophiliacs should never receive aspirin or NSAIDs because of bleeding risk...This might be better stated as: “Opioid analgesia may be a consideration for patients in whom non-opioid analgesics are clinically contraindicated.”*

Theme 1d: Details on risks and benefits

Define risks and benefits and explain methods for evaluating.

- *Benefits > risks is rather subjective and in the eye of the beholder. Can CDC provide more specifics?*
- *No mention of recommended methods to evaluate risk of opioids.*
- *Exactly where is the risk/benefit list coming from?*
- *May consider inclusion of specific recommended tools for evaluation of opioid use risk vs. benefits.*

Theme 1e: Opioids if other treatment fails

Add to the recommendation that opioids should be considered if non-pharmacologic therapy and non-opioid pharmacologic therapy is ineffective.

- *Suggest changing ‘are preferred’ to ‘should be tried first’.*
- *...Alternative therapies exhausted prior to starting opioid therapy.*
- *It may not be appropriate to try every non-pharmacologic or non-opioid approach first, depending on the severity and progression of pain.*
- *Including that opiates should be considered after non-opioid options have failed?*

Theme 1f: Agreement

General statements of support for this recommendation.

- *Agree with Draft Recommendation 1.*
- *This is good as it follows the World Health Organization analgesia treatment ladder.*

CDC Response

- *CDC edited the guideline to further clarify that the risks discussed are risks to the patient specifically, provide definitions of chronic pain and long-term opioid therapy, review the evidence of the effectiveness of opioids in improving pain and function for specific conditions such as low back*

pain and fibromyalgia, provide additional information on multimodal and multidisciplinary strategies, discuss barriers to treatment such as insurance coverage and cost, and specify preferences for use of non-opioid pharmacologic therapy and non-pharmacologic therapy in combination with opioid therapy when opioid therapy is used. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., types of pharmacologic and non-pharmacologic treatments including cognitive behavioral therapy, exercise therapy, and interventional treatments; risks of alternative treatments including the risks for heart attack and stroke with NSAIDs; and evaluation of risks and benefits including improvements in pain or function and risks of abuse, dependence, overdose, and myocardial infarction).

2. Before starting long-term opioid therapy, providers should establish treatment goals with all patients, including realistic goals for pain and function. Providers should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety.

Theme 2a: Details on meaningful improvement

Define meaningful improvement and provide information on measurement (e.g., criteria, frequency).

- *Can you define clinically meaningful improvement?*
- *Make sure that clinically meaningful improvement is defined including specific criteria.*
- *Please provide suggested time intervals for evaluation of clinically meaningful improvement.*
- *This guideline is fundamental to attaining any meaningful measure of improvement in this inherently subjective issue of pain. Patients too often have unrealistic expectations of their medications, and providers use medications without considering the long term goals of therapy.*

Theme 2b: Details on measuring treatment goals

Provide information and tools on measuring function.

- *It would be helpful if the CDC would recommend specific functional scales.*
- *How will function be assessed, monitored, and reported?*
- *What are monitoring and/or auditing criteria once treatment goals are established?*
- *Need to recommend instruments for measuring pain and function.*
- *Inclusion of examples of functional assessment/screening tools to track progress.*

Theme 2c: Emphasis on function

Place more emphasis on, or sole emphasis on, clinically meaningful improvement in function over pain.

- *It is important to clarify that the goal of therapy should be limited to significant improvement in functioning, not pain. Pain as a goal, or endpoint, is too broad and would not limit the current over-utilization of opioid pain medicines.*
- *Pain scale should be removed as a judge of pain when weighing pain and function in this process.*
- *I think the ordering of the goals should be changed to function and pain, to emphasize that function is the primary measurable objective.*
- *Would remove pain from the last sentence.*
- *I don't believe it's reasonable or objective have pain as a goal or measurable for improvements. We really should only be considering function. Pain improvement will follow function.*

Theme 2d: Emphasis on pain

Comments highlight the need to address pain.

- *I believe that keeping pain and function at baseline may be acceptable, not necessarily meaningful improvement in function as that may not be possible.*
- *Pain improvement needs to be [considered].*

- *Disagree with the comments that pain should not be measured. Function is important, but chronic pain can be a chronic disease it may not improve. These patients should not be denied treatment.*
- *Studies in general seem to indicate that there is no clinically significant improvement in function with chronic opioid therapy.*
- *Treatment goals to include decreased level of pain which should increase function. Please listen to the patient if they are still reporting pain, and refer to a pain specialist if uncomfortable about increasing dosage.*

Theme 2e: Patient-centered approach

Comments highlight the need to consider individualized history and treatment goals for each patient.

- *The treatment goals should be tailored to each individual's needs.*
- *This should be revised to be more patient-centered. Pain is a subjective matter and should be treated as such. Clinically meaningful needs to be determined in collaboration with the patient.*
- *Need to make sure you allow provider to take into considerations the patients past history and not assume that everyone starts baseline non-opioids.*
- *Recommendation does not acknowledge that there are patients who suffer from rare pain conditions who have already failed regular pain therapy may need to be treated by a pain specialist.*
- *This recommendation will be difficult if not impossible for those with impaired cognition and many elderly patients. There is no mention here of the role of family caregivers in the treatment goals discussion, and there should be a note of their importance for these patient populations.*

Theme 2f: Details on risk assessment

Provide more information about risk, including when and how to measure.

- *It would be helpful if the CDC would recommend specific risk assessment tools as part of the assessment process.*
- *Document in guideline what CDC would constitute risk.*
- *Would refer clinicians to available validated tools to assess risks of long-term opioid use.*
- *Should include performing a risk assessment prior to starting and periodically during opioid therapy.*

Theme 2g: Written agreement

Recommendation should require written agreement between patient and prescriber.

- *Contract or agreement terminology does not matter, what does matter is a written agreement between the patient and the prescriber. This should be signed by the patient.*
- *The most appropriate terminology/language should be used in the crafting of a written document between the patient and the prescriber. There should be a concerted effort to standardize such a document.*
- *This needs to be done through a pain contract which is signed by both patient and provider.*

CDC Response

- CDC edited the document to further clarify the use of treatment goals for patients already receiving opioids. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., definition of meaningful improvement being a 30% improvement in scores for both pain and function; measurement of treatment goals and use of validated instruments to track patient outcomes such as the "Pain average, interference with Enjoyment of life, and interference with General activity" – PEG – assessment scale; emphasis on both pain and function; and guidance indicating that studies on available risk assessment instruments are sparse with inconsistent results so it is very difficult for providers to predict whether benefits of opioids for chronic pain will outweigh risks of ongoing treatment for individual patients).

3. Before starting and periodically during opioid therapy, providers should discuss with patients risks and realistic benefits of opioid therapy and patient and provider responsibilities for managing therapy.

Theme 3a: Tools on risks/benefits

Provide prescribers tools to discuss risks and realistic benefits with patients.

- *Does the guideline provide advice and/or specific tools on how discussion with patients re: risks and realistic benefits can be put into practice?*
- *Would be helpful to have “Comments for Discussing Opioids with Patients” in the appendix.*
- *Can this then include “risks” printed given that I could then use to show a printed remark to a patient?*
- *Would recommend more specific CDC-developed education regarding opioid risks.*
- *This is helpful as part of standard therapy for any chronic condition to evaluate what the benefits versus risks of treatment. Useful resources for help in guiding discussion about specific harms versus potential benefits would help providers follow this guideline better.*

Theme 3b: Written documentation

Recommendation should include written documentation of provider-patient discussion.

- *Add patient should have full understanding of likely risks and benefits of opioids...this should be documented in easily-understood and mutually-agreed upon informed/written consent.*
- *Should mention the use of an opioid treatment agreement between physician and patient.*
- *It would be optimal to incorporate written informed consent with attested education and a treatment/provider and patient responsibilities contract.*
- *Should discuss with [patient] and record in writing.*
- *A national uniform contract would be helpful.*
- *Providers should discuss and document their discussion and outcome of discussion in office notes. Documentation in office notes allows for accountability of both parties.*

Theme 3c: Realistic benefits

Recommendation should focus realistic benefits on function over pain.

- *“Opioid medications are to improve your functioning and not to necessarily remove all pain.” I tell them that this is to decrease pain to manageable and able to live with some pain. Pain will always be with us in many cases regardless of medications.*
- *With minimal evidence for benefit > risk, what will be said about benefits?*
- *Realistic benefits should qualify that pain cannot be eliminated, usually only 30% improvement and should focus on functional improvement.*
- *Note that the emphasis should be on function and be realistic that opioids cannot eliminate pain.*

Theme 3e: Patient-centered approach

Comments highlight the importance of focusing on individual patient’s treatment goals.

