Medication Safety Committee Meeting

July 11, 2018

California Hospital Association - Boardroom

1215 K Street, Ste 800

Sacramento, CA, 95814

Conference Call Option: 800-882-3610 Passcode: 4206832#

Meeting Book - Medication Safety Committee Meeting

AGENDA - July 11, 2018

Narcotic Inventory Reconciliation Regulations Page 271
Candace Fong

Nursing and Sterile Compounding Page 272
BJ Bartleson/Janette Wackerly

1:00 STANDING REPORTS

Board of Pharmacy
Herold

California Department of Public Health (CDPH)
Lee/Woo

California Society of Health-System Pharmacists (CSHP)
DeMartini

Association of California Nurse Leaders (ACNL)
Tomasi

CHPSO
Jaffe

California Association of Health Facilities (CAHF)

1:45 OTHER BUSINESS
All

NEXT MEETING

Wednesday, October 10, 2018

2:00 ADJOURNMENT
Hanni

CHA MEDICATION SAFETY COMMITTEE
2018 ROSTER

Officers

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Medication Safety Committee
Hospital Representation

BY COUNTY

As of July 2, 2018

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

HOSPITAL MEMBERS		
Contact	**Represented Organization**	**County**
Amy Gutierrez, PharmD	Kaiser Permanente	Los Angeles
Candace Fong, Pharm.D	Dignity Health	Sacramento
Carolyn Brown, RN, MS	Santa Clara Valley Medical Center	Santa Clara
Chris Patty, DNP, RN, CPPS	Kaweah Delta Health Care District	Tulare
Christine Low, Pharm.D	Scripps Green Hospital	San Diego
Deepak Sisodiya	Stanford Health Care	Santa Clara
Diana Schultz, RPh, MHSA	Palomar Medical Center Escondido	San Diego
Doug O'Brien, Pharm.D	Kaiser Foundation Hospitals	Sacramento
Eddie W. Avedikian, PharmD	Providence Holy Cross Medical Center	Santa Barbara
Jeanette Hanni, R.Ph, MPA, FCSHP	Mills-Peninsula Health Services	Santa Clara
Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS	UCSF Medical Center	San Francsico
Kevin Dorsey Tyler, MD, PhD	Enloe Medical Center - Esplanade Campus	Butte
Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN	Providence Little Company of Mary Medical Center Torrance	Los Angeles
Nasim Karmali, RPh	Kaiser Permanente Redwood City Medical Center	Alameda
Richard B. Rabens, MD, MPH, FAAP	Kaiser Permanente Richmond Medical Center	Alameda
Rita Shane, Pharm.D, FASHP, FCSHP	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens, Pharm. D, BCPS	Kaweah Delta Health Care District	Tulare
NON-HOSPITAL MEMBERS		
Art Woo, Pharm.D	California Department of Public Health	Contra Costa
Cari Lee, Pharm.D	California Department of Public Health	San Mateo
Dan B. Dong, Pharm.D, FCSHP	Kaiser Permanente	Alameda
Dan Ross, Pharm.D	California Society of Health System Pharmacists	Sacramento
John Christensen, Pharm.D	California Department of Public Health	Sonoma
Kimberly Kirchmeyer	Medical Board of California	Sacramento
Kimberly Tomasi, MSN, RN	Association of California Nurse Leaders	Sacramento
Loriann DeMartini, Pharm.D	California Society of Health System Pharmacists	Sacramento
Randy Kajioka, Pharm.D	California Correctional Health Care Systems	Sacramento
Virginia Herold	California Board of Pharmacy	Sacramento

GUIDELINES FOR THE
CALIFORNIA HOSPITAL ASSOCIATION
MEDICATION SAFETY COMMITTEE

I. NAME

The name of this committee shall be the Medication Safety Committee.

II. MISSION

The mission of the 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 medications.

III. 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.

IV. COMMITTEE

The Committee (the "Committee") shall consist of a minimum of 16 representatives and not more than 35 representatives from hospital members and the following related organizations:

California Department of Public Health California
Society of Health System Pharmacists California
Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Collaborative Alliance for Nursing Outcomes
Association of California Nurse Leaders California
Medical Association
California HQI and CHPSO
Risk Management Association
Representatives from the following CHA committees/centers:
Center for Behavioral Health
- Rural Health Center
- Quality Committee
- Joint Committee on Accreditation and Licensing Center
- for Hospital Medical Executives EMS/Trauma
- Committee
- Hospital Based Clinics Committee
- Center for Post Acute Care
- Governance

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the Committee. CHA members will be hospital members. Non-hospital members are ex-officio members and can only be appointed to the Committee at the discretion of the CHA staff liaison.
2. The CHA Committee members shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities and specialty facilities. A member may fulfill more than one required membership position.
3. Hospital members are appointed by CHA Staff per recommendation of hospital Committee members and per hospital and non-hospital membership requirements listed above.
4. Guidelines for membership – these guidelines should be used when selecting potential new members for the Committee:
   a) Demonstrated experience in medication safety and understanding of regulatory environment based on current or recent job responsibilities
   b) Contributions to medication safety at the organizational and/or professional level
   c) Practice experience related to medication safety and regulatory compliance: at least 3 years (preferred).
5. Term:
   a) Terms of office shall be based on member participation and desire to remain active on the Committee. The CHA staff liaison will perform an annual review of member attendance, participation and desire to remain active on the committee.
   b) Chairs and Co-Chair positions will be filled by hospital members only and selected by the CHA staff liaison per recommendation of the present chair, co-chairs and by other members of the Committee. They will be selected based on their leadership and desire to fill the position.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee and CHA Board of Trustees.
2. Identify issues and develop possible solutions and best practices to improve the safety of the medication use process.
3. Work cooperatively with key stakeholders to develop creative solutions.
4. Provide communication to member hospitals regarding medication safety issues.
5. Maintain/increased awareness of the legislative and regulatory environment with regard to medication safety issues.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly in person.
2. To maintain continuity, substitution of members should be discussed with the staff liaison and co-chairs on an individual basis.
3. Three consecutive unexcused absences by a Committee member will initiate a review by the co-chairs and CHA staff liaison for determination of the Committee member's continued service on the Committee.
4. Special meetings may be scheduled by the co-chair, majority vote, or CHA staff liaison.

D. VOTING

1. Voting rights shall be limited to members of the Committee, and each member present shall have one vote. Voting by proxy is not acceptable.
2. All matters requiring a vote of the Committee must be passed by a majority of a quorum of the Committee members present at a duly called meeting or telephone conference call.

E. QUORUM

Except as set forth herein, a quorum shall consist of a majority of members present or not less than eight.

F. MINUTES

Minutes of the Committee shall be recorded at each meeting, disseminated to the membership, and approved as disseminated or as corrected at the next meeting of the Committee.

V. OFFICERS

The officers of the Committee shall be the Committee chair, co-chair and CHA staff liaison.

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee chairs and members and CHA staff liaison for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

Goals, and objectives, shall be developed annually by the Committee with approval by the CHA staff liaison. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

Staff leadership at the state level shall be provided by CHA with local staff leadership provided by Hospital Council, the Hospital Association of Southern California, and the Hospital Association of San Diego and Imperial Counties. The primary office and public policy development and advocacy staff of the Committee shall be located within the CHA office.

The Committee staff liaison shall be an employee of CHA.

VII. AMENDMENTS

These Guidelines may be amended by a majority vote of the members of the Committee at any regular meeting of the Committee and with approval by CHA.

VIII. LEGAL LIMITATIONS

Any portion of these Guidelines which may be in conflict with any state or federal statute or regulations shall be declared null and void as of the date of such determination.

Information provided in meetings is not to be sold or misused.

IX. CONFIDENTIALITY FOR MEMBERS

Many items discussed are confidential in nature, and confidentiality must be maintained. All Committee communications are considered privileged and confidential, except as noted.

X. CONFLICT OF INTEREST

Any member of the Committee who shall address the Committee in other than a volunteer relationship excluding CHA staff and who shall engage with the Committee in a business activity of any nature, as a result of which such party shall profit either directly or indirectly, shall fully disclose any such financial benefit expected to CHA staff for approval prior to contracting with the Committee and shall further refrain, if a member of the Committee, from any vote in which such issue is involved.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
April 4, 2018 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present:	Dan Dong, Kathy Ghomeshi, Amy Gutierrez, Virginia Herold, Rory Jaffe, Randy Kajioka, Christine Low, Doug O'Brien, Christopher Patty, Dan Ross, Diana Schultz, Sarah Stephens
Members on Call:	Eddie Avedikian, Carolyn Brown, John Christensen, Jeannette Hanni, Susan Herman, Lori Nolan, Richard Rabens, Rita Shane, Art Woo
Members Absent:	Katie Choy, Loriann DeMartini, Kevin Dorsey-Tyler, Mary Foley, Lisa Hall, Nasim Karmali, Cari Lee, Lisa O'Connell
Guest:	Randi Abate (student with Kathy Ghomeshi), Margarita Chernova (student with Sarah Stephens), Vicky Ferraresi, Michael Tou
CHA Staff:	BJ Bartleson, William Emmerson, Jennifer Lopez, Amber Ott, Debby Rogers, Barb Roth

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong

The committee meeting was called to order by chair Ms. Fong at 10:00 a.m. Ms. Fong briefly reviewed operational items.

II. REVIEW OF PREVIOUS MEETING MINUTES –Fong

The minutes of the January 10, 2018, Medication Safety Committee meeting were reviewed. Amy Gutierrez abstained as she was not present for the January 10, 2018 meeting.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: Minutes approved as presented*

III. New Members:
New member Kim Tomasi will be replacing Pat McFarland as the representative for ACNL. Deepak Sisodiya is the Administrative Director of Pharmacy Services at Stanford Health Care. After discussion the membership voted to approve Mr. Sisodiya's membership.

- *ACTION: Ms. Bartleson to contact Mr. Sisodaya regarding membership in the Medication Safety Committee.*

III. OLD BUSINESS

A. 340B Update (Ott)

The Governor's budget proposal was released in January of this year which includes changes to the 340B Drug Discount Program. CHA is opposed to this proposal. A hearing was held on

Thursday, March 28. Three members of the committee asked many questions and do not appear to be pleased with the proposal. CHA is requesting information from member hospitals in 340B areas on how this proposal will affect them.

- *ACTION: Please send stories to Ms. Ott (aott@calhospital.org) about how this affects your community (3-4 sentences).*

B. CHPAC (Emmerson)

William Emmerson with CHA's Legislative Team presented CHPAC. CHA is encouraging everyone to contribute to the CHA Political Action Committee. Any level of donation is acceptable.

C. Medication Safety Toolkit Update – Bartleson/Roth

Ms. Roth demonstrated how to locate the Medication Safety Toolkit on the CHA website. Ms. Bartleson requested members to forward outstanding items to her and she will ensure they get posted.

- *ACTION: Ms. Bartleson and Mr. Jaffe to discuss collaboration with CHA/HQI for Medication Safety Toolkit.*
- *ACTION: Sterile Compounding grids – Mr. O'Brien to send the completed grids to CHA for distribution and approval by the committee prior to being added to the toolkit.*

D. Sterile Compounding (Fong/Herold)

- *ACTION:*

E. Board of Pharmacy/CAU-CDPH/OSHPD Construction Waiver (Rogers)

CHA is sponsoring AB 2798 which would provide timelines for CDPH to approve/deny applications within 45 days. There will be a committee meeting on this bill in two weeks.

CDPH is proposing to raise hospital fees again. This would be an increase of 103% in last 4 years.

CHA will be hosting two upcoming webinars. The Sterile Compounding webinar on April 17 will be recorded and Medication Safety Committee members will have access to the recording.

- *ACTION: Information only.*

F. AHA Leadership Summit

Special committee recognition of outstanding efforts made by Sarah Stephens, Kathy Ghomeshi and Rita Shane on their proposal submissions to AHA. Although their proposals were not accepted, CHA Medication Safety Committee appreciates their efforts.

- *ACTION: Awards presented.*

IV. LEGISLATION AND REGULATORY

A. SB 1254 (Bartleson/Shane)

Several areas in the bill could cause problems at the hospital level (primarily regarding a potential increase in resources) and the Board of Pharmacy (regarding current staffing regulations). CHA has not made a decision regarding support or opposition of this bill prior to obtaining input from the committee. The committee agreed to review the bill with the

following amendments:

1. **Release of the Pharm tech ratio.**
2. **Add the 100 bed limitation.**
3. **Regulation would only be in effect during hours when the pharmacy is open.**
4. **Regulation to apply to admission instead of discharge.**

Ms. Shane has prepared a wealth of information regarding the importance the approval of this bill. A toolkit for the hospitals, making this information visible to leadership, would be beneficial.

- *ACTION: Ms. Shane to submit recommended amendments for committee review.*

B. SB 1447 (Bartleson)

This Board of Pharmacy (BoP) bill regarding the licensing of Automated Drug Dispensing (ADD) machines. It would allow patients to obtain prescription medication from an ADD machine if they opt into the system at a facility with a healthcare provider. The BoP has control over where the ADD machines are located. Questions about hospital locations to be answered by Ms. Herold.

- *ACTION: Information only.*

C. Legislation (Bartleson)

- *ACTION: Information only.*

V. NEW BUSINESS

A. Opioid Drug Shortages (Herold/Bartleson)

ASHP recently released a helpful document regarding the shortage. It was agreed that switching between products and strengths can be dangerous. Although it may take a crisis to make a change, it was recommended that committee members contact our two senators regarding this problem.

ASHP - ISMP is requesting the filing of incident reports on issues to prove the point. Reports can be filed anonymously.

- *ACTION: Committee members to send a couple of sentences or a paragraph indicating that this is a crisis or catastrophic situation in the making to Ms. Bartleson.*
- *ACTION: Ms. Bartleson to contact CHA Federal office with input from committee members.*

B. **Incidents of Smart Pump Malfunctioning (Bartleson)**

Mr. Woo advised that the brand of pump is being reported is by Alerus. There is not a recall at this time, however this has been problem for a couple of years. The MAUDE device database houses reports from providers on device problems. This is a public database.

- *ACTION: Information only.*

C. **CURES**

- *ACTION:*

D. **Controlled Substance Reconciliation**

- *ACTION:*

E. **FDA 503b**

- *ACTION:*

V. STANDING REPORTS

A. Board of Pharmacy (BoP) – Herold
The Board of Pharmacy has originated several new bills this session.

B. CDPH – Lee, Woo, Christensen

C. CSHP – Ferraresi

D. CALNOC – Foley

E. ACNL – Foley

F. CHPSO – Jaffe
Update on data provided to the committee.

G. CAHF – Hall

VI. OTHER BUSINESS

VII. NEXT MEETING
Wednesday, July 11, 2018

VIII. ADJOURNMENT
Having no further business, the committee adjourned at 1:10 PM

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: CURES

SUMMARY

The Controlled substance Utilization Review and Evaluation System (CURES) was certified for statewide use by the Department of Justice on April 2, 2018. Therefore, the mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II-IV controlled substance becomes effective on October 2, 2018.

CURES contains the following information: patient name, patient date of birth, patient address, prescriber name, prescriber DEA number, pharmacy name, pharmacy license number, date prescription was dispensed, prescription number, drug name, drug quantity and strength, and number of refills remaining.