- *Who decides on the benefits of the therapy doctor or patient? It should be based on patient’s belief if it helps.*
- *The benefit is up to the patient and not the doctor.*
- *This should also consider the patient’s health beliefs.*
- *The patient-centered piece is not stressed; the patient’s expectation should be realistically addressed.*
- *We need to make sure that during the reviews that patients who are determined to need opioid medications are not treated with bias. Pain relief and increase function are indicators that are equally important. The patient needs to feel respected in these discussions.*

Theme 3f: Clarify periodically

Clarify and provide more details about “periodically.”

- *At what intervals are more extensive medical assessments indicated?*
- *Need to be clearer on what is meant by periodically and risks/benefits need to be developed so that providers are clear and consistent.*
- *Seems too vague. It should give specific intervals for pain contract.*
- *Please provide suggested time intervals/ranges for providers “periodically” discussing risks and realistic benefits with patients.*

CDC Response

- CDC edited the document to further include information about strategies to address common adverse effects such as constipation. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on how to talk to patients about benefits and risks of opioids and planned use of precautions to reduce risks; the importance of meaningful communication with patients over just documentation; and time intervals for evaluation of benefits and risks). CDC will also develop translation tools to accompany the guideline to assist with managing opioid therapy with patients.

Opioid selection, dosage, duration, follow-up, and discontinuation

4. When starting opioid therapy, providers should prescribe short-acting opioids instead of extended-release/long-acting opioids.

Theme 4a: Details on transition

Provide details on transitioning patients from short-acting to extended-release/long-acting opioids.

- *Would be nice if document outlines amount of time before changing from short-acting to long-acting therapy.*
- *Provide guidance on how long to keep a patient on short-acting opioids before switch to ER/LA opioids*
- *Consider patients who have already been on short-acting and assist providers in knowing when it is appropriate for long-acting.*

Theme 4b: Patient-centered approach

Requests to allow provider flexibility in decision-making for individual patient situations.

- *Please include some room for clinical care consideration and clinical uncertainty. This is an extremely restrictive recommendation.*
- *Would add ‘in most cases’ because everything should be dependent on the situation.*
- *With the low level of evidence available, it seems that the prescriber is in the best position to make this decision based on the patient’s circumstances.*
- *Consideration for patients in constant pain such as sleep-depriving maladies, should be considered on a case-by-case basis.*
- *This statement seems to be more relevant to non-cancer pain; cancer patients benefit from LA and this distinction would be relevant.*
- *Please advise/discuss when a long-acting opioid may be appropriate for trial over short-acting opioids due to certain factors.*

Theme 4c: Strengthen

Strengthen the recommendation against using extended-release/long-acting opioids.

- *Long-acting should be avoided whenever possible in non-cancer pain.*
- *Need to keep recommendations against or even strengthen recommendations against extended-release opioids*
- *Long-acting extended-release opioids are not useful in acute pain and while they may help in chronic pain, patients must be opioid tolerant to truly benefit from their use.*

Theme 4d: Against short-acting opioids

Comments regarding efficacy of short-acting or similar/greater risks of extended-release/long-acting.

- *Short-acting opioids should not be prescribed on a chronic basis.*
- *Poorly treated acute pain can result in engrained pain signal in nerve path which cannot be reverted...starting with low dose long-action would be appropriate.*
- *Opioid treatment IR or ER pose same risks.*
- *Pharmacologically and pharmacokinetically, not necessarily. Individuals at risk for addiction typically get a larger dopamine surge from IR versus ER.*
- *Short-acting opioids simply mean that many patients will have to take more pills to get through a tough pain period. This seems a little contradictory to your goals.*
- *Short-acting medications allow for more cycles of pain, which wear down a patient's resilience and strength. ER and LA allow patients to rest.*

CDC Response

- CDC edited the document to further clarify the applicability of the recommendation for opioid therapy for chronic pain (i.e., how it applies to both patients starting and continuing opioid therapy), add information about FDA labeling and communication about use of ER/LA opioids, and include information about abuse-deterrent technologies. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on use of and transitions between short-acting and extended-release formulations).

- 5. When opioids are started, providers should prescribe the lowest possible effective dosage. Providers should implement additional precautions when increasing dosage to ≥ 50 MME/day and should avoid increasing dosages to ≥ 90 MME/day.**

Theme 5a: Patient-centered approach

Comments highlight the need to consider individual patient needs and specific conditions (e.g., metabolic disorders, cancer, and genetics).

- *Concerned about the role of genetic metabolites is not considered here and doesn't consider cancer pain.*
- *Patients with metabolic issues might need a higher dosage.*
- *There should be no upper limits as it is all individual, based on genetics.*
- *All relevant to the patient's condition and treatment goals.*
- *It fails to take into consideration individual variability in opioid responsiveness.*
- *For legitimate, compliant pain patients...this is a sentence to increased disability and pain and even suicide.*

Theme 5b: Comments on specific dosages referenced

Comments raised with regard to specific dosages and/or processes for deriving them.

- *There is no “hard” inflection point of daily dose versus risk. The language of this recommendation must be adjusted accordingly.*
- *Having exact numbers limits prescribing.*
- *Humans process medications differently. Putting limits in milligrams is unacceptable.*
- *Part of the problem with various currently available guidelines is precisely the lack of dose limits, which makes it very difficult for managed care institutions to implement quantity level limit criteria.*
- *This should be done on a case-by-case basis, not one size fits all. That’s why providers are seeing the patients as individuals.*
- *Setting dosage limits here that are inconsistent with other established guidelines may also create confusion and conflict.*
- *Dose limits are VERY important in guidelines; please do not remove.*
- *As these guidelines are directed at primary care, it is presumed this would be the threshold level to refer to a pain specialist. Good for business but this will possibly create a barrier to access.*

Theme 5c: Details on specific dosage limit

Provide more information about the specific limits in this recommendation (e.g., evidence, difference from existing guidelines).

- *VA and Department of Defense guidelines have used 45mg and 100mg as opposed to 50mg and 90mg respectively. What is the evidence behind these doses?*
- *Some previous recommendations have mentioned 100 or 120 mg per day in morphine equivalents as a “conventional” maximum.*
- *Specify evidence for the 90 mg/d upper limit—this is low for patients with severe pain regardless of etiology (i.e., cancer or non-cancer [pain]).*
- *Note that the Washington State MED was 120 and recently reduced to 80. Again what is the evidence?*

Theme 5d: Guidance on titrating dose

Provide guidance on titrating patients’ dosage.

- *Should include how long to wait before considering increasing the dose.*
- *Please include titration guidance.*
- *Should also include by what percent a dose should be increased each time.*
- *Need to provide guidance on proper assessment of opioid withdrawal.*

Theme 5e: Guidance for need > 90 MME/day patients

Provide guidance on what to do with patients currently > 90 MME/day.

- *Needs to provide what other options are available if dosages are needed above 90 morphine equivalents.*
- *What do providers do if these doses are reached?*
- *Add what are options if patient is at or above 90 mg including referral to specialist, increased monitoring, tapering off opioids.*
- *May want an additional recommendation or comment for patients who are already above 90 MME and what should be done in those situations (recommendations about counseling about high dose and immediate tapering).*
- *Add that patients receiving higher dosages should be weaned to lower dosages, with close support and supervision from the prescriber or another appropriate member of the treatment team, such as a clinical pharmacist.*

Theme 5f: Guidance on MME conversion

Provide guidance on MME conversion.

- *Prescribers need established and evidence-based morphine equivalent guidelines in order to follow this guideline*
- *Table with ME for other opioids would make this much more usable. Oral morphine thought to be poorly absorbed so chart of MME would be helpful.*
- *Is the CDC going to issue recommendations on MED calculations for medications like methadone that have a variety of recommendations?*

5g: Define additional precautions

Clarify what “additional precautions” are recommended.

- *Suggest further definition of “implement additional precautions.”*
- *The document should express what additional precautions would be, if possible.*
- *What is meant by additional precautions? Naloxone?*

CDC Response

- CDC edited the document to further clarify that caution should be used when prescribing opioids at any dosage, recommend that dosage be increased by the smallest practical amount, recommend re-evaluation of patients after increasing dosage, and add information about importance of compliance with state requirements for clinical protocols at specific dosage levels. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., information about decision-making for dosage threshold, information about state policies with different limits, titration guidance and resources, and defining additional precautions).

- 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, providers should prescribe the lowest effective dose of short-acting opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three or fewer days will usually be sufficient for non-traumatic pain not related to major surgery.**

Theme 6a: Comments on duration

Comments specific to the reference of three or fewer days as usually sufficient for non-traumatic pain.

- *The recommended duration of 3 days would be too short for many medical illnesses, often requiring hospitalization, for which major surgery is not indicated.*
- *This is a well stated recommendation. Agree.*
- *The recommendation of 3 or fewer days will barely get patients through a weekend, and they will end up in the emergency department.*
- *Agree with 3 or fewer days but when necessary amount and duration should be tied to anticipated tissue recovery.*
- *Maybe more like a 5-7 day supply for a short duration for non-traumatic pain. If patient needs further evaluation they often do not have access to that evaluation within 3 days.*
- *Most acute pain situations take more than three days to resolve. To prevent the onset of Centralized Pain Syndrome acute pain must be treated quickly and adequately.*
- *I strongly support and agree with a supply for “three or fewer days” of opioid use for non-traumatic pain not related to major surgery. Thank you.*

Theme 6b: Evidence for three days

Provide evidence supporting recommendation of three or fewer days

- *Want to see the evidence supporting this 3 day limit as it relates to specific medical conditions.*
- *I would be interested in knowing the background evidence for three or fewer days use and not longer.*

- Overall, important concept for all providers to realize and discuss with patients. Additional recommendations for time course of typical acute traumatic injuries would be helpful (if such data exists). ...Evidence showing shorter duration would help support this guideline.
- Question the limitation of three days, since it seems arbitrary. It is important for the guidelines to share the empirical basis or research that supports the three day limit.

Theme 6c: Patient-centered approach

Concerns this recommendation does not consider individual patient needs and specific conditions

- Pain is individualized, so a three day limit except for major surgery, fails to recognize this and undertreated pain could lead to a chronic condition.
- This is not sufficient for sickle cell patients who have both acute and chronic pain. Also, their pain is non-traumatic and may often last more than 3 days.
- Too many patients are being summed up as if they are not individualized. Treatment needs to be specific to individual patients and account for metabolism and severity of condition as well as history with opioids.
- The capping of dose and duration are based upon group mean population statistics, not individual need. Therefore flexibility must be given to patients who fall outside these group parameters.

Theme 6d: Increases barriers

Questions whether this will increase barriers to accessing treatment (e.g., emergency department wait times, insurance reimbursement).

- This will have major implications for follow up in emergency rooms and primary care and may decrease access and increase wait times.
- Be aware that a three day timeframe will be fodder for insurance company and utilization review denial. I agree with the general application...but offer caution for the unintended consequences.
- If too few prescribed these are the patients that end up in the emergency rooms suffering from poor relief, such events become costly and are not necessary if done correctly.

Theme 6e: Define lowest effective dose

Provide more information about lowest effective dose and how it is determined.

- Who determines lowest effective dose?
- Determining lowest effective dose is significant challenge giving varying individual responses to opioids.

CDC Response

- CDC edited the document to further clarify the applicability to outpatient settings, provide a definition for acute pain, and add guidance on determining the lowest effective dose. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., rationale for three day default for most nontraumatic pain not related to major surgery).

- 7. Providers should evaluate patients within 1 to 4 weeks of starting long-term opioid therapy or of dose escalation to assess benefits and harms of continued opioid therapy. Providers should evaluate patients receiving long-term opioid therapy every 3 months or more frequently for benefits and harms of continued opioid therapy. If benefits do not outweigh harms of continued opioid therapy, providers should work with patients to reduce opioid dosage and to discontinue opioids when possible.**

Theme 7a: Details about patient evaluation

Provide more information about patient evaluation, including how to evaluate and at what frequency, and for risk/benefit assessment tools.

- *What constitutes a good evaluation should be described.*
- *Evaluate how? In person? Over the phone? Virtually? Are nurses or other medical staff allowed to gather evaluation data from patient for provider review or must it be done only by the prescribing provider?*
- *How is the provider supposed to determine whether benefits outweigh harms? Is there an algorithm or some other standard way to do that?*
- *Need to define benefit vs. harm*
- *An opportunity to provide guidance about how to evaluate risks and benefits.*

Theme 7b: Focus on function

Recommendation should focus patient evaluation on function.

- *Assessment of function language will likely be important to add.*
- *Use objective measures of function rather than some vague number of complaint.*
- *Emphasize that function should be tracked and documented because it is more objective.*

Theme 7c: Three months too long

Recommendation should require evaluation more frequently than every three months.

- *Evaluation could possibly be more frequent than every 3 months.*
- *Please review the evidence about the 90-day cliff (i.e., patients taking chronic opioids > 90 days are at much higher risk of addiction so 90 days should be avoided). This frequency of re-evaluation would not allow mitigation of this 90-day chronic use situation.*
- *Recommend that follow on period be reduced to 1 month to ensure close monitoring of improvements in pain and function. Three months perpetuate problem of tracking improvement.*

Theme 7d: Patient-centered approach

Highlights importance of individual patient needs and specific conditions.

- *Consideration needs to be made for patients who live at a distance from their healthcare provider.*
- *Should not apply to cancer patients, even if not end of life. Bone and metastatic breast cancer patients may live a long time in agony.*
- *Many patients with chronic pain are treated successfully with opioids and never develop addiction. It is inappropriate to advocate withdrawing and limiting effective treatment for such patients.*

Theme 7e: Resources on tapering

Provide resources on tapering therapy and more information on discontinuing opioids.

- *Is the CDC going to issue recommendations on opioid weaning, including prescriber tools...and patient materials to help with coping?*
- *Be mindful of the general lack of resources for assisting patients to discontinue therapy.*
- *Resources to help with weaning patients off opioids would be helpful.*
- *A recommendation(s) on how to discontinue chronic opioids should be included.*
- *When a patient cannot continue opioid therapy, an alternative treatment plan should be developed between the provider and patient. This is where insurers are significantly lacking in stepping forward to cover this gap where patients may turn to heroin or other illegal drugs in attempting to manage their chronic pain.*

CDC Response

- *CDC edited the document to further clarify the focus on opioid therapy for chronic pain, specify regular assessment of all patients receiving long-term opioid therapy, note the potential for earlier*

follow-up to provide the greatest opportunity to prevent the development of opioid use disorder, and add guidance on use of virtual visits and follow-up. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., focus on function, use of assessment tools, and resources on tapering).

Assessing risk and addressing harms of opioid use

- 8. Before starting and periodically during continuation of opioid therapy, providers should evaluate risk factors for opioid-related harms. Providers should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid-related harms are present.**

Theme 8a: More on risk factors

Provide more details about risk factors for opioid-related harms, including assessment tools.

- *Provide specific examples of what risk factors for opioid related harms might be (alcohol use, benzos, previous addiction, etc.)*
- *The research is very definitive that a formalized risk assessment tool be used. Many physicians are assessing risk by “gut feelings” and these have been shown to be wrong a significant percentage of the time. This needs to be stronger in that a risk assessment should be formalized evidence-based tool.*
- *Experts need to give input as to what are risk factors to evaluate, perhaps give statistically valid tools, etc.*
- *Could include recommendation to use one of the standardized screening tools to assess risk for opioid abuse.*

Theme 8b: Tapering to mitigate risk

Recommendation should include require tapering when risk factors are present.

- *Should also include tapering/discontinuing the opioid in addition to offering naloxone.*
- *Consideration to non-opioid alternatives to avoid dependency, misuse, diversion. If risk is identified, weaning and discontinuing opioids.*
- *Anyone on opioids which are higher than new ceiling dosages then effort will be made to not abandon patient but to gradually taper dosage while offering non opioid therapies.*
- *If there is a patient at risk for overuse, reduction of opioid as in taper and referral to treatment may be needed.*

Theme 8c: Clarify offering naloxone

Provide more information and guidance about offering naloxone.

- *Please be much more specific in terms of this recommendation in relation to offering naloxone in treatment, this is especially in light of the increased cost of “abuse-resistant” opiates.*
- *If naloxone is specifically being recommended, it needs to be further elucidated the type of patients who need to be prescribed naloxone.*
- *Naloxone is only indicated if there is an assessed risk of overdose. It will not mitigate other opioid-related harms. The wording is misleading.*
- *Would be cautious because industry is likely pushing for [naloxone]; is there good evidence for it?*
- *Elaborate and clarify use of naloxone. This needs separate recommendation.*
- *This recommendation could be strengthened with additional guidance on selection of patients for consideration of naloxone prescribing.*

Theme 8d: Strengthen naloxone recommendation

Strengthen recommendation of providing naloxone to mitigate risk for opioid-related harm.

- *I recommend making the naloxone recommendation stronger. I would recommend that prescribers default to co-prescribing naloxone unless there's a good clinical reason not to.*
- *Naloxone can be considered whenever high dose opioid are prescribed- as a safety measure even for the household of a cancer patient- diversion followed by overdose can occur.*
- *Certainly co-prescription should be encouraged with any ER or high-dose opioid prescription.*
- *Make this stronger. High risk of diversion. Chronic pain scripts should always come with naloxone.*
- *Naloxone should be co-prescribed.*

CDC Response

- CDC edited the document to further clarify the time periods for evaluating risk factors and provide resources for prescribing naloxone in primary care settings. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., details about risk factors, use of assessment tools, and guidance on offering naloxone).