Tina Farales is the new Department of Justice Director for Cures. We have attempted to have her meet with us for an update but she has been unavailable. We have received a concern that certain vendors have not been included in the CURES alignment process.

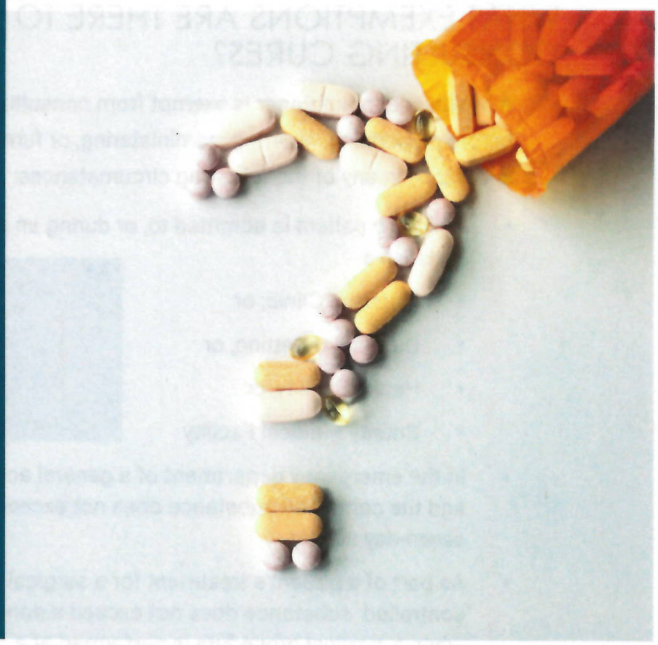
ACTION REQUESTED

- Are you experiencing any difficulty with you EMR vendor and the CURES connection?
- Are you experiencing any other difficulties with CURES?

Attachment: CURES Flyer
DOJ Letter 4-9-18
CURES AB-40 Stakeholder Webinar Q&A
Health and Safety Code Section 11165.4

BJB:br

CURES 2.0
MANDATORY USE
BEGINS OCTOBER 2, 2018



The Controlled Substance Utilization Review and Evaluation System (CURES) was certified for statewide use by the Department of Justice (DOJ) on April 2, 2018. Therefore, the mandate to consult CURES prior to prescribing, ordering, administering, or furnishing a Schedule II–IV controlled substance becomes effective on October 2, 2018. Visit www.mbc.ca.gov/CURES for detailed information regarding CURES 2.0.

Note: The phrase "controlled substance" as used in this guide refers to a Schedule II, Schedule III, or Schedule IV controlled substance.

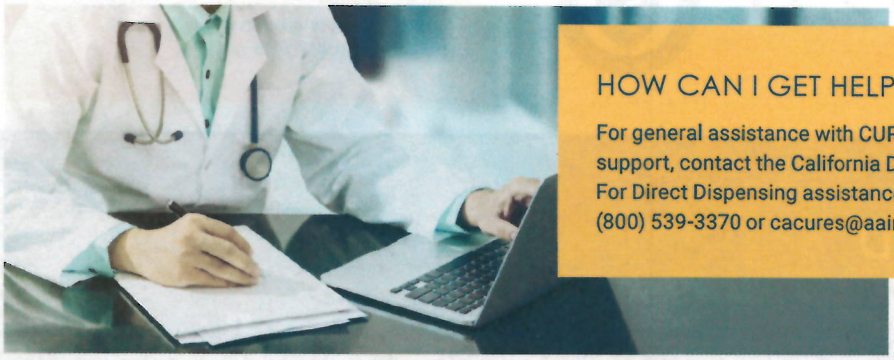
WHEN MUST I CONSULT CURES?

- The first time a patient is prescribed, ordered, administered, or furnished a controlled substance, unless one of the exemptions on back apply.
- Within the twenty-four hour period, or the previous business day, before prescribing, ordering, administering, or furnishing a controlled substance, unless one of the exemptions on back apply.
- Before subsequently prescribing a controlled substance, if previously exempt.
- At least once every four months if the controlled substance remains a part of the patient's treatment plan.

> "First time" is defined as the initial occurrence in which a health care practitioner intends to prescribe, order, administer, or furnish a controlled substance to a patient and has not previously prescribed a controlled substance to the patient.
>
> — *Health and Safety Code (HSC), § 11165.4(a)(1)(B)*

WHAT PROTECTIONS ARE THERE FOR PRESCRIBERS?

- There is no private cause of action for a prescriber's failure to consult CURES.
- For complete information on the mandatory requirement to consult CURES, please read HSC § 11165.4.
- If you have any further questions, please seek legal counsel.



HOW CAN I GET HELP WITH CURES?

For general assistance with CURES, including training and CURES usage support, contact the California DOJ at (916) 210-3187 or CURES@doj.ca.gov. For Direct Dispensing assistance, contact Atlantic Associates, Inc. at (800) 539-3370 or cacures@aainh.com.

(Rev. 05-2018)

WHAT EXEMPTIONS ARE THERE TO CONSULTING CURES?

- A health care practitioner is exempt from consulting the CURES database before prescribing, ordering, administering, or furnishing a controlled substance in any of the following circumstances:
  - While the patient is admitted to, or during an emergency transfer between a
    - Licensed Clinic, or
    - Outpatient Setting, or
    - Health Facility, or
    - County Medical Facility

> The facilities listed are specifically defined in statute commencing with HSC § 1200, § 1248, § 1250, and § 1440, respectively.

  - In the emergency department of a general acute care hospital, and the controlled substance does not exceed a non-refillable seven-day supply.
  - As part of a patient's treatment for a surgical procedure, and the controlled substance does not exceed a non-refillable five-day supply when a surgical procedure is performed at a
    - Licensed Clinic, or
    - Outpatient Setting, or
    - Health Facility, or
    - County Medical Facility, or
    - Place of Practice

> "Place of Practice" is defined as a Dental Office pursuant to Business and Professions Code § 1658.

  - The patient is receiving hospice care.
- What if it is not reasonably possible for a prescriber to access the information in CURES in a timely manner?
  - If another individual with access to CURES is not reasonably available, a five-day supply of the controlled substance can be prescribed, ordered, administered, or furnished as long as there is no refill allowed. In addition, the prescriber must document in the patient's medical records the reason for not consulting CURES.
- What if I determine that consulting CURES would result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition?
  - A prescriber may provide a non-refillable five-day supply if they make this determination. The prescriber must document in the patient's medical records the reason for not consulting CURES.

WHAT IF I EXPERIENCE TECHNICAL DIFFICULTIES WITH CURES?

There are exemptions to consulting CURES if there are technical difficulties accessing CURES, such as CURES is temporarily unavailable for system maintenance, or you experience temporary technological or electrical failure and CURES cannot be accessed (e.g., power outage due to inclement weather).

A prescriber should contact the CURES Help Desk at (916) 210-3187 or cures@doj.ca.gov for assistance accessing their CURES account.

Note: A prescriber must, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within their control.

CURES 2.0

MEDICAL BOARD OF CALIFORNIA
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XAVIER BECERRA
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State of California
DEPARTMENT OF JUSTICE

BUREAU OF CRIMINAL IDENTIFICATION
& INVESTIGATIVE SERVICES
CURES PROGRAM
P.O. BOX 160447
SACRAMENTO, CA 95816-1089

April 9, 2018

TO: ALL CURES USERS

RE: CURES 2.0 CERTIFICATION

Pursuant to Section 11165.4(e) of the Health and Safety Code, the Department of Justice certifies that, as of April 2, 2018, the CURES database is ready for statewide use and that the Department of Justice has adequate staff, user support, and education. **Mandatory CURES consultation becomes effective on October 2, 2018, six months after certification.**

To whom does the mandatory CURES consultation requirement apply?

The mandatory consultation requirement of SB-482 applies to any health care practitioner with both (1) a Drug Enforcement Administration Controlled Substance Registration Certificate and (2) a California licensure as any one of the following:[1]

Dentist
Physician
Naturopathic Doctor
Optometrist
Osteopathic Doctor
Physician Assistant
Podiatrist
Registered Certified Nurse Midwife (Furnishing)
Registered Nurse Practitioner (Furnishing)

However, the mandatory use requirement of SB-482 **does not apply** to the following health care practitioners:[2]

Veterinarians
Pharmacists

[1] Health and Safety Code, §§ 11150 and 11165.4(a)(1)(A)(i).
[2] Health and Safety Code, § 11165.4(b).

Under what circumstances are health care practitioners required to consult CURES?

The mandatory consultation requirement of SB-482 will require health care practitioners identified in the above section to consult the CURES database to review a patient's controlled substance history under both of the following circumstances:[3]

1. Before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time; and

2. At least once every four months thereafter if the substance remains part of the treatment of the patient.

"First time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, III, or IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.[4]

What exemptions apply to the mandatory consultation requirement?

There are several exemptions to the mandatory use requirement outlined in Health and Safety Code section 11165.4(b) and (c). For reference, attached is a copy of the statute with the exemptions to the mandatory consultation requirement highlighted in red.

Additional information concerning CURES registration, User Guides and Frequently Asked Questions is available at https://oag.ca.gov/cures.

For questions and/or training requests, please contact the CURES Program at CURES@doj.ca.gov or 916-210-3187.

[3] Health and Safety Code, § 11165.4(a).
[4] Health and Safety Code, § 11165.4(a)(1)(B).

Health and Safety Code 11165.4.

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient, he or she shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before he or she prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

CURES AB-40 Stakeholder Webinar Q&A

The below questions were submitted to CURES during the Assembly Bill (AB) 40 Stakeholder Webinar hosted by the California Department of Justice. Please note that because the Department of Justice is still developing this solution, some of the answers are subject to change. These answers reflect the best information available to the Department of Justice at this time.

1. **Do searches have to be a perfect match on the submitted criteria? For example, will the system match the name Bill to William?**

   ANSWER: Searches default to a partial match. However, searches can be conducted as a partial or exact match and would match the name Bill to William.

2. **What information is presented on the patient picklist once a query has been made? How is patient prescription data from the picklist returned?**

   ANSWER: The picklist includes the first name, last name, date of birth, gender, and address of the patients that match the submitted criteria. The correct patients are selected from the picklist and the associated prescription data is returned to the Health Information Technology (HIT) system.

3. **Why is only first name, last name, and date of birth required for searches? Is there more information that can be submitted to decrease the likelihood that a patient picklist is presented to the provider?**

   ANSWER: As with the current CURES portal, there will be optional fields, such as address, that can be included to limit the number of potential matches.

4. **Will there be functionality to auto-resolve patient queries, or will there always be a need to use a picklist?**

   ANSWER: CURES will not auto-resolve patient entities. However, each HIT may elect to develop and implement algorithms for entity resolution on their end.

5. **Have you considered using the Appriss commercial interface or other vendor solutions that are implemented in other states?**

   ANSWER: We are exploring different solutions, but no final decision has been made at this time.

6. **Is the API endpoint RESTful?**

   ANSWER: This has not been finalized, but at this time we are planning to use RESTful API.

7. **Can queries for multiple patients or on behalf of multiple prescribers be processed in bulk?**

ANSWER: Batch processing will not be available with the initial release. However, we will explore this for future releases.

8. **Can hospitals use a Health Information Exchange (HIE) to connect to the AB-40 web service?**

   ANSWER: Hospitals may connect through their HIE. AB40 allows access to CURES via an HIE that has a memorandum of understanding (MOU) with the DOJ, or the Web Portal.

9. **EPIC already has an existing integration with PDMPs in other states. Has there been any work on interfacing with the EPIC API?**

   ANSWER: Not specifically. However, the standards that data will be provided in could allow for integration to be performed by the client.

10. **Will delegates be able to initiate queries on behalf of prescribers and dispensers via the integration interface?**

    ANSWER: Yes, delegates will be able to initiate patient activity reports on behalf of parent prescribers and dispensers. Delegate functionality would be limited to initiating queries, similar to the web portal. The statutes governing CURES do not authorize direct access by delegates to patient dispensation records contained within CURES. Moreover, the establishment of delegates would still be established by parent prescribers and dispensers through the web portal.

11. **Who must execute an MOU, when do you expect to have it completed, and how are the terms being developed?**

    ANSWER: In accordance with AB-40, DOJ is required to make CURES data available to authorized users through a HIT system, provided the entity operating the HIT system certifies compliance with DOJ technical and security requirements and enters into an MOU with DOJ. DOJ is currently developing the MOU, and expects to circulate it to interested parties prior to October 1, 2018. The MOU will focus primarily, though not exclusively, on DOJ technical and security requirements.

12. **Once DOJ has a final product, will it host another webinar to demo the workflow? Also, how can we volunteer to help with the testing?**

    ANSWER: It is anticipated that DOJ will do a walk through when ready for testing. DOJ will be soliciting for volunteers to do testing.

13. **What is the difference between the HIT and the organization that hosts/controls the CURES database? Is it the same organization?**

ANSWER: The California Department of Justice, Prescription Drug Monitoring Program, administers the CURES database. The HIT is the consumer of the web service.

14. How will technical and security requirements for HIT access be determined? What standards will be used?

ANSWER: We will use current, standard technologies and security methodologies based on state and federal requirements. The standards to be used are still under review.

15. Will AB 40 be a set of web services that the HIT system can consume, as opposed to just authentication?

ANSWER: Correct, integration under AB-40 will be a web service that can be consumed by the HIT.

16. Will CURES provide any sort of alerting or real time decision support, similar to immunization registries, or simply provide data to HIT systems for interpretation and action?

ANSWER: CURES patient alerts are currently available via the web portal. We are currently exploring the feasibility of providing patient alerts via integration.

17. Is each hospital expected to build this integration individually? If not, how will this be deployed statewide?

ANSWER: Hospitals that elect to participate in integration will consume and render CURES data via their HIT system.

18. Will there be some sort of flag sent back that we can save which indicates the last successful query, so that we do not waste time querying when it's not required (e.g. already done today, yesterday)?

ANSWER: CURES will not provide such a flag, but this may be a solution that individual HIT systems can develop and implement on their end.

19. SB-482 requires providers to document that they have checked the CURES database within a certain time frame. This is supposed to go into effect six months after the "database has been certified."

ANSWER: The Department of Justice certified statewide system and program readiness on April 2, 2018. The requirements of SB-482 take effect October 2, 2018, six months after the certification. More information regarding SB-482, including the full text of the bill, can be found at the following address: http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160SB482

20. Will DOJ be hosting follow up meetings?

ANSWER: The Department of Justice is currently evaluating the need for follow-up meetings regarding AB-40.

21. Where are we today relative to where we want to be on 10/1/2018?

ANSWER: We are working on developing high-level technical requirements, security requirements, and a web service prototype.

22. Will CURES store a patient's medical record ID when a successful query is completed, so that on subsequent queries matching can be improved at a particular hospital?

ANSWER: No. All prescription data currently in CURES is provided by dispensers, and this data does not include medical record ID.

23. This appears to be a single-sign on process, am I mistaken?

ANSWER: This is a machine-to-machine web service solution, not single-sign on. However, we are currently exploring single sign-on functionality.

24. We offer communication with NCPDP and through single-sign-on connections via web. We need CURES to support one of those to get direct integration. Do you plan to support one or both of those?

ANSWER: We are still researching this issue.

25. What is the format / protocol for the CURES query 1 / query 2 is it an Integrating the Healthcare Enterprise (IHE) profile? E.g., xcpd/xca?

ANSWER: This has not been determined at this time.

26. Will the flow in this diagram use standards-based transactions (e.g. smart on fhir, ncpdp, etc.)? If so, what standards will be supported?

ANSWER: This has not been determined at this time.

27. What are the rate limits on queries / API requests?

ANSWER: This has not been determined at this time.

28. Have you considered using SureScripts record locator services?

ANSWER: Not at this time.

29. Will CURES use oAuth to allow single sign on?

ANSWER: This has not been determined at this time.

30. How do stakeholders work with the DOJ to help develop standards?

ANSWER: CURES will use industry standards where ever possible and feasible.

31. Are you considering using the NCPDP medication history request/response transaction as a method for connecting the data to HIT? That transaction method is widely considered an industry standard for transmitting PDMP information per ONC's recent guidance.

ANSWER: DOJ is considering several standards, including NCPDP.

32. Will you have a unique ID for every patient returned?

ANSWER: Not in the sense that you can query using a unique patient ID and have all prescription information for that patient returned.

33. How would AB-40 work in mobile environment?

ANSWER: DOJ intends to use RESTful API. We will provide the consumable data and it is up to the entity operating the HIT to determine how it will be displayed. We are working to make it as flexible as possible.

34. Please consider the performance of this solution - is there a target response time for the API?

ANSWER: DOJ's goal is that the performance will be equal to or better than the current CURES portal for any given transaction.

State of California

HEALTH AND SAFETY CODE

Section 11165.4

11165.4. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time he or she prescribes, orders, administers, or furnishes a controlled substance to a patient, he or she shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in his or her role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before he or she prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

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(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

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(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason he or she did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or when it cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within his or her control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(Added by Stats. 2016, Ch. 708, Sec. 3. (SB 482) Effective January 1, 2017. Section operative on October 2, 2018, pursuant to subdivision (e).)

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Drug Shortages

SUMMARY

Hospitals continue to report narcotic drug shortage issues. Attached is the FDA Report on Drug Shortages for Calendar Year 2017. While there are fewer shortages reported by the FDA since 2011, and they reiterate their work with DEA and manufacturers on allotment quotas, etc., we continue to have problems. The last EMS Commission Meeting also reported severe shortages in the pre-hospital environment (see attached article). They are trialing Ketamine utilization as a mitigation measure.

CHA performed a survey (attached) on the narcotic drug shortage issue which was shared with Senator Feinstein who arranged a conference call with us, Board of Pharmacy and the DEA. (Attachment- California Hospital and Health System IV Opioid Shortage, 4/16/2018). The DEA responded they had loosened their previous allotment quotas and the manufacturers were the problem at this point.

ACTION REQESTED

- Feedback on narcotic shortage and mitigation measures.
- Any other opportunities for CHA to intervene for change?

Attachments: FDA Report on Drug Shortages, 2017
Kristi Koenig Article
CHA Monkey Survey Results
CHA Position Statement on IV Opioid Shortage
FDA Letter
Injectable Opioid Shortages – Suggestions for Management and Conservation
NYT – Hospitals Face Drug Shortages

BJB:br

Report on Drug Shortages for Calendar Year 2017

Required by

Section 506C-1 of the Federal Food, Drug, and Cosmetic Act

Food and Drug Administration
Department of Health and Human Services

_____ Date_____
Scott Gottlieb, M.D.
Commissioner of Food and Drugs

Table of Contents

EXECUTIVE SUMMARY

This fifth annual report to Congress summarizes the major actions taken by the Food and Drug Administration (FDA) during calendar year (CY) 2017 to prevent or mitigate drug shortages[1] in the United States. Because drug shortages can pose a significant public health threat that can delay, and in some cases even deny, critically needed care for patients, shortages remain a top priority for FDA. As a result of actions by the President, Congress, and FDA, manufacturers are notifying FDA about potential shortages earlier than in the past. Early notification of potential shortages gives FDA additional time to work with manufacturers and other stakeholders to identify ways to maintain treatment options and prevent a shortage. Using a range of available tools, including regulatory flexibility and discretion when appropriate, FDA's Center for Biologics Evaluation and Research (CBER) and FDA's Center for Drug Evaluation and Research (CDER) worked with manufacturers to successfully prevent 145 shortages from January 1 to December 31, 2017. In addition, the number of new shortages tracked by CBER and CDER for this same period is 39, compared to a peak of 251 new shortages during the full calendar year of 2011.[2]

Based on our experience to date and the data on drug shortages presented in this report, FDA believes that the requirements related to early notification of potential shortages and FDA's own actions are helping to reduce the threat and impact of drug shortages. FDA will continue to prioritize this important public health issue, working to ensure the availability of necessary drugs and biological products for the American public.

[1] For purposes of this report, the term "drug shortage" includes shortages of human drug and biological products. The report may individually refer to shortages tracked by FDA's Center for Drug Evaluation and Research or FDA's Center for Biologics Evaluation and Research, if the context requires distinguishing between these.

[2] This fifth annual report to Congress addresses all covered drug and biological products. This includes all drugs within the meaning of section 506C(h)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as well as other products tracked by CDER's Drug Shortage Staff, such as biological products approved under section 505 of the FD&C Act. This also includes biological products licensed under section 351 of the Public Health Service Act and tracked by CBER's Office of Compliance and Biologics Quality, such as vaccines and blood products. See Appendix 3 for a breakdown of 2017 CBER and CDER numbers.

INTRODUCTION

The Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted on July 9, 2012. Title X of FDASIA, which addresses drug shortages, took effect on the date of enactment and, among other things, amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.) by updating section 506C. Section 506C sets forth the requirement that manufacturers notify FDA of a permanent discontinuance or interruption in the production of certain prescription drugs that are life-saving, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition. In addition, section 1002 of Title X of FDASIA added section 506C-1 to the FD&C Act, requiring FDA to file an annual report to Congress on drug shortages.[3] FDA is submitting this annual report to fulfill its obligations under section 506C-1. The report provides background about drug shortages and FDA efforts to address them to date. FDA also responds to the specific issues listed under section 506C-1. The analyses reflect data collected and evaluated by FDA's Center for Biologics Evaluation and Research (CBER) and FDA's Center for Drug Evaluation and Research (CDER) from January 1, 2017, through December 31, 2017. This report also summarizes some important ongoing activities FDA believes will help to address drug shortages in the future. A list of definitions and three appendices, which include the statutory language regarding annual reporting on drug shortages and the breakdown of data supplied by CBER and CDER, are included at the end of this report.

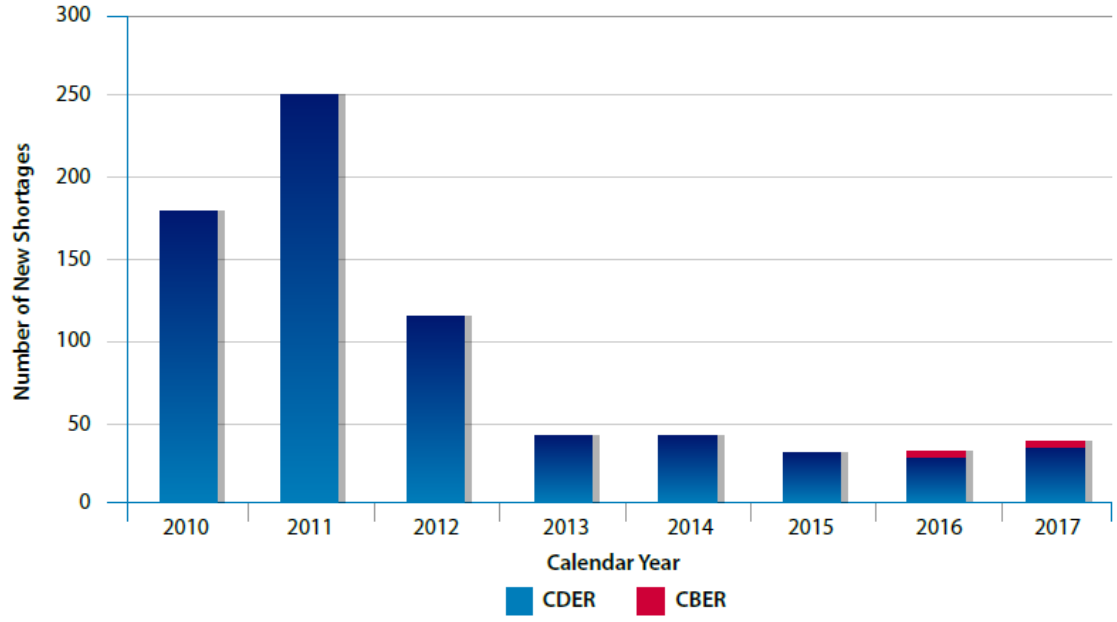
BACKGROUND

Drug shortages can have serious and immediate effects on providing needed therapies to patients, and preventing shortages is a priority for FDA. At the height of the drug shortage crisis, the number of new shortages tracked by CDER quadrupled, from approximately 61 shortages in 2005 to more than 250 in 2011.

The following figure shows the number of new drug shortages identified by year from 2010 through December 31, 2017.

[3] Section 506C-1 of the FD&C Act initially required the annual report on drug shortages to be submitted to Congress "not later than the end of each calendar year." To meet this deadline, the annual reports submitted to Congress presented data and information on drug shortages gathered during the first three quarters of the calendar year. The 21st Century Cures Act, which was enacted on December 13, 2016, amended section 506C-1 to require that "[n]ot later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report, with respect to the preceding calendar year, on drug shortages…"

Figure 1. Number of New Drug Shortages Per Year, 2010 - 2017[4]



Although the number of new drug shortages has declined since 2011 as a result of work by many groups including the FDA, shortages continue to pose a real challenge to public health. This is especially the case when a shortage involves a critical drug to treat cancer, to provide parenteral nutrition, or to address another serious medical condition, such as the shortage of intravenous saline solution. While there has been a steady decrease in new shortages over the past few years, 2017 has been a challenging year for shortages. First, there was a major manufacturer who shut down a facility for remediation purposes resulting in loss of manufacturing capacity needed for the supplies of numerous products. Critically, disruptions were also caused in the Fall of 2017 by Hurricanes Harvey, Irma, and Maria—the latter of which ravaged Puerto Rico, an island that is home to numerous manufacturing facilities. This created delays in the release of some products, resulting in both new shortages as well as the worsening of existing shortages. FDA's efforts to respond to the hurricanes are summarized later in the report.

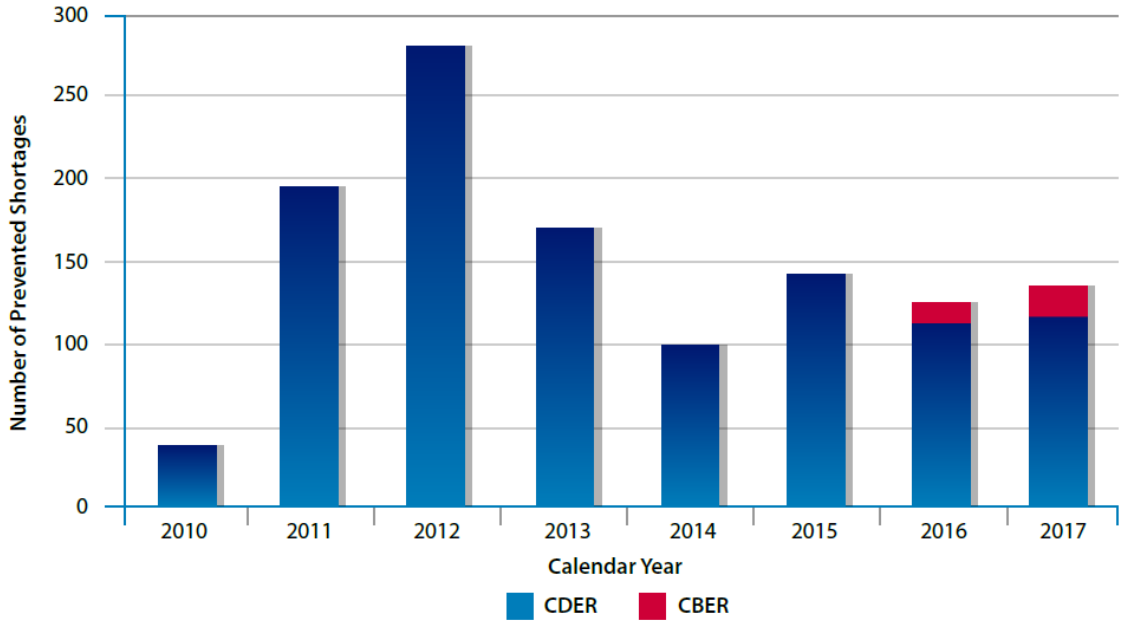
Shortages can delay or deny needed care for patients, creating a potential lapse in medical care. Shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks. As summarized below, to prevent these situations from occurring, FDA has used a variety of methods to prevent shortages, working within the confines of the statutory and regulatory framework in place and in partnership with manufacturers and other stakeholders. As tracked by CDER, FDA helped prevent 282 drug shortages in 2012, 170 shortages in 2013, 101 shortages in 2014, and 142 shortages

[4] This fifth annual report to Congress is the second year to include reporting for both drug and biologic products. See Appendix 3 for a breakdown of 2017 CBER and CDER numbers.

in 2015. In 2016, FDA, as tracked by CBER and CDER, helped to prevent 126 shortages; in 2017, the Agency helped to prevent 145 shortages.[5]

The following figure shows the number of prevented drug shortages identified by year from 2010 through 2017.

Figure 2. Number of Prevented Drug Shortages Per Year, 2010 - 2017[6]



Several actions have been taken in recent years that helped FDA address drug shortages.

1. Executive Order 13588 – Reducing Prescription Drug Shortages

In response to a dramatic increase in shortages, on October 31, 2011, the President issued Executive Order 13588, recognizing that "shortages of pharmaceutical drugs pose a serious and growing threat to public health…endanger patient safety…burden doctors, hospitals, pharmacists, and patients…and increase health care costs."[7] The Executive Order acknowledged the need for a "multifaceted approach" to address the many different factors that contribute to drug shortages. The Executive Order directed FDA to take steps to help prevent and reduce current and future disruptions in the supply of life-saving medicines, including notifications and expedited reviews, as appropriate.

[5] See supra n. 2.
[6] This fifth annual report to Congress is the second year to include reporting for both drug and biologic products. See Appendix 3 for a breakdown of 2017 CBER and CDER numbers.
[7] Executive Order 13588, available at http://www.whitehouse.gov/the-press-office/2011/10/31/executive-order-reducing-prescription-drug-shortages

2. FDA Safety and Innovation Act

With the passage of FDASIA on July 9, 2012, FDA was given important new authorities related to drug shortages. For example, section 1001 of FDASIA broadened the scope of the early notification provisions by requiring manufacturers of ***all prescription drugs*** that are life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition (whether approved or unapproved) to notify FDA of a permanent discontinuance or temporary interruption in manufacturing. FDASIA also allowed FDA to require, by regulation, early notification of discontinuances or interruptions in manufacturing of biologics. FDASIA requires FDA to send a non-compliance letter to firms that fail to notify FDA in accordance with section 506C, as amended by FDASIA. FDA sent the first two letters in 2014, and an additional two letters in 2016. Section 506C also authorizes FDA to expedite reviews of drug applications and supplemental applications and to expedite inspections that could help mitigate a shortage. Other FDASIA requirements with respect to prescription drug shortages include improving FDA's internal and external communications about shortages, improving communication between FDA and the Drug Enforcement Administration (DEA) regarding shortages of controlled substances, and developing a strategic plan to enhance FDA's response to preventing and mitigating drug shortages.