9. **Providers should review the patient's history of controlled substance prescriptions using state PDMP data to determine whether the patient is receiving excessive opioid dosages or dangerous combinations that put him/her at high risk for overdose. Providers should review PDMP data when starting opioid therapy and periodically during long-term opioid therapy (ranging from every prescription to every 3 months).**

Theme 9a: Mandated use

Make recommendation stronger to require PDMP review before every prescription.

- *PMP should be mandated!*
- *Should be consult the PDMP for every prescription not a range to every 3 months.*
- *PDMP data review before first prescription is written should be required. Ongoing review of PDMP data for every prescription should be required.*
- *Providers should be mandated to use state PMP data to prescribe opioid therapy.*

Theme 9b: State connections

Recommendation should encourage and support state interoperability or interstate access (e.g., data sharing, national PDMP).

- *One of the problems with PDMPs is the lack of coordination among states, including adjacent states. Does the CDC have plans to address that issue?*
- *Need national PDMP especially near state borders.*
- *Would be very useful to have the CDC create a national prescription drug monitoring program.*
- *Also, having inter-state access to prescription drug monitoring [program] should be mandatory, especially in areas like the mid-Atlantic region where states are smaller and closer together and patients can move from state to state easily.*
- *For patients and doctors who live in or practice in areas near state lines, both states' PDMPs should be checked.*

Theme 9c: Address limitations

Highlights existing limitations of PDMPs (e.g., not every state has PDMP, provider access, data not timely, data not complete, systems vulnerable to fraud, systems not user-friendly.)

- *Recommendations should be made about states that do not have state monitoring program. It is also difficult for monitoring close to state lines where patient can go between multiple states.*
- *Not all pharmacies are swift to report these types of prescriptions.*

- *Need to address issue of not all pharmacies are entering data into PMP especially when patients are paying cash for prescriptions.*
- *Our state does not have a Prescription Drug Monitoring Program, any other recommendations?*
- *CDC should recommend that entities other than physicians have access to the PDMP sites for each state (e.g., PBMs, third party workers comp administrators, and other authorized and appropriate organizations).*
- *Multiple and fake IDs make it difficult. Need access to state's driver's license database to validate ID.*
- *Recommendations for appropriate set up of PDMPs should be included to decrease variation and problems with the systems (updated data, ease of use).*

Theme 9d: Data interpretation

Provide guidance and tools on how to interpret PDMP data and clarify “excessive opioid dosages or dangerous combinations.”

- *Would mention that data indicates that > 4 or more prescribers/pharmacies in one year raises concern for doctor shopping.*
- *Would really like to know what is a “dangerous combination”? Currently some say benzo and opioid, or is it benzo, opioid, muscle relaxant, or what?*
- *If managed within a primary care office, there should not be multiple prescribers involved. The flag should go up if receiving from multiple providers.*

Theme 9e: Guidance if problem identified

Provide guidance on what a provider should do if a problem is identified during PDMP review.

- *Patients should not be given ultimatums that remove their access to opioid therapy if unable to attend recommended adjunct therapies due to cost prohibited issues.*
- *Guidelines could incorporate discussion on what physicians should do when they identify a patient with a potential substance use disorder, aside from not prescribing...CDC needs to start highlighting the need to address substance use disorder.*
- *This recommendation must further state that providers must be trained on evidence-based actions to take based on PDMP data. There are many examples of providers dropping patients who may have untreated pain or addiction problems. That is an inappropriate response, and that needs to be made clear.*
- *Recommendation should be included regarding appropriate use of PDMPs and not using data to automatically dismiss patients.*
- *PDMP results [should] not be misapplied to categorically deny or discontinue opioid prescribing for patients with records indicative of receipt of other controlled substances, including methadone for treatment of substance use disorders.*

CDC Response

- *CDC edited the document to further clarify checking of PDMP data when patients are receiving high dosages and the applicability of the recommendation for opioid therapy prescribed for chronic pain. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., information about state policies and accessibility, discussion of barriers, and guidance about interpreting PDMP data for clinical decision making).*

10. Providers should use urine drug testing before starting opioids for chronic pain and consider urine drug testing at least annually in all patients on long-term opioid therapy to assess for prescribed medications as well as other controlled substances and illicit drugs.

Theme 10a: Frequency based on risk

Revise recommendation to clarify that frequency of urine drug testing should be based on risk (e.g., increased risk, increased frequency).

- *That is not what evidence based studies have recommended. Should be more than one a year. Should be based on risk. High risk should be each time prescribed etc.*
- *Providers should consider evidence based guidelines and group patients by low, medium and hi risk and conduct drug screening based on risk level.*
- *The minimum frequency of required UDT is inconsistent with the PDMP requirement of 3 months. The latter should be extended to at least annually, with more frequent encouraged as clinically indicated.*
- *Recommend risk stratification for all patients, this will guide frequency of testing.*
- *At least annually but should clearly address/emphasize...the greater the real or perceived degree of risk the greater the frequency of UDS.*
- *UDS testing frequency should be adjusted for opioid risk factors, results of prior testing, adherence.*

Theme 10b: Type of testing

Provide details and guidance on which types of tests are recommended and effective.

- *UDT must be not only quick in house panel of enzyme testing but also alcohol metabolites and broad sensitive and specific tests such as liquid chromatography, mass spectroscopy for 150 agents.*
- *General testing for opioids does not test for all opioids (i.e., fentanyl, methadone, buprenorphine, oxycodone are examples of opiates that will not show as a positive in a general opioid screening).*
- *Are there any recommendations for measuring alcohol use that is not in most UDS?*
- *Needs to be more than just a dip stick, needs to be immunoassay, sent to lab. Dip sticks are not accurate and can be easily fooled.*
- *You need to be more specific about what urine drug testing screens are most appropriate as some antibiotics and other drugs can mimic opioids in the urine drug screen.*
- *Witnessed, chain of command, methodology used, substances tested for, normal values, etc. are all potential variables in the term "urine drug testing."*

Theme 10c: Guidance if problem identified

Provide guidance on what a provider should do if a problem is identified in urine drug test results.

- *The use of urine drug screens in gauging suitability for chronic opioid therapy is also complicated by the evolving legal landscape around medical and recreational marijuana, which should not be regarded as a contraindication for opioid therapy.*
- *Should be some mandate that a follow up test be done by outside lab for inappropriate testing outcomes.*
- *A statement of the obvious is implied, but should be stated: any patient who tests positive for illicit drugs should not be prescribed opioid analgesic therapy.*
- *If failed tests, MD should be required to take action for failed screens and non-compliance.*
- *Please include information about how to use the results of the testing to further define risks and care planning needs of the patients rather than defining the patient as non-compliant and breaching "pain contracts" resulting in a provider "firing" the patient.*

Theme 10d: Address barriers

Highlights barriers to urine drug testing (e.g., cost, transportation).

- *May create a severe burden on patients who do not easily have access to transportation, severely disabled, elderly or have absolutely no risk factors.*
- *Does the guideline describe specific facilitators and barriers to application of urine drug testing?*

- *Who is going to pay for all the drug testing? Pain patients don't have extra money for the testing, not on government help.*
- *These tests tend to be very expensive, and are sometimes not covered by insurance. The burden of these tests often then falls on patients, who may be unable to access needed opioid therapy because of inability to pay for drug tests.*

Theme 10e: Patient-centered approach

Stresses importance of individual patient needs and specific conditions.

- *Suggest including a comment about excluding certain populations.*
- *Should not apply to cancer patients. This urine testing adds to the stigma of pain management, for cancer patients.*
- *Does not take into consideration that all humans process medications differently. Many patients have been wrongly accused of drug diversion because prescribed drugs were not found upon urine testing.*
- *Shouldn't this be between the provider and patient?*

Theme 10f: Random testing

Recommendation should include that urine drug testing be random.

- *Should be randomly done during visits.*
- *Wording should include random urine drug testing.*
- *Needs to be done randomly by calling a person into the office.*

Theme 10g: Pill counts

Add to recommendation doing random pill counts.

- *A random pill count would be very beneficial as well.*
- *Further consider pill counts as part of monitoring use of medications to screen for overuse/abuse/diversion.*

CDC Response

- *CDC edited the document to further clarify guidance on random drug testing, burden for patients, inclusion of high risk patients, and testing of urine compared to saliva. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on types of testing, interpretation of findings, and how to use the findings in practice).*

11. Providers should avoid prescribing of opioid pain medication and benzodiazepines concurrently whenever possible.

Theme 11a: Other drug classes

Recommendation should include other classes of drugs that increase risk when combined with opioids (e.g., muscle relaxants, sedatives, hypnotics, sedative-hypnotics, CNS depressants, psychoactives, atypical antipsychotics, stimulants, OTC sleep medications).

- *Patients taking opioids with medications such as benzodiazepines and other sedative-hypnotics are at increased risk.*
- *Appreciate this recommendation that combination opioid-BZP use has higher risks than opioids alone. ...Recommend adding comment about combination opioid use with "muscle relaxant medications..." In fact the "trinity" of opioid + muscle relaxant + BZP is well known and of even greater risk. Please add information on use of muscle relaxant meds in combination with opioids.*
- *Include other drug interactions...with potential adverse effects.*

- *Should also refer to not prescribing additional opioids for pain in those receiving methadone or other opioid therapy for opioid dependence.*
- *Need to be more specific. May need additional resources to guide clinicians.*

Theme 11b: Patient-centered approach

Stresses importance of individual patient needs and specific conditions.

- *I disagree with opioid and benzo combo. I have GAD and severe pain. I was dropped from these meds cold turkey a year ago and find it hard to function.*
- *For those with anxiety disorders there is no reasoning for this.*
- *This should also be considered on a case-by-case basis as some conditions requires both types of medications.*
- *Long-acting benzos can be helpful when treating chronic pain who suffer from other symptoms along with pain.*
- *While there are risks...there are substantial benefits for some patients who are treated with...the long-acting benzodiazepine clonazepam...along with long-acting opioids for pain relief.*

Theme 11c: Coordinating care

Recommendation should encourage coordination of care with other prescribers.

- *So glad to see this recommendation. ...Make [prescribers] aware that patients may be receiving from more than 1 provider.*
- *Many times specialists place patients on one of these medications while primary care maybe using the other class of medication.*
- *Agree strongly. And find out why opioid or benzo—see under-treated anxiety.*
- *It may be important for physicians to coordinate patient care closely and check the state PDMP to avoid the concurrent prescribing of benzodiazepines and opioids.*
- *These medications may not be prescribed by the same provider. Word it so that it is clear that this has to do with any provider.*

Theme 11d: Patients on both

Provide guidance about what should be done for patients prescribed both opioid pain medication and benzodiazepines.

- *Fine to discourage initiation, but also important to acknowledge appropriately managed tapers for the many that already have co-prescriptions.*
- *Alternative therapies to replace the benzos?*
- *If benzodiazepine is required, mental health provider should be contacted to be in concurrence of both benzodiazepine and opioid use.*
- *Providers should consider non-opioid alternatives for claimants that require other medications for anxiety, depression.*

Theme 11e: Alcohol

Recommendation should provide guidance about risk of alcohol use with opioid pain medication.

- *Could we include risk of alcohol?*
- *Alcohol use should be included in this list.*

Theme 11f: Explain risk

Recommendation should include description of risk and encourage patient education on risk.

- *It should be spelled out that risk increases with combined use of these agents.*
- *Patients should also be strongly counseled about the risks of these medications while on opioid therapy.*
- *Would strengthen this appropriate recommendation with “can result in death.”*

- *Add to this one “and without educating the patient about the dangers of taking these meds together.”*

CDC Response

- CDC edited the document to further clarify recommendations for circumstances when a patient is already receiving benzodiazepines. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., guidance on consultation with other providers, consideration of alcohol use, and patient education).

12. Providers should offer or arrange evidence-based treatment (usually opioid agonist treatment in combination with behavioral therapies) for patients with opioid use disorder.

Theme 12a: Expand opioid agonist treatment

Broaden recommendation beyond opioid agonist treatment to include medication-assisted treatment (e.g., naltrexone, Suboxone, buprenorphine).

- *Change “opioid agonist therapy” to “medication-assisted treatment” to include naltrexone when indicated.*
- *Is this medication-assisted treatment?*
- *Should say “medication-assisted treatment” in place of “opioid agonist treatment” as naltrexone is gathering an increasing evidence base and is an opioid antagonist rather than an opioid agonist.*

Theme 12b: Address barriers

Highlights existence of barriers to treatment (e.g., access, cost).

- *I completely agree however we have poor resources available to patients.*
- *There are no Suboxone clinics closer than 2 hours from where we live.*
- *Treating opioid use disorder may require certain state-specific certifications for treating substance abuse.*
- *Opioid agonist is very expensive [for] chronic pain patients without government assistance.*
- *Allow prescribing (following mandatory education) by all prescribing disciplines.*
- *Buprenorphine is cost prohibitive. Increasingly, patients have to pay out of pocket for these medications. Cost is a very important consideration.*
- *Urge CDC to recommend that all opioid prescribers obtain training and apply for a waiver to prescribe buprenorphine, particularly in light of well-documented treatment gaps.*

Theme 12c: Expand behavioral therapy

Broaden the recommendation around behavioral therapies (e.g., not just for patients with opioid use disorder).

- *This is critical as many PCP do not believe addiction is a chronic condition; very important to be part of initial opioid plan as long term use typically leads to this, most times unintended. Consider expounding information on brain disease of addiction.*
- *Behavioral therapy must be provided and should not be an option. Evidence-based practice requires all patients receive behavioral health as most have co-occurring disorders and should not be untreated during course of care.*
- *Cognitive behavior therapy is useful not just for those with opioid use disorder, but for anyone with chronic pain.*
- *Providers should offer or arrange evidence-based treatment in combination with behavioral therapies for all patients, not just those with opioid use disorder.*

Theme 12d: Guidance on discontinuing

Provide additional guidance on discontinuing opioids.

- *Add patients who are not adhering to treatment agreement or appear to be abusing opioids or other addictive substances should be strongly encouraged to accept linkage to alternative treatment including opioid replacement therapy.*
- *Opioid use disorder and concurrent chronic should only use non-opioid for pain and MAT then only for craving and not pain.*
- *Any recommendation to discontinue opioids due to safety concerns or concern for opioid use disorder should include a discussion of the potential risks of a patient transitioning themselves to non-prescription opioids including heroin. Patients with a diagnosis of opioid use disorder do need to be offered maintenance treatment with ORT such as methadone or Suboxone.*
- *Patients can be admitted for detox however there is no “bridge” for them from detox and their future.*
- *Consideration to functional restoration programs in conjunction with weaning or detox programs for patients on long term opioids.*

Theme 12e: Define opioid use disorder

Provide more information on opioid use disorder.

- *Please clarify opioid use disorder. All patients who use opioids are not addicts and don't have a mental health disorder.*
- *Given that these recommendations are for the general PCP, define opioid use disorder.*
- *The use of the term opioid use disorder is very vague. This term could apply to anyone taking prescribed opioids. The term addiction should be used.*
- *As written, the guideline does not convey its meaning to someone who is not already familiar with the language of pain management and addiction therapy specialists.*

CDC Response

- CDC edited the document to further clarify “opioid agonist treatment” by specifying medication-assisted treatment, clarify evidence for medication-assisted treatment and behavioral therapies, mention barriers such as insurance coverage and patient cost, and provide resources for information about evidence-based psychosocial treatment. In addition, please note that much of the requested information and/or suggestions for clarification received specific to this recommendation are already addressed within the supporting text in the full guideline document as a means for providing a rationale for this specific recommendation statement (e.g., definitions of medication-assisted treatment, behavioral therapy, and opioid use disorder, and guidance on opioid discontinuation).

General Comments

13. Guidelines methods and evidence

Theme 13a: Explain quality of evidence and strength of recommendation

Describe how quality of evidence and strength of recommendation relate.

- *Link between strong rec and low quality of evidence warrants comment.*
- *Eleven of the twelve recommendations are strong recommendations, yet all are based on low or very low quality evidence. It is impossible to know if this is appropriate without seeing the evidence.*
- *Strongly recommend that the CDC make clear that these guidelines should never preclude an individualized approach to meeting patients' legitimate needs. Any guideline with a “strong recommendation” should be downgraded when there is only “low quality evidence.”*

- *Please explain the classification schema GRADE, which separates ratings of recommendation from ratings of evidence (i.e., strong recommendation, weak evidence). This dichotomy seems irrational & allows for subjective, arbitrary conclusion.*
- *I really feel like most of these recommendations could be much stronger. To affect change we need to be stronger in our recommendations and guidelines.*
- *I heartily endorse in principle a guideline for pain management based on systematic review of the medical literature using the GRADE methodology.*

Theme 13b: Evidence review and data

Comments about the scientific evidence used to develop recommendations and potential limitations.