3. FDA Strategic Plan to Prevent and Mitigate Shortages

On October 31, 2013, FDA issued its *Strategic Plan for Preventing and Mitigating Drug Shortages*.[8] The plan contains details on the origin of drug shortages, FDA's processes and procedures for helping to prevent or mitigate shortages, and FDA's strategy for strengthening those processes and procedures. The plan also recommends actions that other stakeholders can consider to help prevent shortages.

4. Final Rule – Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products

On July 8, 2015, FDA published a final rule to implement certain drug shortage provisions of section 506C, as amended by FDASIA.[9] Among other requirements, the rule requires all applicants of covered approved drug or biological products, including certain applicants of blood or blood components for transfusion, and all manufacturers of covered drug products marketed without an approved application, to notify FDA electronically of a permanent discontinuance or an interruption in manufacturing of the product that is likely to lead to a meaningful disruption in supply (or a significant disruption in supply for blood or blood components) of the product in the United States. The rule became effective on September 8, 2015. As noted above, last year's report to Congress was the first to include reporting for all covered drug and biological products.

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[8] To view the strategic plan and related information, visit http://www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM372566.pdf.

[9] 80 FR 38915 (July 8, 2015). See also 21 CFR 310.306, 314.81, and 600.82.

DATA SOURCES USED IN THIS REPORT

The data used to fulfill the reporting requirements of section 506C-1 are collected by several program areas within FDA. Tracking the data for reporting requirements related to drugs and biological products (the number of products in shortage) is within the purview of CBER's Office of Compliance and Biologics Quality (CBER/OCBQ) and CDER's Drug Shortage Staff (DSS). Similarly, CBER/OCBQ and DSS track information about notifications and their source (and, therefore, the number of reporting manufacturers). In contrast, reporting requirements related to expedited review are tied to specific *submissions* by manufacturers that are experiencing production disruptions or manufacturers that are adding or expanding their production capabilities to address a specific shortage. CBER and CDER offices reviewing these submissions track which reviews and related inspections they expedite as a part of a larger set of activities related to their review of submissions. Other reporting requirements for this report relate to instances of regulatory flexibility and discretion. These specific cases, all requiring separate regulatory and scientific evaluation and justification, are tracked by CBER/OCBQ and CDER's Office of Compliance (CDER/OC).

ANNUAL REPORT REQUIREMENTS PER 506C-1

Section 1002 of Title X of FDASIA added section 506C-1 to the FD&C Act, requiring FDA to file a report to Congress on drug shortages at the end of each calendar year.

The statutory requirements for the report and the data addressing those requirements are as follows.

> ***Requirement 1*: Specify the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year.**

For calendar year 2017, FDA was notified of 520 potential drug and biological product shortage situations by 86 different manufacturers.

> ***Requirement 2*: Describe the communication between FDA field investigators and CDER/OC and DSS, including FDA's procedures for enabling and ensuring such communication.**

CDER/OC and the FDA field investigators in the Office of Regulatory Affairs (ORA) are crucial to FDA's prompt response to a drug shortage. These two groups have separate functions with respect to drug shortages. Consistent with sections 506D(b) and (c) of the FD&C Act, CDER/OC communicates with DSS on warning letter and enforcement action recommendations being reviewed within CDER/OC. FDA field investigators in ORA typically conduct inspections at manufacturing facilities and report on their findings. For example, if the investigators identify actions or activities during an inspection that may have a detrimental impact on product availability, information

regarding the observations and the products manufactured can be relayed to CDER immediately so that DSS can begin to assess the supply situation for those products. These procedures are critical to FDA's efforts to prevent and mitigate a potential drug shortage.

To facilitate communications between ORA and FDA medical product centers, which include CBER and CDER, ORA issued Field Management Directive (FMD) #15 in July 2012. FMD #15 established drug shortage coordinators in ORA so that each FDA field district has a District Drug Shortage Coordinator who serves as the point of contact between ORA and FDA's medical product centers. The District Drug Shortage Coordinator is responsible for notifying the relevant FDA center of any issue that has the potential to lead to a product shortage (e.g., information obtained during an inspection or other field activities). FMD #15 clarified communication roles, responsibilities, and expectations related to potential and current product shortage situations between ORA and the centers.

***Requirement 3*: List the major actions taken by the Secretary to prevent or mitigate drug shortages.**

Mitigation efforts begin once FDA has confirmed that a shortage exists or could occur. The actions FDA can take to prevent or mitigate a shortage include, as appropriate:

- Identify the extent of the shortfall and determine if other manufacturers are willing and able to increase production to make up the gap;
- Expedite FDA inspections and reviews of submissions attempting to restore production;
- Expedite FDA inspections and reviews of submissions from competing entities who are interested in starting new production or increasing existing production of products in shortage;
- Exercise temporary regulatory flexibility for new sources of medically necessary drugs;
- Work with the affected manufacturers to ensure adequate investigation into the root cause of the shortage; and
- Develop risk mitigation measures, to allow individual batches of a drug product to be released even when quality assurance requirements were not met.

FDA can use one or more of these mitigation tools, or seek to develop other options, depending on the severity of the potential shortage and the surrounding circumstances. When selecting specific tools, FDA continues to work with the manufacturer to tailor its response to the specific situation. As a part of these actions, FDA also frequently

communicates available information about a potential shortage or existing shortage to affected stakeholders and monitors the shortage until it has been resolved.

- **List the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year.**

FDA expedited the review of 132 submissions in 2017.[10]

- **List the number of establishment inspections or re-inspections related to mitigation or prevention of a shortage that the Secretary expedited under section 506C(g)(2) during such calendar year.[11]**

FDA prioritized 30 establishment inspections to address drug shortages in 2017.[12]

***Requirement 4*: Describe the coordination between FDA and DEA to prevent or alleviate drug shortages.**

If a drug at risk of shortage is a controlled substance, FDA works closely with the Drug Enforcement Administration (DEA) in efforts to prevent or mitigate the shortage. Among other issues, DEA is responsible for setting aggregate limits on the amount of each controlled substance that may be manufactured and for allocating to each manufacturer a specific percentage of the aggregate limit (a quota). This tight control over controlled-substance products requires FDA and DEA to coordinate when a shortage of a controlled substance is looming. For example, FDA may work with DEA to enable a manufacturer to increase its allotted quota if this step would help avoid a shortage of the product.

Recognizing this need, FDASIA included provisions on improved coordination and communication between FDA and DEA regarding a potential shortage of a controlled substance. To help streamline and improve communications, FDA and DEA developed a memorandum of understanding (MOU). The MOU sets forth steps and procedures, including identifying contacts, for efficiently tracking and exchanging relevant information.[13]

***Requirement 5:* Identify the number of (and describe) instances in which FDA exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage.**

[10] See Appendix 4 for a breakdown of submission types.

[11] Includes prioritized inspections or site reviews for new applications or supplements that were granted expedited review due to drug shortage.

[12] Note that not all submissions to FDA require inspections, but some submissions may involve multiple sites that require multiple inspections.

[13] The MOU can be found at http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm440091.htm.

FDA's standards of safety, efficacy, and quality for approval do not change in a shortage situation. FDA's preferred solution to a shortage is to help ensure that there is a supply of approved drugs and biological products sufficient to meet patient demand, as well as meet the appropriate quality, safety, and efficacy standards. However, FDA recognizes that there can also be risks to patients if treatment options are not available for critical conditions; the Agency also understands the importance of using appropriate tools for a given situation to prevent or mitigate a shortage. In appropriate cases, the temporary exercise of regulatory flexibility and discretion has proven to be an important tool in ensuring access to treatment options for patients in critical need.

During CY 2017, FDA exercised regulatory flexibility and discretion in 57 instances, affecting 33 products.[14] Examples of situations in which FDA exercised regulatory flexibility and discretion to prevent or mitigate a shortage are listed below:

- FDA used temporary regulatory flexibility and discretion for medically necessary products that presented quality issues through the use of measures to mitigate the risks associated with those products when weighed against the risk to patients of not receiving the drug, as follows:
  - Filters were supplied with a product to remove particulate matter,
  - Extra testing for product quality or identity was completed before releasing the product into the marketplace,
  - Third-party oversight of production was instituted to monitor quality issues, and
  - Special instructions were provided to health care professionals and patients.

- FDA used temporary regulatory flexibility and discretion to permit continued distribution of a drug product to mitigate or resolve a drug shortage while FDA reviewed a supplement/proposed change to address a problem with the drug product.

- FDA used temporary regulatory flexibility and discretion with regard to new sources of medically necessary drugs, including FDA-registered foreign sources, in rare instances when all alternative approaches were exhausted.

- FDA permitted expanded access to investigational drugs for treatment use under an investigational new drug application (IND) (21 CFR 312.315(a)(3)(ii)) to mitigate a shortage of an approved drug product.

***Requirement 6*: List the names of manufacturers issued letters under section 506C(f).**

[14] One instance of regulatory flexibility may affect more than one product. Conversely, a shortage of one product may involve multiple instances of regulatory flexibility.

Under section 506C(f) of the FD&C Act, if a manufacturer fails to provide notification of a discontinuance or interruption in manufacturing as required by section 506C, FDA must issue a letter to that manufacturer stating that the notification requirement was not met. The manufacturer is required to respond to FDA's letter within 30 calendar days, providing the reason for noncompliance and the required information on the discontinuance or interruption. Within 45 calendar days of its original letter to the manufacturer, FDA is required to post that letter and any response received on FDA's website,[15] with appropriate redactions to protect trade secrets or confidential commercial information, unless FDA determines that the original notification was issued in error or, after review of the manufacturer's response, that the manufacturer had a reasonable basis for not notifying FDA as required.

To date, FDA has issued four non-compliance letters under section 506C(f). No letters were issued in 2017. The letters sent by FDA and the responses received from the manufacturers are available on FDA's website.

***Requirement 7*: Specify the number of drug shortages occurring during 2017.**

The data from CDER's drug shortage database[16] shows that the number of new shortages has significantly decreased in recent years, from 117 in 2012 to 44 in 2013, 44 in 2014, 26 in 2015, and 26 in 2016. Unfortuanately, this downward trend did not continue into 2017, as previously discussed. As of December 31, 2017, there were a total of 39 new drug and biological product shortages identified.[17] In 2017, FDA prevented 135 drug and biological product shortages.

Another data point to note is the number of ongoing shortages yet to be resolved from previous years. FDA identified 97 ongoing CDER-tracked shortages at the end of CY 2013, 74 ongoing CDER-tracked shortages at the end of CY 2014, 64 ongoing CDER-tracked shortages at the end of CY 2015, and 48 ongoing CBER and CDER-tracked shortages at the end of CY 2016. As of December 31, 2017, there were 41 ongoing shortages, the lowest number since FDA started collecting such data.

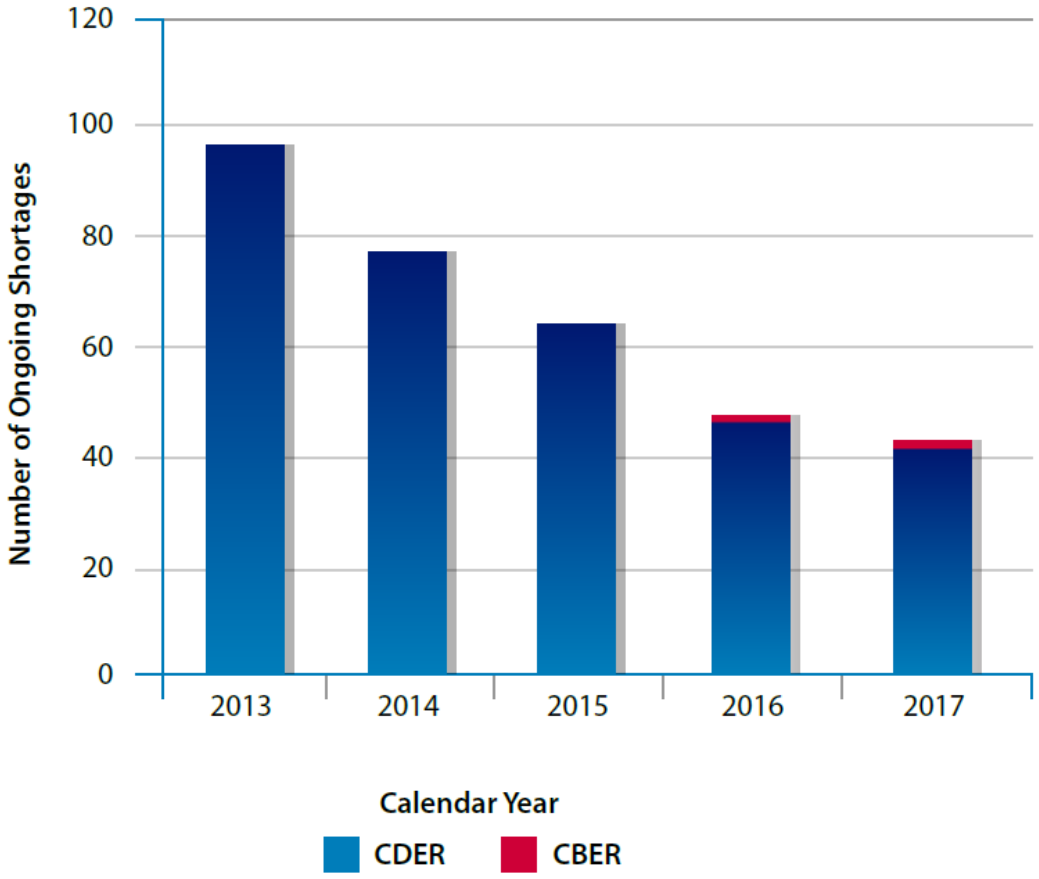
Figure 3. Number of Ongoing Drug Shortages Per Year, 2013 - 2017[18]

[15] Links to letters of non-compliance with notification requirement can be found at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm403902.htm.

[16] CDER's drug shortage statistics can be found at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm050796.htm.

[17] See Appendix 3 for a breakdown of 2017 CBER and CDER numbers.

[18] This fifth annual report to Congress is the first year to include both reporting for those covered drug and biologic products. See Appendix 3 for a breakdown of 2017 CBER and CDER numbers.



CONTINUED DRUG SHORTAGES EFFORTS IN 2017

1. **Hurricane Maria and the Impact on Puerto Rico's Manufacturing Facilities**

Hurricane Maria devastated the Caribbean in 2017 and had a major impact on drug manufacturing. The FDA responded to these challenges. Given the extraordinary situation in Puerto Rico, FDA worked closely with local and federal authorities, and the manufacturers of FDA-regulated products with manufacturing facilities located in Puerto Rico, to help address the needs caused by challenges to the basic infrastructure in Puerto Rico after Hurricane Maria made landfall. FDA contacted other federal agencies and local authorities to assist manufacturers in addressing challenges such as gaining access to fuel and/or generators; clearing roads for safe travel and transport; and securing air, sea, and land transport priority for critical raw ingredients. Before the hurricane made landfall, FDA worked to identify potential risks to the drug supply. After the hurricane made landfall, FDA quickly worked with local and federal agencies to perform an assessment of impact.