- *The systematic review is flawed...it reaches very different conclusions—in large part due to raising standards for inclusion of studies in the newer review to the point where no study of effectiveness or efficacy now met inclusion criteria.*
- *A wholesale adoption of guidelines that do not embody up-to-date, diverse medical perspectives could exacerbate the prescription drug abuse epidemic.*
- *Are there valid statistics indicating differences in opioid conversions by practitioner types, which may lead to situations of opioid overdose?*
- *Is CDC considering synthesizing literature studies on the efficacy (pain, function) of opioids for chronic non-cancer pain? Is CDC considering publishing a synthesis of risks of chronic opioid therapy (e.g. side effects, misuse, abuse, addiction, overdose)?*
- *Reassess evidence associated with current draft recommendations that may translate to unintended consequences resulting in increased burdens and poor outcomes for the patient with chronic pain.*
- *Request that the pain management guidelines be held to the same standard of evidence that other studies are; quotes there is no evidence that opiates are effective long term, but do you have evidence that acetaminophen, massage, or other treatments are effective long term? Without those studies, how can we deny opiate pain medication?*
- *Will CDC comment/describe evidence base for specific non-pharmacologic therapy and non-opioid pharmacologic therapy for chronic pain? I agree also that the evidence for chronic opioids for chronic pain is weak to non-existent. I suggest that this statement be made clearly in the recommendations!*

Theme 13c: Review and reconciliation with other guidelines

Complete a comparative examination of existing opioid prescribing guidelines for chronic pain (e.g., state guidelines, WHO, FDA).

- *CDC should review and consider the draft National Pain Strategy when making any determinations about opioid prescribing guidelines.*
- *FDA issued voluntary prescribing guidelines for long-acting opioids (opioid REMS). These guidelines were wholly inadequate, thus I strongly recommend that, to the extent that there is overlap between the two sets of guidelines, that CDC work with FDA to implement the new CDC guidelines...*
- *American Pain Association is working on some guidelines as well in this direction protecting interests of real pain patients and doctors who will like to appropriately treat pain. Really commend CDC in taking a good initial step in the right direction, against this huge epidemic killing many young ones.*
- *Concerned that, CDC draft guidelines inconsistent with established best practices, they will potentially make it difficult for patients who rely on them for pain control to access them from clinicians who are clear on how best to use them.*
- *Doesn't mention the World Health Organization 3-step ladder of treatment.*

Theme 13d: Peer review process

Comments about the inclusion and engagement of partners; qualification of reviewers; and transparency of the constituent engagement process.

- *Please make sure that your expert panel includes valuable representation.*

- *Share expert panel and conflict of interest (COI) statements before this is finalized; would like to see a listing of the names of expert panel involved.*
- *Are the state HDs considered Stakeholders for review purposes?*
- *We urge CDC to publish these recommendations in order to gain the broadest input and extend the comment period.*
- *Challenging to comment on guidelines without seeing the accompanying text or the evidence report.*
- *Pharmacists play a critical role in all facets of the chronic pain care management. It is important that pharmacists and other relevant health care professionals are included in the development, refinement, and finalization of the Guidelines.*

CDC Response

- CDC edited the document to further explain the GRADE approach, and revised terminology to be consistent with other CDC efforts; specifically, terminology used within recommendations issued by the Advisory Committee for Immunization Practices (ACIP). ACIP uses the GRADE approach, with terms that better organize the level of evidence and strength of recommendations.
- In this guideline, using the ACIP GRADE approach, CDC clarified that the body of evidence is categorized in a hierarchy. This hierarchy reflects degree of confidence had in the effect of a clinical action on health outcomes. The categories include the following types of evidence:
 - Type 1 evidence: randomized controlled trials, or over-whelming evidence from observational studies; equivalent to “high” quality evidence
 - Type 2 evidence: randomized controlled trials with important limitations, or exceptionally strong evidence from observational studies; equivalent to “moderate” quality evidence
 - Type 3 evidence: observational studies, or randomized controlled trials with notable limitations; equivalent to “low” quality evidence
 - Type 4 evidence: clinical experience and observations, observational studies with important limitations, or randomized controlled trials with several major limitations; equivalent to “very low” quality evidence
- The ACIP GRADE approach used in this guideline likewise presents recommendations in the following two categories:
 - Category A: recommendations: apply to all persons in a specified group and indicate that most patients should receive the recommended course of action (equivalent to a “strong” recommendation)
 - Category B recommendations: indicate that there should be individual decision making; different choices will be appropriate for different patients, such that providers must help patients arrive at a decision consistent with patient values and preferences, and specific clinical situations (equivalent to a “weak” recommendation)
- CDC clarified that Category A recommendations can be made based on type 3 or type 4 evidence when the advantages of a clinical action greatly outweigh the disadvantages based on a consideration of benefits and harms, values and preferences, and costs.
- CDC also added information about the quality of evidence for alternative treatments and medication-assisted treatment/psychosocial treatment for substance use disorder.
- Please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., detailed clinical and contextual evidence reviews; explanation of GRADE methodology; inclusion of names of core experts, stakeholders, federal partners, and peer reviewers; discussion of conflict of interest protocols for the core expert group; and consideration of other guidelines).
- The plan for constituent engagement, stakeholder review, and peer review was placed on the NCIPC Peer Review Agenda website prior to the constituent, stakeholder, and peer reviewer engagement (<http://www.cdc.gov/injury/fundedprograms/peerreview.html>). CDC posted a fact sheet on the

guideline and the clinical practices addressed within on the Injury Center website (<http://www.cdc.gov/drugoverdose/prescribing/guideline.html>).

14. Implementation and dissemination

Theme 14a: More provider education

Comprehensive prescriber/provider education is needed.

- *Any doctor prescribing pain medication should be trained in addiction—I have worked for over 20 years treating addiction in jail ... What I see is that Pain Management doctors often miss glaring indications of misuse, abuse and addiction.*
- *Recommend national educational goals for use of opioid pain relievers, both in the short term for current providers, and ongoing as part of continuing medical education.*
- *What the CDC should require as a first step is a requirement for a minimum number of hours of education/training/pain in medical, nursing, etc.*
- *Inform PCP to anticipate tolerance, dose escalation, and planning how to address long-term dependence.*

Theme 14b: Develop translation documents and evidence-based tools

Providers need practical tools to adopt guidelines; focusing on screening pain patients for risk factors, managing pain patients, and identifying when patients are abusing medications.

- *Many prescribers have no idea what evidence based measures they should be taking.*
- *An algorithm for prescribing opioids should be followed for function and observed pain only.*
- *You mention specifically morphine equivalents. Will there be published standard conversion ratios?*
- *Should include a hot line for providers to discuss cases with a qualified pain management doctor.*
- *Include what prescriber responsibilities are for management? Such as using PDMPs & checking UDS*
- *Facilitate screenings and referrals to high-quality, on-demand treatment for substance use disorders and commonly co-occurring conditions, such as HIV and hepatitis C.*
- *Recommend implementation of evidence-based practices when controlled medications are prescribed...treatment contracts, using an instrument such as the addiction behavior checklist.*
- *Please assist prescribers with a public information campaign to the public to assist this change in the prescribing environment.*

CDC Response

- CDC is dedicated to developing translation documents and evidence-based tools that will be disseminated after guideline publication and available on the Injury Center website. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., needs for education and mentions of available resources).

15. Health and psychological implications

Theme 15a: Stigma

Comments about treating/labeling opioid use as negative and the associated stigmatization, harassment, discrimination, and social bias.

- *Provide clarification and dispel myths, especially the false dichotomy of legitimate patients vs. abusers; all are patients and yes harm occurs in non-medical users but a clear acknowledgement that harm also occurs in medical users.*
- *The guidelines place the burden of proof on both the doctor and patient. If a patient has a chronic pain condition, they have to prove it to their physician. What it will do is further complicate proper and appropriate pain treatment options and negatively stigmatize the much larger group of people who rely on these medications.*

- *The risk for drug overdose by chronic pain sufferers is very low. Don't group chronic pain sufferers in with the abusers.*
- *Regarding comment re: "drug seeker"—Many are trying to treat their withdrawal symptoms; stigmatizing language.*
- *I have already been demonized by doctors, pharmacists, nurses etc. for taking narcotic painkillers.*
- *Chronic pain people are taking their own lives, since the medical governing boards have caused so many obstacles to obtaining relief.*

Theme 15b: Consequences of interfering with access

Comments about whether reducing access for those with legitimate need and denying care to people with chronic pain may lead to unnecessary suffering, depression, disability and even suicide.