1. A list of high-priority FDA-regulated products with manufacturing facilities in Puerto Rico was identified.

2. A detailed assessment of the storm's effects on the manufacture of these FDA-regulated products was performed.
3. FDA worked with all manufacturers that have facilities in Puerto Rico to assess the potential impacts on their facilities to avoid—whenever possible—shortages of critical FDA-regulated medical products. During and following the storm, FDA worked with manufacturers to determine whether facilities were damaged or not operational, or if they were still operational and could continue to function and manufacture on generator power.
4. FDA communicated with outside groups and the public with updates concerning the overall situation in Puerto Rico and status of FDA-regulated products manufactured in Puerto Rico.
5. FDA worked with other local and federal agencies to help get needed supplies and infrastructure to critical facilities.

One particular focus of the FDA's work after Hurricane Maria was related to the availability of sterile saline solution, a critical drug product used in many clinical situations. Sterile saline solution has been intermittently in shortage for several years as manufacturing capacity has worked to keep up with demand. Hurricane Maria disrupted the manufacturing of sterile saline solution at the Baxter Healthcare Corporation manufacturing facility located in Puerto Rico, resulting in a worsening of the availability of sterile saline solution in the United States. FDA took a variety of actions to address this ongoing shortage:

1. FDA did not object to the temporary importation of sterile saline solutions not approved for use in the United States which were manufactured at Baxter Healthcare Facilities located in Ireland, Australia, Mexico, Canada, and Brazil, nor did the FDA object to the temporary importation of sterile saline solution not approved for use in the United States manufactured at a B. Braun Medical, Inc. manufacturing facility located in Germany.
2. FDA expedited review of drug applications from additional manufacturers of sterile saline solutions to help relieve this shortage. In 2017, the Agency approved sterile saline solutions manufactured by Fresenius Kabi USA, LLC and Laboratorios Grifols, S.A., and the Agency anticipates that availability of these products will help to alleviate the ongoing shortage of sterile saline solutions.
3. FDA has coordinated with outside groups to promote understanding and transparency regarding the saline shortage, including product utilization.
4. FDA has communicated extensively about the shortage of sterile saline solutions.[19]

[19] Press announcements from FDA Commissioner Scott Gottlieb on FDA's hurricane response:
2018
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm595020.htm
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592617.htm
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm591391.htm
2017
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm585720.htm
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm580290.htm

2. FDA Public Communications Regarding Drug Shortages

In March 2015, FDA launched its first mobile application (app) that provided the public with easier and faster access to important information about drug shortages. The free mobile app was an innovative tool designed to identify current drug shortages, resolved shortages, and the discontinuations of drug products. The app provides health care professionals and pharmacists with real-time information about drug shortages to help them make treatment decisions. Users of this app can search or browse by a drug's brand name, generic name, active ingredient, or therapeutic category. The app can also be used to report a suspected drug shortage or supply issue to FDA. The mobile app was further enhanced in August 2016 for Android devices. Android device users can receive notifications when there is new or updated information about a shortage of a drug product or about a drug within selected therapeutic categories. We continue to work to have this feature available in the iOS format as well. As of December 31, 2017, there have been almost 48,000 installs of the Drug Shortage App.

Further outreach during 2017 included 10 presentations given to professional and patient advocacy organizations, industry and trade associations, and stakeholder groups.

3. FDA Drug Shortage Assistance Award

In September 2014, FDA created the FDA Drug Shortage Assistance Award[20] to publicly recognize drug companies and manufacturers that have demonstrated a commitment to preventing or alleviating drug shortages of medically necessary drugs. This award recognizes efforts of drug manufacturers who, while maintaining federally mandated quality standards, have worked in cooperation with FDA and implemented strategies to help provide a steady supply of medically necessary drugs for patients at a time when critical drug shortages pose a challenge for health care providers and patients nationwide. FDA hopes that shining a spotlight on the efforts of drug manufacturers that have gone above and beyond in this area will encourage other manufacturers to follow suit.

On December 20, 2017, FDA issued its fourth Drug Shortage Assistance Award to Adienne Pharma & Biotech for its efforts in alleviating a shortage of thiotepa for injection, as well as submitting and obtaining approval for a new drug application for Tepadina (thiotepa) for injection.

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https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm579493.htm
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577338.htm
https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm577112.htm

[20] Information about FDA's Drug Shortage Assistance Award can be found at http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm415807.htm.

4. FDA Internal Efforts Regarding Drug Shortages

The establishment of the Office of Pharmaceutical Quality (OPQ) within CDER created a single unit dedicated to product quality by improving FDA's oversight of quality throughout the lifecycle of a drug product. DSS has important and frequent interactions with OPQ as well as CDER/OC to assess drug shortage risk at manufacturing sites as a preventive effort to address shortages.

DSS also works closely with CDER's Office of Generic Drugs (OGD) and Office of New Drugs (OND) on shortage mitigation and prevention efforts and, when a product quality review is involved, DSS, OGD, and OND work with OPQ to ensure coordination across offices. OGD, OND, and OPQ work expeditiously to review and approve abbreviated and new drug applications, as well as supplements, for drug products that are in shortage.

Likewise, CBER/OCBQ has procedures similar to CDER/OC and DSS, and works closely with all CBER product review offices concerning shortage mitigation and prevention efforts. CBER/OCBQ also works to facilitate and ensure coordination across CBER product review offices.

CONCLUSION

Drug shortages remain a significant public health issue in the United States and a top priority for FDA. To address them, FDA is working with manufacturers and other partners to help prevent shortages from occurring and to mitigate the impact of shortages that cannot be prevented. As a part of this work, early and open dialogue between FDA and manufacturers is critical to our success. Because of important actions taken by the President and Congress, FDA has been able to learn of possible shortages before they occur and take steps to prevent or mitigate them. During 2017, FDA helped prevent 145 potential new shortages, and there were 39 new shortages for 2017. While important progress has been made in preventing drug shortages from occurring, FDA continues to work to ensure that patients in the United States will have access to the medicines they need. This report reflects FDA's commitment to continue our important work to prevent or mitigate drug shortages.

APPENDIX 1

DEFINITIONS

Drug Shortage: A *drug shortage* means a period when the demand or projected demand for the drug within the United States exceeds the supply of the drug.

Biological Product Shortage: A *biological product shortage* means a period when the demand or projected demand for the biological product within the United States exceeds the supply of the biological product.

Meaningful Disruption: A *meaningful disruption* means a change in production that is reasonably likely to lead to a reduction in the supply of a drug or biological product by a manufacturer that is more than negligible and affects the ability of the manufacturer to fill orders or meet expected demand for its product. A meaningful disruption is not an interruption in manufacturing due to matters such as routine maintenance and does not include insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period.

Significant Disruption: A *significant disruption* means a change in production that is reasonably likely to lead to a reduction in the supply of blood or blood components by a manufacturer that substantially affects the ability of the manufacturer to fill orders or meet expected demand for its product. A significant disruption does not include interruptions in manufacturing due to matters such as routine maintenance or insignificant changes in manufacturing so long as the manufacturer expects to resume operations in a short period.

Life Supporting or Life Sustaining: *Life supporting* or *life sustaining* is used to describe a drug or biological product that is essential to, or that yields information that is essential to, the restoration or continuation of a bodily function important to the continuation of human life.

APPENDIX 2

SEC. 506C–1. ANNUAL REPORTING ON DRUG SHORTAGES.

(a) ANNUAL REPORTS TO CONGRESS.—Not later than March 31 of each calendar year, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report with respect to the preceding calendar year on drug shortages that—

(1) specifies the number of manufacturers that submitted a notification to the Secretary under section 506C(a) during such calendar year;

(2) describes the communication between the field investigators of the Food and Drug Administration and the staff of the Center for Drug Evaluation and Research's Office of Compliance and Drug Shortage Program, including the Food and Drug Administration's procedures for enabling and ensuring such communication;

(3) (A) lists the major actions taken by the Secretary to prevent or mitigate the drug shortages described in paragraph (7);

(B) in the list under subparagraph (A), includes—

(i) the number of applications and supplements for which the Secretary expedited review under section 506C(g)(1) during such calendar year; and

(ii) the number of establishment inspections or reinspections that the Secretary expedited under section 506C(g)(2) during such calendar year;

(4) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages;

(5) identifies the number of and describes the instances in which the Food and Drug Administration exercised regulatory flexibility and discretion to prevent or alleviate a drug shortage;

(6) lists the names of manufacturers that were issued letters under section 506C(f); and

(7) specifies the number of drug shortages occurring during such calendar year, as identified by the Secretary.

APPENDIX 3

Breakdown of CDER and CBER Shortage Numbers, 2017

	CDER	CBER
NEW SHORTAGES	35	4
PREVENTED SHORTAGES	132	13
ONGOING SHORTAGES	38	3
NOTIFICATIONS	470	50
NO. OF MANUFACTURERS NOTIFYING	70	23
ACTIONS TAKEN TO MITIGATE SHORTAGES		
REGULATORY FLEXIBILITY AND DISCRETION	55	2
EXPEDITED REVIEWS	116	16
EXPEDITED INSPECTIONS	30	0

APPENDIX 4

Breakdown of Expedited Reviews by Submission Type

	EXPEDITED REVIEWS
CDER NDA/NDA SUPPLEMENTS	43
CDER ANDA/ANDA SUPPLEMENTS	71
CDER BLA/BLA SUPPLEMENTS	2
CBER BLA/BLA SUPPLEMENTS	16

The Opioid Crisis in America: Too much, too little, too late

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Section Editor: Mark I. Langdorf, MD, MHPE
Submission history: Submitted February 28, 2018; Accepted February 28, 2018
Electronically published March 13, 2018
Full text available through open access at http://escholarship.org/uc/uciem_westjem
DOI: 10.5811/westjem.2018.2.38087
[West J Emerg Med. 2018;19(3)557–558.]

TOO MUCH

There is widespread awareness of one component of today's opioid crisis in America – the overuse of opioid medications. With overdose deaths reaching epidemic levels, some U.S. states have issued emergency declarations to bring legal authorities to bear for this unprecedented situation. Following a 2015 fall in life expectancy for the first time in decades, the Centers for Disease Control and Prevention identified opioid overdoses as a major contributor to this increase in population mortality. On October 26, 2017, the President of the United States declared the opioid epidemic to be a "national public health emergency";[1] the declaration was renewed on January 24, 2018.

Prescription opioids have been a major contributor to addiction and overdose deaths. While in the not-too- distant past, physicians were trained to treat pain aggressively, and even to consider pain to be a fifth vital sign that must be immediately addressed, strong caution is now advised when prescribing opioids. Comprehensive mitigation strategies have been enacted, including a requirement to check databases of prior opioid prescriptions before dispensing new pain medications.

As the emergency medical services (EMS) medical director for a large county with a population of approximately 3.3 million residents spread over more than 4,000 square miles, I have joined others in the implementation of various strategies to prevent opioid overdose deaths. This includes developing policies and protocols to authorize and train law enforcement and emergency medical technician first responders, in addition to higher-trained personnel such as paramedics, to administer naloxone to patients with hypoventilation after opioid use. But naloxone is a short-lived emergency intervention, not a complete solution to a long-term problem.

TOO LITTLE, TOO LATE: ANOTHER OPIOID CRISIS

Despite the abundance of opioids in our communities, particularly when compared with other countries, there are patients who legitimately need treatment of their pain and are in danger of not receiving it. Pain should be treated as early as possible to halt its escalation. This is especially true in emergency settings, including treatment by paramedics in the prehospital environment.

Today we are experiencing a national shortage of critical life-saving medications and drugs needed immediately to mitigate suffering.[2] This "too little" gap has been exacerbated by the recent hurricane event in Puerto Rico – a very important source of medical drug and device manufacturing, which has markedly diminished on account of destruction wrought by the storm, and the glacial pace of recovery and restoration. Should there be a national effort to restore pharma production in the U.S. territory of Puerto Rico? Or an effort to rebuild elsewhere? Or should we expand our efforts to purchase medications from other countries?

This emergency drug shortage crisis – including opioids – has led to challenges in reliable and consistent access to important medications in our nation's emergency departments and hospitals as well as the prehospital setting. If not addressed more consistently nationwide, could this escalate to the point where we regularly lack the resources to treat pain and other time-sensitive conditions in an emergency situation?

As an EMS medical director, part of my job is to authorize destruction of expired opioids in the prehospital setting. This requirement is tragic, especially when science tells us that these drugs are effective long after their official expiration dates and prehospital agencies are severely challenged by lack of timely access to these suffering-reducing medications. While it is possible to apply for "shelf life extension" and "emergency use authorization" for these expired products,[3] obtaining authorization is generally not feasible or timely due to the current complex regulatory framework for use of expired drugs. Thus, once the expiration date arrives, it is "too late."

Important initiatives such as Executive Order 13588, Reducing Prescription Drug Shortages, signed by President Obama on October 31, 2011, and Title X of the Food and Drug Administration Safety and Innovation Act of 2012, signed into law on July 7, 2012, have increased industry notification requirements for impending shortages, but more is needed. An evidence-based, federal extension of authorization

for use of expired medications for a reasonable period of time during a period of national shortages might be one option for addressing this emerging new twist on the "too little, too late" national opioid shortage.

NATIONAL CALL TO ACTION

Critical drug shortages have been addressed in the past, for example, by the Association of State and Territorial Health Officials (ASTHO) in 2012,[4] with supporting evidence from an Institute of Medicine report entitled "Crisis Standards of Care–A Systems Framework for Catastrophic Disaster Response."[5] Yet, this important suite of suggested solutions has not been implemented to any large degree and, in fact, seems to have been dwarfed by the current attention focusing on opioid overdoses.

At the time of publication of the ASTHO document, it was estimated that nearly 40% of the short-supply drugs contributed negatively to emergency care delivery. The report described a menu of strategies to address resource shortfalls, including techniques for conservation, substitution, and adaptation. It further suggested the potential to tap into existing federal and state emergency stockpiles . . . but the reality is that regulatory authority is generally lacking for this action.

We must rekindle our national efforts to address this other manifestation of the current opioid crisis, that is, the one of "too little, too late." These emergency drug shortages require critical attention and acknowledgment. Certainly it is essential to limit opioid use when unnecessary as well as to explore non-opioid alternatives for pain treatment. This could include techniques as simple as using ice packs and splinting, as novel as emergency acupuncture, or usage of other less-commonly employed analgesics in the emergency setting such as ketamine, intravenous acetaminophen or ketorolac, and nitrous oxide. The bottom line, however, is that there is a legitimate need for opioids, when properly prescribed.

The emergency drug shortage situation appears to be escalating across America. We need help on the front lines to ensure we will have the means to alleviate suffering from acutely painful conditions. This means exploring the creative solutions mentioned above as well as other innovative, science-supported approaches to provide timely access to analgesia. Certainly let's put a stop to the declared national opioid crises, but let's also enact long-term strategies to ensure sufficient opioid production and access for essential patient care. Opioids are an important tool in the armamentarium for pain treatment. While we apply temporary regional mitigation strategies to address critical drug shortages, a long-term solution that identifies and eliminates the root causes of the crisis must be mobilized. In the meantime, our attention should not be solely focused on the popularized opioid crisis. In the case of opioids while there is too much, we also have too little, too late.