- *Please do not make it more difficult for those of us who suffer daily pain to get proper medication so that we can function on daily basis, go to work, etc.*
- *Encourages CDC to adopt evidence-based best practices for the prescribing of controlled substance, which reflect the need to ensure that patients with legitimate need for controlled substances have access to their medications while reducing the risk of diversion, misuse, and abuse.*
- *People with severe chronic pain will be punished due to the actions of careless abusers. Institute a tougher monitoring plan, but please do not cause people like me to suffer even more. It would be inhumane.*
- *People who abuse prescription medications obtain them illegally (theft, black market, fraud). Hindering legitimate access to treatment will not prevent a single overdose, nor save a single life.*
- *Opioids are just one tool among many and discussions focused predominantly on restricting access reinforce the misconception that narcotics are the most important tool in the minds of both patients and health care professionals.*
- *Reevaluate what guidelines can be put into place to protect, not punish those of us who are responsible. While I agree that controlling the illegal distribution and recreational use of prescription medication is very important, our needs are also important.*

Theme 15c: Mental health and substance abuse

Address patients with co-occurring substance use disorders or other mental health disorders and their right to effective pain management, which may include chronic opioid therapy.

- *Consideration must be given to the potential for these guidelines to inadvertently discourage effective pain management strategies for people with substance use disorders, a vulnerable and often stigmatized population...CDC should therefore make an explicit statement against bias and stigma, and affirming the right to effective pain management for patients with substance use disorders.*
- *Recs are great but are not strong enough on mental health/comorbidities and should stress need to have psychologists/etc. to help.*
- *Chronic pain is a significant comorbidity for many people with substance use disorders, and under treatment of pain in this population may exacerbate substance use disorders or compromise effective treatment and recovery.*
- *Provide information on neurobiology of addiction. I work with PCP who are completely uninformed.*

CDC Response

- CDC considered comments about access and stigma in reviewing the framing and orientation of the guideline. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., effects of prescribing policies on access and existence of mental health conditions and other comorbidities).

16. Considerations for clinical decision-making and clinical care

Theme 16a: Patient-centered care and rare conditions

Take a patient-centered approach and consider specific medical conditions (e.g., rare pain disorders).

- *Your guidelines do not address chronic pain such as RSD/CRPS, Fibromyalgia, Rheumatoid Arthritis, etc. It is well documented that RSD/CRPS pain is rated higher on the McGill pain index than cancer pain yet you only mention cancer patients in your guidelines.*
- *I now suffer from Adhesive Arachnoiditis and the only quality of life I can muster relies on my access to opioid medications. Please reconsider these strict guidelines that are ONLY going to make life unlivable for legitimate, law-abiding citizens.*
- *I have autoimmune disorders, severe neuropathy, Stiff Person Syndrome and autonomic dysfunction. I do take tramadol to get me through the day but do keep hydrocodone on hand for very bad days.*
- *Would like to see a recommendation against treating chronic LBP, HA, and FMS in working aged adults with opioids.*

Theme 16b: Treatment planning and protocols

Multidisciplinary approach needed to provide useful and effective treatment interventions.

- *A strength to this guideline is that it strongly emphasizes the responsibility of clinicians to establish treatment goals and to weigh progress in relation to risks to patient safety. This basic philosophy is found throughout the summary and is commendable.*
- *Contract needs to be required when prescribing opioid therapy and should be reviewed throughout the course of treatment.*
- *Specify that all patients with chronic pain should be treated with multidisciplinary approaches targeted at simultaneously reducing pain severity and increasing physical and psychological functioning.*
- *Are there specific pain condition treatment plans in the pipeline (i.e. nociceptive, neuropathic, etc.)?*
- *Effective chronic pain care requires access to a wide range of treatment options, including biomedical, behavioral health and complementary treatment.*
- *Consider including a standalone recommendation to include behavioral health in the treatment of complex chronic pain.*

Theme 16c: Abuse-deterrent formulations

Include information on using abuse-deterrent formulations to reduce opiate prescriptions and overdoses.

- *Given the discussion around risk of addiction, consider adding in abuse-deterrent opioids as a benefit in the risk benefit assessment equation.*
- *Prescribe controlled substances with abuse-deterrent formulations to reduce the risk of diversion, misuse, and abuse.*
- *Encourage CDC to take into consideration impact that abuse deterrent opioids could have on abuse and diversion...Prescribers should be encouraged to prescribe the most abuse deterrent medicine that is appropriate for their patients.*
- *Providers who prescribe long-term opioid therapy should consider, as the first choice, an FDA approved opioid with abuse-deterrent properties described in the labeling*

Theme 16d: Doctor-patient relationship

Consider the competence of providers and the integrity of the doctor-patient relationship.

- *... I refill under my doctor's supervision. I am sure if he felt I was growing dependent or requesting refills too often, he would let me know. I think you need to TRUST the doctors' decisions. They are the experts when it comes to diagnosis and treatment.*
- *Please let doctors view their patients case by case and not force the doctors to have to withhold valuable much needed medication for us to survive. Is the CDC now going to do a study on how many*

of us will end up in divorce, death due to suicide, on street drugs ourselves, on welfare because we are bed bound and unable to care for our own families? This will all be due to loss of the meds.

- *Doctors should be allowed to determine best care for their patients -- How about you let physicians be physicians and choose the course of treatment they deem fit. Not long ago physicians were being sued for NOT controlling pain, now they are being dictated to for trying to relieve pain.*
- *We need to find a way to monitor writing habits more effectively. There are Drs out there who prescribe haphazardly.... who write scripts knowing they aren't needed. That should be stopped.*

CDC Response

- CDC edited the document to further clarify evidence and guidance about multimodal and multidisciplinary treatments and abuse-deterrent formulations. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within the supporting text in the full guideline document (e.g., applicability to common conditions; provider-patient relationship and communication strategies).

17. Suggested content

Theme 17a: Requests for clarification, explanation, or indications of uncertainty

Clarify meaning, provide rationalization, or explain intent within the content or supporting documentation for recommendations.

- *It was stated that guidance is for primary care physicians and not experienced pain specialists, but it needs to be made repeatedly clear in every recommendation. Otherwise, guidelines are likely to be misunderstood and misapplied.*
- *Clearly articulate intended population (e.g., that these guidelines do not pertain to patients receiving end-of-life care (palliative care)).*
- *There is no distinguishing between cancer and non-cancer chronic pain.*
- *Agree that these guidelines are generally appropriate for non-cancer related pain. However...pain should be treated according to its severity and impact on function and revised in observation of the outcomes of treatment. Contrasting cancer and non-cancer-related pain too starkly risks trivializing all chronic pain of non-cancer origin. Would take great care in wording related to this issue.*
- *Will document include background data explaining/defining expected benefits or anticipated risks?*
- *Use practitioners instead of the term providers.*
- *Delete "chronic" from the title of the guidance. Several of the guidelines pertain to treating acute pain instead or in addition to chronic pain (specifically, guideline #3, #4, #5, #6, #8, #9, #11 and #12). Clarify that the guidelines do not apply to chronic cancer pain, in addition to end-of-life care.*
- *The risk to whom? Does this include the risk to the prescriber of regulators who don't like professionals who prescribe opioids?*
- *Include a description of how to appropriately document the need for a guideline exception.*
- *Why is the target audience limited to Primary Care Providers? Should include all providers who prescribe. Excluding prescribers suggests they have 'carte blanche' to prescribe whatever they wish.*
- *Will CDC be recommending any monitoring by CMS, NCQA, JCAHO of following of these recommendations?*
- *At what point should a PCP refer to a Pain Specialist; how can a PCP determine which Pain Specialty providers are legit?*
- *Very important for patients to understand the risks and therefore mixed messages about 'safety/efficacy' should not in general be promoted.*
- *Is there an expected minimal medical exam and laboratory work up prior to initiating opiate therapy for chronic pain?*

Theme 17b: Suggested recommendations/other guidelines/regulation needs

Opioid prescribing practices, additional guidelines, necessary regulations, and recommendations statements for consideration.

- *Will there be guidelines for acute pain?*
- *This should be law to review before all prescriptions for controlled substances.*
- *Any chance that dispensing guidelines are going to be addressed also? As a pharmacist... there are no clear-cut guidelines other than our better judgment on how & when to dispense these medications.*
- *There needs to be better control over pain clinics.*
- *Consider including an additional recommendation to include that patient should be locked in to one opioid prescriber and one pharmacy.*
- *I would just like to emphasis the need and importance for robust guidelines that do take a stance on max dose/quantity etc. to help curb the current opioid epidemic.*
- *Would like to see an explicit recommendation against the use of Methadone.*
- *Add a recommendation to avoid administration of parenteral opioids for patients already on chronic opioids, especially in ED/Urgent Care settings.*
- *We believe that the guidelines should also include guidance on appropriate opioid prescribing of acute/chronic non-cancer, non-end of life pain for patients on methadone or buprenorphine therapy.*
- *Is there a plan for guidelines for pain specialists who follow people long term on opioid therapy?*
- *Chronic pain pathophysiology (nociceptive, neuropathic, and sensory hypersensitivity) should be assessed prior to selecting the appropriate first line pharmacologic and non-pharmacologic therapy.*
- *Add guideline that cautions against opioid analgesia for pregnant women. Pregnant women with a diagnosis of opioid abuse disorder should be treated consistently with guideline #12*
- *Does this include marijuana? How do we incorporate the use of marijuana in treatment safely?*

Theme 17c: Additional resources, data, and citations

Suggested research studies, guidelines, and evidence for consideration.

- *Take Massachusetts guidelines into consideration during its review process. The CDC guidelines comport to a large degree with the MMS guidelines with the exception ...the MMS guidelines do not apply to patients with cancer, patients in hospice or palliative care and inpatients of hospitals and nursing homes.*
- *VA Opioid Taper Guidelines*
- *[Current Access to Opioids—Survey of Chronic Pain Patients](#), Practical Pain Management, March 2014—Cited reasons for suicidal ideation were increased pain (100%) and opioid withdrawal (35.5%).*
- *Emergency department opioid prescribing guidelines adopted by Maryland Hospital Association.*
- *Please see CLAAD's National Strategy ...which has been vetted and endorsed by more than 30 not-for-profit health and safety organizations, as well as the recently published article: A Call for Differential Diagnosis of Non-Specific Low Back Pain To Reduce Opioid.*
- *Updated Medical Board of California guidelines represent more flexible and mindful approach*
- *Ziegler, S.J. (2015). The proliferation of dosage thresholds in opioid prescribing policies and their potential to increase pain and opioid-related mortality. Pain Medicine (accessible via Early View, first published online in advance of print: 27 JUN 2015 | DOI: 10.1111/pme.12815); October 2015 is anticipated hard copy issue.*

CDC Response

- *CDC edited the document to further clarify the scope and audience of the guideline and the patients to which it applies (excluding active cancer treatment, palliative care, and end-of-life care), provide definitions for terms (e.g., acute pain, chronic pain, long-term opioid therapy), and indicate that the guideline offers recommendations rather than prescriptive standards and that providers should consider the circumstances and unique needs of each patient. In addition, please note that much of the requested information and/or suggestions for clarification received are already addressed within*

the supporting text in the full guideline document (scope and audience of the guideline, policy considerations, and resources).



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Hospitals launch specialty pharmacies to curb drug costs

By [Melanie Evans](#) | December 12, 2015



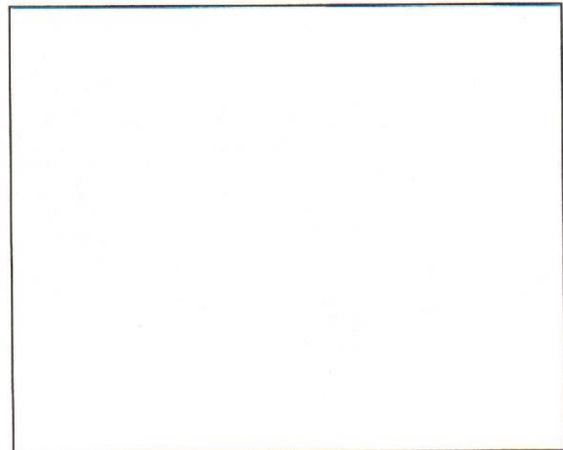
Banner Health spent \$1 million on a drug-dispensing robot for its specialty pharmacy's home-delivery service.

With specialty drug spending soaring 60% in the past five years, large [health systems](#)^[1] have

jumped into the specialty pharmacy business to assert some control over those costs by dispensing the drugs to their patients and covered employees.

Health systems say those pharmacies help them better manage outpatient drug costs. A growing number of insurance contracts and Medicare initiatives tie payments to quality metrics that reach beyond hospital stays to hold providers accountable for patients' total medical costs, including drugs.

It's also a robust business for those



systems that can successfully negotiate with manufacturers and health plans so they can compete with the bigger players.

“It you want us to be responsible for the total cost of care, allow us to be able to care comprehensively for these patients,” said Dick Schirber, a spokesman for ExceleraRx Corp., a for-profit specialty pharmacy services company owned by six health systems. Comprehensive care, Schirber said, includes managing the very expensive prescriptions that patients take at home for cancer or chronic diseases, so that providers have more control over waste as well as complications.

ExceleraRx provides services to system-owned specialty pharmacies, such as negotiating with drugmakers and handling data reporting.

Phoenix-based **Banner Health**^[2] started its own specialty pharmacy last year, taking its business away from Premier, which acquired Commcare Specialty Pharmacy in 2010 for \$35.9 million.

Banner employees enrolled in the system's health plan were the pharmacy's first customers.

“For everyone, everywhere, the pharmacy expense is increasing,” said Pam Nenaber, Banner's CEO of **pharmaceutical**^[3] operations.

Banner Health hired three clinical pharmacists, three patient advocates and three staff members to support operations. The system also spent \$1 million on a drug-dispensing robot for the specialty pharmacy's new home-delivery service. The robot fills pill bottles, which are verified by a pharmacist before being shipped. Clinical pharmacists also talk to patients at home to answer prescription questions.

In the first year, Banner shaved about 1% off its specialty drug spending for about 1,200 workers and their families covered by the system's employee health plan.



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Health systems think they can do a better job managing specialty drug costs if they're the ones selling them, but they'll have to learn how to compete with big players like CVS.

Health systems that own specialty pharmacies argue they can do a better job overseeing the use of the drugs they dispense. That's because their pharmacies can easily access medical records, laboratory results and physician notes, allowing pharmacists to closely monitor the effectiveness of the drugs prescribed and react quickly when something goes wrong or patients need help.

"They know if the patient is getting the value for the high-cost drug," said Steven Rough, director of pharmacy for the University of Wisconsin Hospital and Clinics, which began handling transplant drugs in 2006 and expanded its specialty pharmacy in 2011.

Launching a specialty pharmacy does not require significant capital investment, and the high prices of the drugs—even sold at slim margins—make it possible to quickly see a return on that investment.

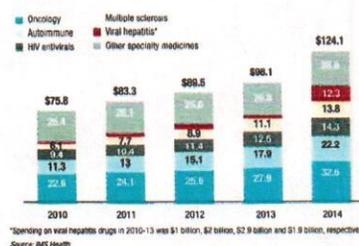
"It's a quite viable business," said Scott Knoer, chief pharmacy officer at the **Cleveland Clinic**^[4], which opened its specialty pharmacy roughly a year ago, and advises other systems to do the same. "Get on it and get on it fast," he said.

The Cleveland Clinic estimates it will recoup its upfront investment from the specialty pharmacy's profits within 16 months of opening.

That's true even as the Ohio health system expands its operations. The pharmacy is hiring more staff because the volume of prescriptions has increased about 10% a month. It now employs 25 workers, and that number is expected to reach 66 employees within three years.

New drugs last year boosted spending for specialty pharmaceuticals 25% over the prior year, IMS Health reported in April. Specialty drugs to treat diseases such as cancer, multiple sclerosis and hepatitis C now account for one-third of drug spending. Sovaldi and other new treatments for hepatitis C boosted spending by \$12.3 billion, IMS said.

The surge in specialty drug spending
Spending in billions



Pharmaceuticals still account for just 10% of U.S. healthcare spending, but a 12.3% surge in 2014—including \$12.6 billion spent on new specialty drugs to treat hepatitis C—contributed to the year's uptick from the record-slow health spending that started with the Great Recession.

That growth makes dispensing specialty drugs an increasingly important piece of healthcare delivery, as well as an attractive business line, said John Ransom, a managing director of healthcare research at Raymond James. "It's riding the wave of where the innovation is," he said.

But systems will face fierce competition as they try to ride that wave, Ransom said. "It can be a tough business."

They will have to vie with national pharmacies like CVS Health, Express Scripts and Diplomat Pharmacy to be included in health insurance networks. CVS and Express Scripts also own [pharmacy benefit-management companies](#)^[5], so they "have a vested interest in limiting the network of specialty pharmacies because they are specialty pharmacies," Ransom said.

Pharmaceutical manufacturers also limit shipping of some of their drugs to a handful of pharmacies, in what are called limited-distribution networks.

Getting a spot in drug manufacturers' limited networks requires intense negotiation, and the capacity to report quality and use data back to drugmakers.

ExceleraRx, launched in 2012 with investment from Minneapolis-based Fairview Health Services, helps its owners and clients with those tasks. Englewood, Colo.-based Catholic Health Initiatives, which opened its own specialty pharmacies in Kentucky and Nebraska last year, invested in ExceleraRx to "supercharge" the new business line, said Nick Barto, the health system's senior vice president for capital finance.

However, another danger for providers is that patients may begin to see them as "the organization that's providing the drugs that you can't afford," said Benjamin Isgur, director of thought leadership at PriceWaterhouseCoopers' Health Research Institute.

But health system executives say they've hired staff to help patients identify discounts, coupons and other financial aid for drug costs not covered by insurance. And health systems can further market their independence from shareholders and the pharmaceutical industry.

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