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Conflicts of Interest: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. No author has professional or financial relationships with any companies that are relevant to this study. There are no conflicts of interest or sources of funding to declare.

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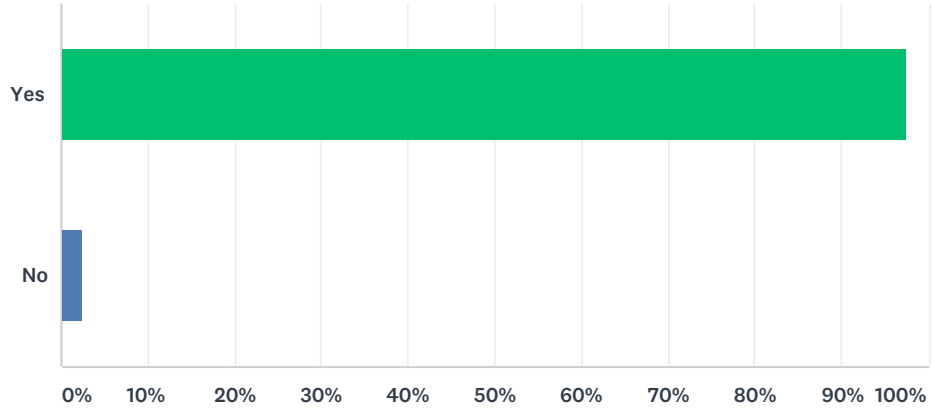
Q1 Are you experiencing an IV opioid shortage at your facility?

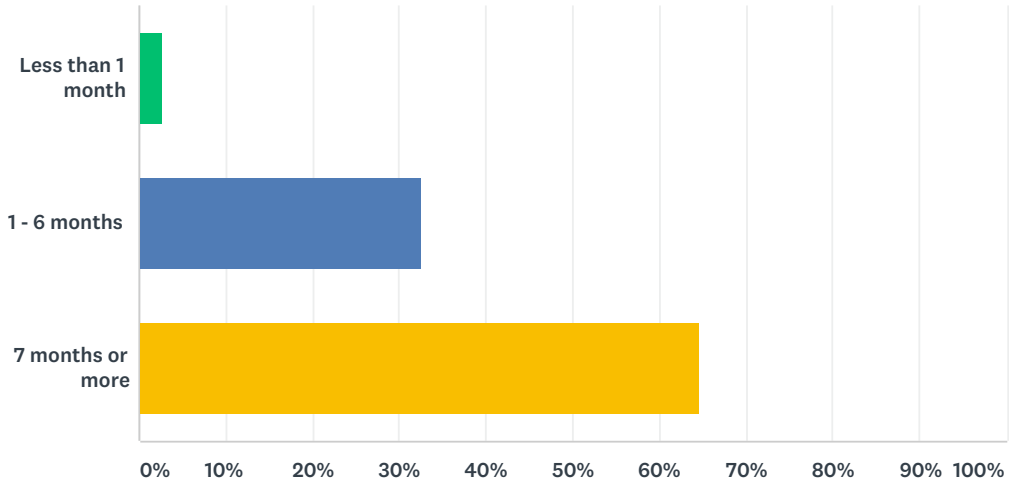
Answered: 115 Skipped: 0



ANSWER CHOICES	RESPONSES	
Yes	97.39%	112
No	2.61%	3
Total Respondents: 115		

Q2 If yes, for how long?

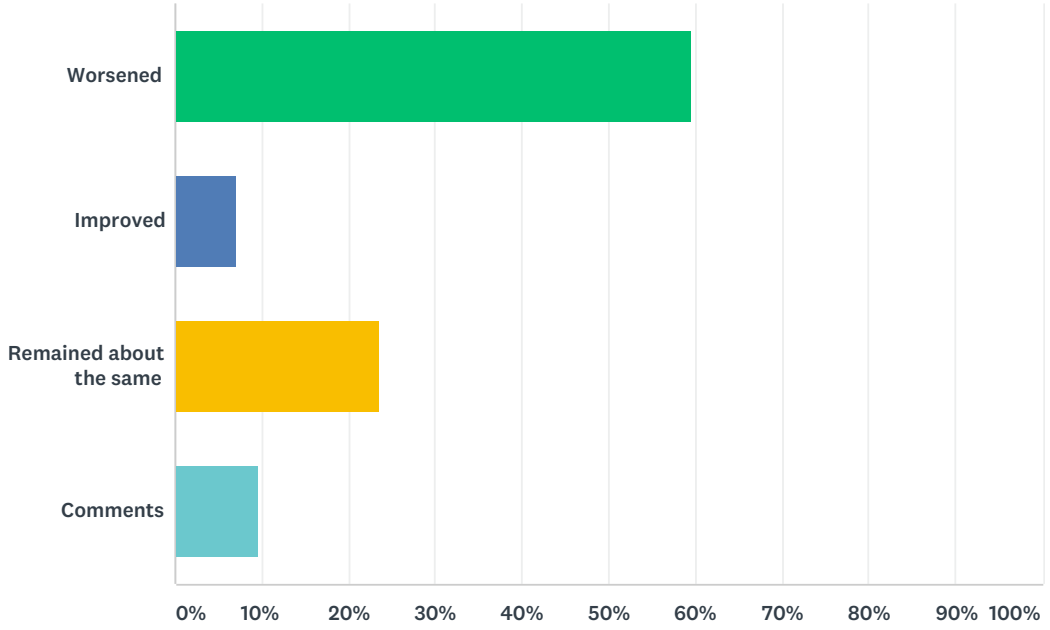
Answered: 110 Skipped: 5



ANSWER CHOICES	RESPONSES	
Less than 1 month	2.73%	3
1 - 6 months	32.73%	36
7 months or more	64.55%	71
TOTAL		110

Q3 Over time, the shortage has?

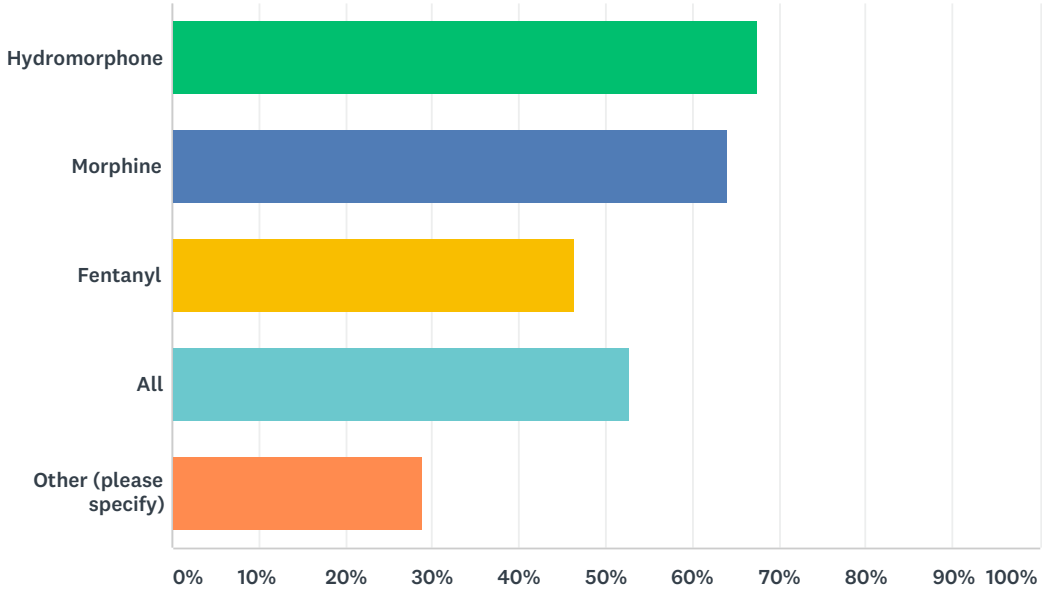
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Worsened	59.65%	68
Improved	7.02%	8
Remained about the same	23.68%	27
Comments	9.65%	11
TOTAL		114

Q4 What drug shortages are you experiencing? (choose all that apply)

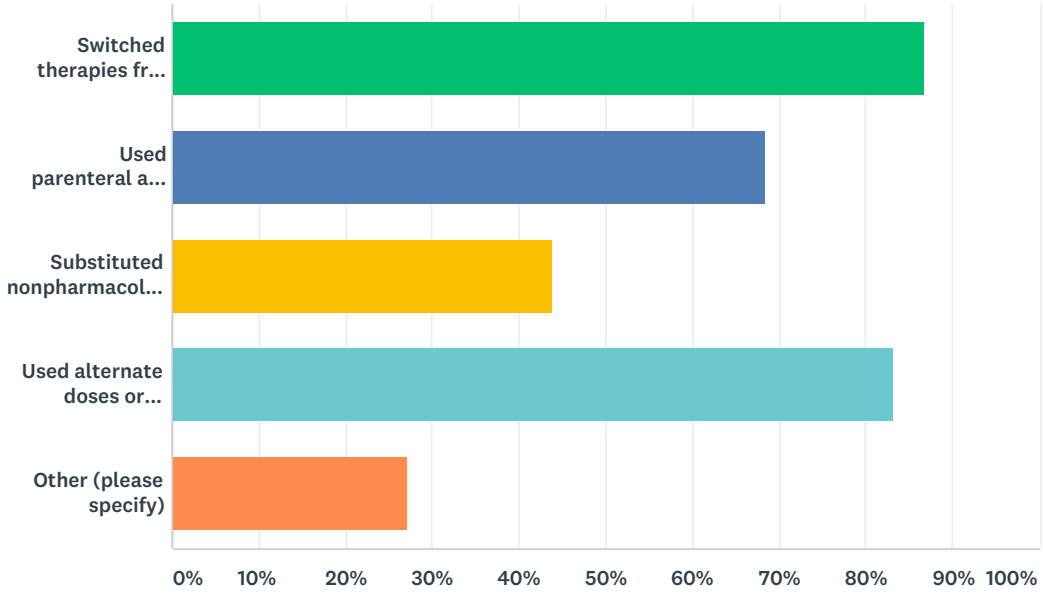
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Hydromorphone	67.54%	77
Morphine	64.04%	73
Fentanyl	46.49%	53
All	52.63%	60
Other (please specify)	28.95%	33
Total Respondents: 114		

Q7 What types of mitigation measures have you implemented?(choose all that apply)

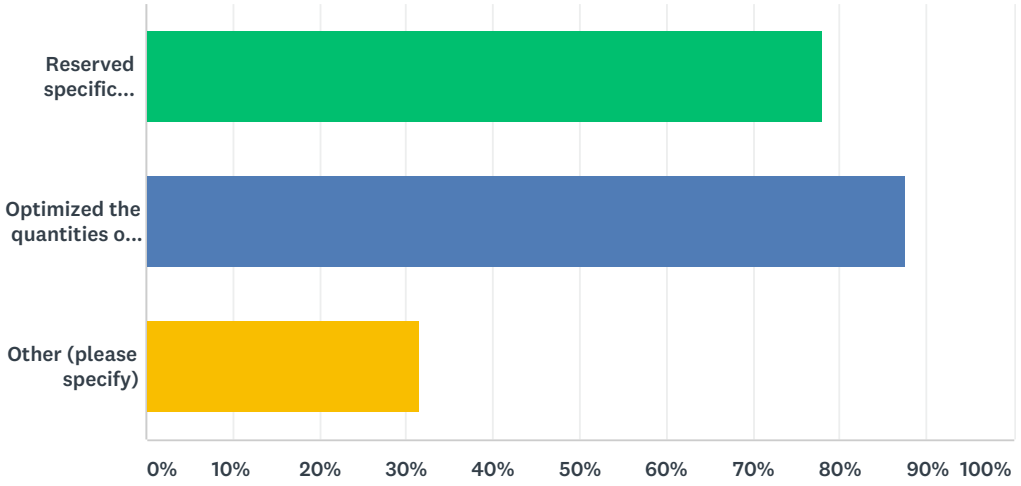
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Switched therapies from IV to oral or enteral.	86.84%	99
Used parenteral and enteral alternatives.	68.42%	78
Substituted nonpharmacologic treatments such as nerve blocks or other pharmacologic adjuncts.	43.86%	50
Used alternate doses or alternative drug substitutions.	83.33%	95
Other (please specify)	27.19%	31
Total Respondents: 114		

Q8 List the inventory control strategies you have deployed, such as: (choose all that apply)

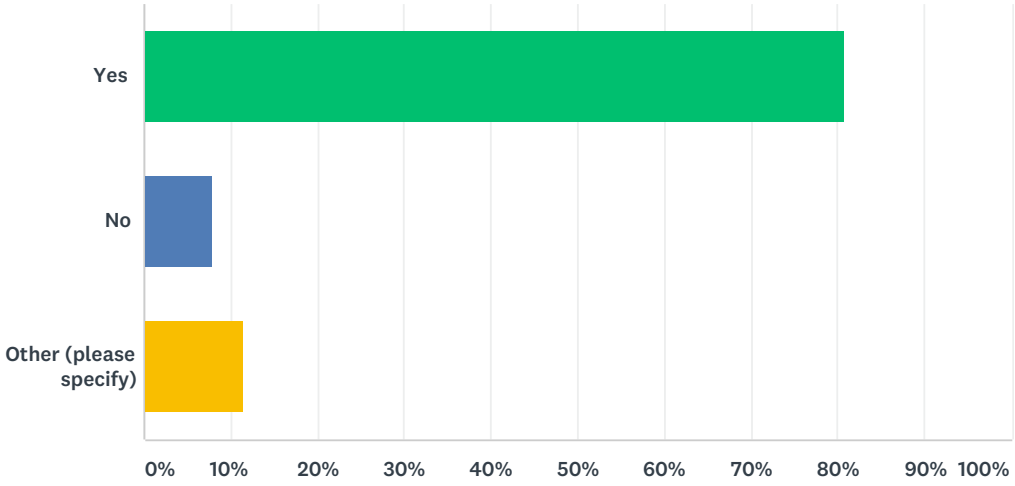
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Reserved specific injectable opioids for specific indications and limiting it for others.	78.07%	89
Optimized the quantities of injectable opioids kept in automated dispensing cabinets.	87.72%	100
Other (please specify)	31.58%	36
Total Respondents: 114		

Q9 Have you explored all options for purchasing products from other wholesalers or manufacturers?

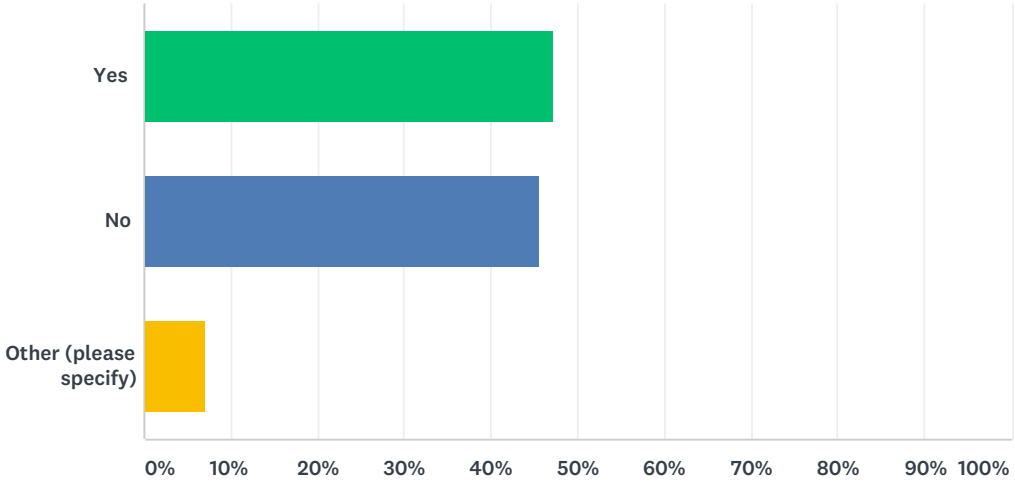
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	80.70%	92
No	7.89%	9
Other (please specify)	11.40%	13
TOTAL		114

Q10 Have you repackaged opioids from larger vials or syringes?

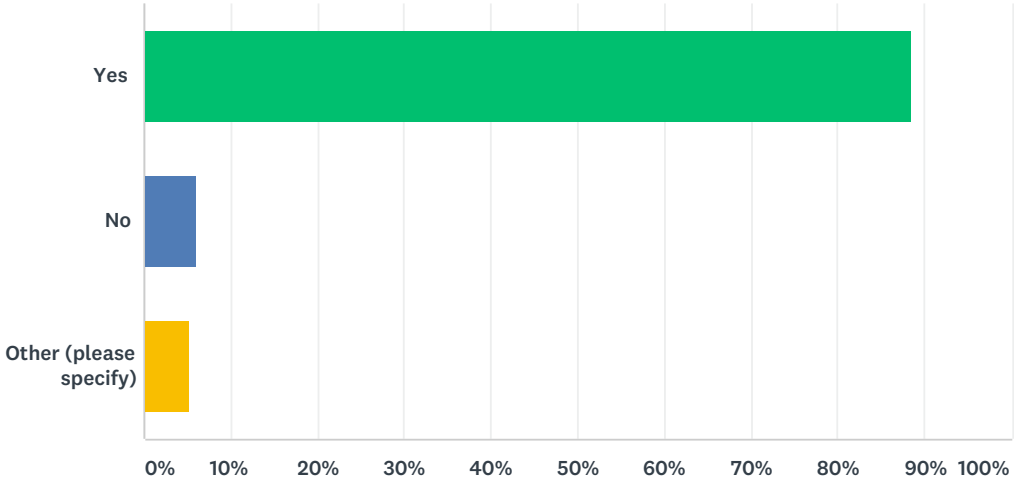
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	47.37%	54
No	45.61%	52
Other (please specify)	7.02%	8
TOTAL		114

Q11 Are you concerned about patient safety issues this may create?

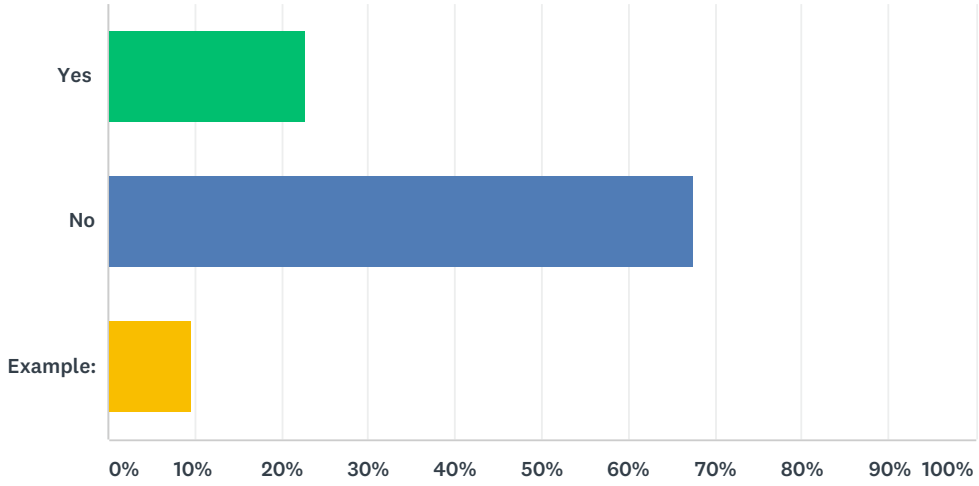
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	88.60%	101
No	6.14%	7
Other (please specify)	5.26%	6
TOTAL		114

Q12 Are other providers, such as nurses, performing IV opioid medication preparation and administration activities not normally done in the past?

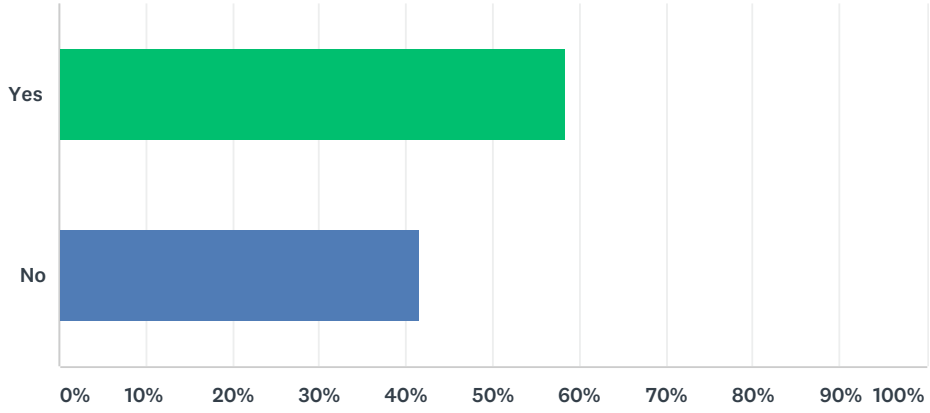
Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	22.81%	26
No	67.54%	77
Example:	9.65%	11
TOTAL		114

Q13 Have you experienced patient satisfaction issues?

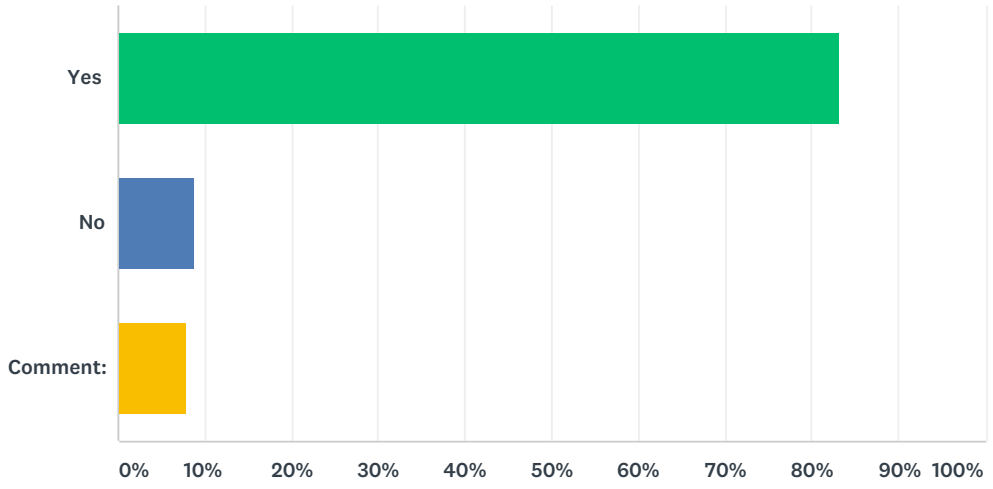
Answered: 108 Skipped: 7



ANSWER CHOICES	RESPONSES	
Yes	58.33%	63
No	41.67%	45
TOTAL		108

Q14 Have you experienced provider (RN, MD) satisfaction issues?

Answered: 114 Skipped: 1



ANSWER CHOICES	RESPONSES	
Yes	83.33%	95
No	8.77%	10
Comment:	7.89%	9
TOTAL		114

Q15 Responder information (optional)

Answered: 66 Skipped: 49

ANSWER CHOICES	RESPONSES	
Name	96.97%	64
Company	100.00%	66
Address	0.00%	0
Address 2	0.00%	0
City/Town	0.00%	0
State/Province	0.00%	0
ZIP/Postal Code	0.00%	0
Country	0.00%	0
Email Address	96.97%	64
Phone Number	0.00%	0

Q5 What is the most recent projection for product availability from your wholesaler?

Answered: 112 Skipped: 3

#	RESPONSES	DATE
1	varies	5/24/2018 3:35 PM
2	Intermittent availability. Cannot predict exact dates	5/24/2018 1:52 PM
3	Inconsistent and sporadic availability	5/24/2018 11:58 AM
4	2019	5/24/2018 6:33 AM
5	unknown release date!!!	5/23/2018 1:40 PM
6	unknown	5/22/2018 3:24 PM
7	currently we are not able to know. we find out almost too late	5/22/2018 2:07 PM
8	End of summer	5/22/2018 11:20 AM
9	Undetermined	5/21/2018 4:26 PM
10	it varies by week and by product. We expect all products to be on limited allocation until 2nd Qtr 2019.	5/20/2018 3:25 PM
11	First Quarter 2019	5/18/2018 2:53 PM
12	Not date provided	5/18/2018 2:14 PM
13	varies from week to week	5/18/2018 12:58 PM
14	Some release by pfizer (main spplier) but only 1 week supply of dilaudid. Then won't be available from pfizer again until July. Not sure when westward releasing again. Mostly getting morphine 4 mg from this company.	5/18/2018 6:41 AM
15	July 2018	5/17/2018 2:15 PM
16	Shipments are spotty but we are sourcing to special vendors.	5/17/2018 12:21 PM
17	Intermittent supplies will continue.	5/17/2018 12:16 PM
18	Each product is different and no ETA on many products. 503B distributors we buy product from as well and they can't get product. Product from 503b pharmacies have extended dating so less waste. Organizations are having to compound product giving it 24 hour expiration dating and having to wast product more.	5/17/2018 11:26 AM
19	Projected availability has changed often and has become unpredictable.	5/17/2018 10:43 AM
20	Date continues to change	5/17/2018 9:58 AM
21	In some cases "unknown" but routinely time frames are extended, small allocations are infrequent.	5/17/2018 9:30 AM
22	They will not commit to any date or time frame and have placed us on a very low rate of allocation which is not sufficient for the patients we serve.	5/16/2018 5:00 PM
23	Continued limited availability. I received an email from Pzifer/Hospira that morphine and dilaudid next release will be in July.	5/16/2018 3:22 PM
24	Currently says end of May first week of June	5/16/2018 1:35 PM
25	Some morphine, dilaudid and fentanyl strengths remain unavailable from our wholesaler with no posted release date. Duramorph continues to be unavailable	5/16/2018 10:24 AM
26	None given that is reliable	5/16/2018 9:23 AM
27	We get a messages saying something like this: Intermittent backorder next release date Late June 2019. Vendor experiencing delays in production. Full recovery TBD	5/16/2018 7:55 AM

28	July 2019	5/16/2018 6:57 AM
29	depends on the medication, but some as short as a few months, some longer	5/16/2018 6:31 AM
30	first quarter 2019	5/16/2018 4:55 AM
31	third quarter 2018	5/15/2018 9:23 PM
32	NA	5/15/2018 9:02 PM
33	Stated to be improved for hydromorphone and morphine within the next 3 months but Hospira carpujects for morphine and hydromorphone are stated to be short until 2nd quarter of 2019.	5/15/2018 5:32 PM
34	First quarter 2019 per the manufacturer's plant, mid-June per wholesaler	5/15/2018 4:35 PM
35	6/2019	5/15/2018 4:31 PM
36	Hydromorphone is winter 2018.	5/15/2018 4:16 PM
37	No estimated time of arrival, random small allocations available	5/15/2018 4:16 PM
38	not transparent	5/15/2018 3:51 PM
39	Pfizer correction estimated 1st quarter 2019	5/15/2018 3:47 PM
40	Their predictions are unreliable.	5/15/2018 3:47 PM
41	projected November 2018 availability for some of the items in shortage	5/15/2018 3:44 PM
42	Varies day to day....there are no projections that mean anything	5/15/2018 3:12 PM
43	unpredictable and Intermittent releases; anticipated recovery ranges from Q2 2018 - 2019 or TBD	5/15/2018 1:18 PM
44	Wholesalers are not able to project product availability. In talking with the manufacturers, Pfizer is not projecting recovery until next year. They comprise of 80% of the market share. Other manufacturers are not able to keep up with the demand since everyone in the nation is now turning to these manufacturers to supply and they do not have the capacity to meet market demand. Also, DEA has placed quotas on how much manufactures can make which adds to the shortages, in that the manufactures that are picking up for the lack of manufacturing from Pfizer, their manufacturing quota placed on them from the DEA may not meet the needs of the market	5/15/2018 1:11 PM
45	episodic availability	5/15/2018 1:06 PM
46	late fall to early 2019	5/15/2018 11:59 AM
47	Unknown release date per wholesaler.	5/15/2018 11:47 AM
48	End of June, but the projections often change...	5/15/2018 10:57 AM
49	Hydromorphone IV - no ETA. Morphine IV - variable.	5/15/2018 10:55 AM
50	Some relief in next few months, but intermittent and expected to go through end of year (or at least 4th quarter 2018).	5/15/2018 10:50 AM
51	no date availability.	5/15/2018 10:36 AM
52	On Limited supply. We only get products in small increments and various times.	5/15/2018 10:22 AM
53	Unknown	5/15/2018 9:43 AM
54	July 2018	5/15/2018 8:52 AM
55	March 2019	5/15/2018 6:58 AM
56	It is hard to tell as many say date not avaiable from manufacturer. Even if there is a release of some drug, it is never enough to meet continuous patient care needs for the size of our hospital. You always have to try to forecast when it will be avaiable try to order a lot and hope you get something or you will never get anything. It requires you to change your purchasing patterns to carry more drug on hand at times than you would usually buy with normal purchasing patterns.	5/14/2018 11:25 PM
57	on allocation	5/14/2018 8:07 PM
58	it varies	5/14/2018 7:14 PM
59	Amerisource bergen	5/14/2018 6:13 PM
60	it varies depending on the opioid product	5/14/2018 5:02 PM

61	Depends on the drug, but it can be as early as June for some items.	5/14/2018 5:02 PM
62	Unsure	5/14/2018 5:00 PM
63	June replenishment. We cannot source premade PCA from 503B pharmacies..... Almost out of INJ Morphine/Hydromorphone	5/14/2018 4:57 PM
64	The date changes each month. There is no resolution.	5/14/2018 4:45 PM
65	The manufacturer can not give us a date.	5/14/2018 4:34 PM
66	Varies per drug and dosage	5/14/2018 4:27 PM
67	intermittent availability until at least July but main supplier will not be able to meet demand until 2019	5/14/2018 4:20 PM
68	No projection	5/14/2018 4:17 PM
69	June 2018	5/14/2018 4:15 PM
70	Allocation	5/14/2018 4:10 PM
71	N/A	5/14/2018 3:50 PM
72	June 2019	5/14/2018 3:39 PM
73	none	5/14/2018 2:01 PM
74	It's all on allocation. Return to normal is uknown.	5/14/2018 1:45 PM
75	Some morphine is possibly available. Simplist brand. 2mg/mL syringes.	5/14/2018 1:40 PM
76	day to day	5/14/2018 1:40 PM
77	allocation	5/14/2018 1:33 PM
78	Sporadic projections, largely manufacturer-specific. Pfizer not expected to resolve until 2nd quarter 2019. Other suppliers have intermittent releases and allocations.	5/14/2018 1:25 PM
79	2019	5/14/2018 1:10 PM
80	Our wholesaler is filling back orders for drug products. We still cannot get the pre-filled syringes we normally stock, so we've had to use vials and different dose sizes to get by.	5/14/2018 1:00 PM
81	Date not provided	5/14/2018 12:45 PM
82	Cannot provide	5/14/2018 12:42 PM
83	1 month wait	5/14/2018 12:28 PM
84	Only allocations based on a percentage of our previous usage history	5/14/2018 12:09 PM
85	End of May/June 2018	5/14/2018 12:08 PM
86	Day to day	5/14/2018 12:02 PM
87	Summer 2018	5/14/2018 11:48 AM
88	Fentanyl - no estimated resupply date Hydromorphone - some presentations in early July Morphine - some presentations in early May	5/14/2018 11:14 AM
89	Little feedback from our wholesaler. We were told to backorder multiple NDC's	5/14/2018 11:03 AM
90	They have slow releasing fentanyl and hydromorphone for the past 2 month.	5/14/2018 10:38 AM
91	Availability is unknown by the wholesaler-we receive small shipments on a periodic basis, but never know when and what we will receive.	5/14/2018 10:30 AM
92	No date given, they say they don't know when available (Cardinal)	5/14/2018 10:23 AM
93	Mid summer 2018	5/14/2018 10:11 AM
94	Unknown	5/14/2018 9:54 AM
95	On allocation no specific date on availability is given to us	5/14/2018 9:46 AM
96	6/14/18	5/14/2018 9:43 AM
97	fall/winter 2018	5/14/2018 9:38 AM

98	Anywhere between July 2018 and Feb 2019	5/14/2018 9:08 AM
99	No specific date	5/14/2018 9:07 AM
100	N/A	5/14/2018 8:56 AM
101	Vague and inconsistent. Promises for release are not accurate.	5/14/2018 8:55 AM
102	no commitments on product availability	5/14/2018 8:51 AM
103	Q1 2019	5/11/2018 9:40 PM
104	Intermittent	5/11/2018 5:58 PM
105	Sometime 2019	5/11/2018 5:56 PM
106	some morphine and dilaudid being allocated every other week, but in general wholesaler just keeps extended the availability date with no allocation of drug	5/11/2018 4:49 PM
107	unknown . Supplies has been sporadic	5/11/2018 4:12 PM
108	Don't know	5/11/2018 3:51 PM
109	Estimate release dates have been unreliable. When available, supply is limited or on allocation	5/11/2018 3:51 PM
110	Dilaudid and morphine by summer. Others listed are unknown.	5/11/2018 3:41 PM
111	We are getting some product but on allocation and amount received is less than needed to meet patient needs	5/11/2018 3:29 PM
112	June 2019	5/11/2018 3:24 PM

Q6 How often have wholesaler projections changed?

Answered: 109 Skipped: 6

#	RESPONSES	DATE
1	monthly	5/24/2018 3:35 PM
2	weekly	5/24/2018 1:52 PM
3	Inconsistent and sporadic availability is the norm	5/24/2018 11:58 AM
4	weekly updates provided	5/24/2018 6:33 AM
5	sometimes daily. more often, opioids are not available for extended time . Projections have either not been given or unknown release date	5/23/2018 1:40 PM
6	often	5/22/2018 3:24 PM
7	very often	5/22/2018 2:07 PM
8	100% of the time.	5/22/2018 11:20 AM
9	seldom, typically without resolution date	5/21/2018 4:26 PM
10	they generally change weekly based upon manufacturer supply changes	5/20/2018 3:25 PM
11	Monthly	5/18/2018 2:53 PM
12	Has not changed. They continue to say that they have no stock	5/18/2018 2:14 PM
13	weekly	5/18/2018 12:58 PM
14	Constantly. You need to check daily if not several times a day.	5/18/2018 6:41 AM
15	daily	5/17/2018 2:15 PM
16	Frequently	5/17/2018 12:21 PM
17	They do not give us projections.	5/17/2018 12:16 PM
18	Often. Too often.	5/17/2018 10:43 AM
19	It changes PRN & not on a regular basis	5/17/2018 9:58 AM
20	Routinely	5/17/2018 9:30 AM
21	Variable without any real guidance and always blaming the manufacturers.	5/16/2018 5:00 PM
22	Wholesaler sends out monthly reports on orders vs supply. Challenge is the supply is not available from the wholesalers.	5/16/2018 3:22 PM
23	Continuously the date is pushed back	5/16/2018 1:35 PM
24	every other week approximately	5/16/2018 10:24 AM
25	often. but never to our advantage of receiving product---only more delays	5/16/2018 9:23 AM
26	weekly/monthly - depending on the drug	5/16/2018 7:55 AM
27	Frequently	5/16/2018 6:57 AM
28	often. Projected release dates are often delayed by months	5/16/2018 6:31 AM
29	Monthly	5/16/2018 4:55 AM
30	initially it was supposed to be 2019	5/15/2018 9:23 PM
31	unknown	5/15/2018 9:02 PM
32	Frequently- the allocation system that was implemented has been very challenging. Despite historical usage data, we are receiving only a very small fraction of the number ordered.	5/15/2018 5:32 PM

33	Their projections generally list a date about 2 weeks away AND WE NEVER GET CLOSER. Their projections have been two weeks away since I started this job in February. If the true target is months, they should be more accurate!	5/15/2018 4:35 PM
34	Weekly	5/15/2018 4:31 PM
35	The real question is how often the drug manufacturer's projections change? It has been a moving target since January.	5/15/2018 4:16 PM
36	Can change on a daily basis	5/15/2018 4:16 PM
37	All the time. Plus information arrives too late.	5/15/2018 3:51 PM
38	Quarterly	5/15/2018 3:47 PM
39	Often.	5/15/2018 3:47 PM
40	monthly	5/15/2018 3:44 PM
41	All the time	5/15/2018 3:12 PM
42	Very often; projections are not reliable	5/15/2018 1:18 PM
43	N/A - see above	5/15/2018 1:11 PM
44	not applicable	5/15/2018 1:06 PM
45	weekly	5/15/2018 11:59 AM
46	Not often and no specific dates or plan.	5/15/2018 11:47 AM
47	consistently, every month	5/15/2018 10:57 AM
48	Regularly	5/15/2018 10:55 AM
49	Every month or so, mostly extending shortage information.	5/15/2018 10:50 AM
50	weekly	5/15/2018 10:36 AM
51	Unknown	5/15/2018 10:22 AM
52	N/A	5/15/2018 9:43 AM
53	About monthly	5/15/2018 8:52 AM
54	weekly	5/15/2018 6:58 AM
55	They change weekly.	5/14/2018 11:25 PM
56	?	5/14/2018 8:07 PM
57	daily	5/14/2018 7:14 PM
58	monthly	5/14/2018 6:13 PM
59	unpredictable	5/14/2018 5:02 PM
60	Often, whenever the manufacturers fail to deliver on the initial ETA.	5/14/2018 5:02 PM
61	frequently	5/14/2018 5:00 PM
62	Weekly	5/14/2018 4:57 PM
63	Changes weekly.	5/14/2018 4:45 PM
64	Too many to count.	5/14/2018 4:34 PM
65	availability changes constantly	5/14/2018 4:27 PM
66	every 2-3 weeks	5/14/2018 4:20 PM
67	No projection	5/14/2018 4:17 PM
68	Weekly.	5/14/2018 4:15 PM
69	Frequently	5/14/2018 4:10 PM
70	Unknown	5/14/2018 3:50 PM
71	Weekly, sometimes we are able to order more and sometimes we get zero in our order.	5/14/2018 3:39 PM

72	all the time	5/14/2018 2:01 PM
73	Frequently. Unreliable dates.	5/14/2018 1:40 PM
74	daily	5/14/2018 1:40 PM
75	No firm dates are set and even if they are, they are changed often.	5/14/2018 1:33 PM
76	Weekly	5/14/2018 1:25 PM
77	Has not been wholesaler, it has been manufacturer - Pfizer predicts 2019 and they were 50% of market	5/14/2018 1:10 PM
78	Depending on the drug, some projections have changed weekly.	5/14/2018 1:00 PM
79	Not provided	5/14/2018 12:45 PM
80	every other month..	5/14/2018 12:28 PM
81	Almost daily	5/14/2018 12:09 PM
82	quite a bit	5/14/2018 12:08 PM
83	Stayed consistent. They have been very helpful in attempting to obtain product or alternative products for us.	5/14/2018 12:02 PM
84	Every month	5/14/2018 11:48 AM
85	Weekly	5/14/2018 11:14 AM
86	Daily	5/14/2018 11:03 AM
87	daily	5/14/2018 10:38 AM
88	The wholesaler says they don't know when they will receive product.	5/14/2018 10:30 AM
89	Every month for 6 months	5/14/2018 10:23 AM
90	Everytime	5/14/2018 10:11 AM
91	Unknown	5/14/2018 9:54 AM
92	Not changed	5/14/2018 9:46 AM
93	Weekly	5/14/2018 9:43 AM
94	has been variable - depending upon product	5/14/2018 9:38 AM
95	Typically every 1-2 months	5/14/2018 9:08 AM
96	weekly	5/14/2018 9:07 AM
97	N/A	5/14/2018 8:56 AM
98	Just about every time	5/14/2018 8:55 AM
99	Often	5/14/2018 8:51 AM
100	at least monthly and continue to be pushed back	5/11/2018 9:40 PM
101	Every month	5/11/2018 5:58 PM
102	Constantly	5/11/2018 5:56 PM
103	weekly	5/11/2018 4:49 PM
104	unable to keep track with so frequent occurences	5/11/2018 4:12 PM
105	they don't know and none of the dates have been accurate	5/11/2018 3:51 PM
106	Very often, which makes it challenging to ensure adequate supply for patient care	5/11/2018 3:51 PM
107	A lot of times.	5/11/2018 3:41 PM
108	Frequently with sometimes drug not arriving when expected	5/11/2018 3:29 PM
109	Daily	5/11/2018 3:24 PM

CHA
California Congressional
Action Program
2018

Intravenous Opioid Shortage

- **California hospitals and health systems are facing a severe injectable IV opioid shortage, due to the DEA's reduction of production quotas and manufacturing issues.**
- **We support efforts to stem the opioid epidemic. However, selective injectable IV opioid use in hospitals is a critical component of quality patient care and pain management.**
- **We urge the DEA to continue to adjust procurement quotas and consider other measures to address the ongoing shortage.**

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Issue

Hospitals and health systems are facing a critical shortage of injectable intravenous (IV) opioid medications — including morphine, hydromorphone and fentanyl — that are used in a variety of practice settings to treat acute or chronic pain. Injectable IV opioids are critical to treating pain needs of patients undergoing interventional procedures, pre- and post-operative procedures, intensive critical wound treatment, surgeries and procedures that would otherwise require general anesthesia. Often, hospitals rely on these drugs to treat patients who cannot take oral opioid medications. These medications are also frequently used in intensive care units for surgical, trauma, burn or oncology patients when it is not clinically appropriate to use oral opioids. A diminished supply of these critical drugs — or no supply at all — prevents patients from getting the care they need.

The shortage of these medications is largely attributable to manufacturing delays and the Drug Enforcement Administration's (DEA) decision to reduce quotas for opioid manufacturers. The quota reduction — 25 percent in 2017 and 20 percent in 2018 — is intended to respond to recent opioid crises by balancing the production of products needed for legitimate use against the production of an excessive amount of potentially harmful substances. Pfizer, which manufactures over 60 percent of injectable IV opioids, recently stopped production due to manufacturing issues and voluntarily surrendered a portion of its quota allotment. The DEA reallocated this allotment to three DEA-registered manufacturers, but — because they do not primarily produce injectable IV opioids — there is no guarantee that their production will happen quickly enough to make up for massive backorders before Pfizer's projected reopening in 2019.

Position

The severe shortage of injectable IV opioids threatens patient care in hospitals and surgical centers. CHA shares the DEA's concern that these medications are well managed, particularly in light of the national opioid epidemic. We fully support efforts to stem the opioid epidemic and advocate use of alternate and advanced pain management techniques, as well as safe and judicious opioid use. However, selective administration of injectable IV opioids remains an essential component of patient pain management.

Hospital and health system access to these drugs in a timely manner is critical to safe, efficient patient care. We urge the DEA to continue to use its discretionary authority to review production quotas and to implement any other procedures necessary until the shortage resolves.

Analysis

When faced with the dilemma of medication shortages such as this, hospitals work long hours to find alternatives. When unable to use the injectable IV opioid of choice, prescribers are forced to order whichever injectable IV opioid is available. However, because dosing equivalency between the injectable IV opioids differs significantly, the risk of medication errors increases. Moreover, using a more potent opioid based on lack of supply alone defeats national efforts to use these drugs only when absolutely necessary.

CALIFORNIA HOSPITAL ASSOCIATION

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's work to mitigate shortages of intravenous drugs, shorten supply disruptions and better predict vulnerabilities

For Immediate Release

May 31, 2018

Statement

Without question, one of the most frustrating challenges that health care providers and patients must contend with is when a drug that's medically necessary and critical to patient care is unavailable due to a shortage. We know that the uncertainty over how long a drug will be in shortage, how to ration supplies in the meantime, or worse, how to prepare for a sudden event that might place unforeseen demands on a product that's in short supply, adds burdens and stress on providers and patients.

The FDA also understands that hospitals and other health care facilities can feel blindsided by these shortages. They can seem abrupt, and may be. Drug shortages also have significant costs to our overall health care system. The FDA is committed to taking new steps to address the root cause of more of these shortage situations.

While the causes of drug shortages vary, most shortages are due to disruptions in supply chain availability of actively marketed products. Among these interruptions, manufacturing and quality issues are the leading causes of drug shortages. This includes outdated equipment in need of repair or replacement, unexpected issues with a product's composition, and a manufacturer's inability to maintain facility and product quality. The availability of raw materials can also be a key factor in creating supply disruptions. A disruption from one supplier of raw materials can affect production for many drug makers who all depend on that one source of raw material. Companies that supply raw materials can also be subject to quality problems, leading to shortages.

Only 2 percent of shortages are a result of product discontinuation. For example, when companies that make competing products merge, and discontinue one of the competing products, this can cause a shortage. Manufacturers often make production decisions based on business considerations, such as a product's profitability, manufacturing costs, distribution quotas and patent life. We know that business decisions at any point along the drug supply chain can lead to shortages. Historically, many drugs in short supply have been low-profit generic medications, for which the investment needed to ensure continued production can be less than that for higher profit products.

Even in the absence of any production issues and decisions, there are other issues that can precipitate a shortage.

For example, an unforeseen increase in clinical demand, changes in clinical practice guidelines, or even FDA approval of a new indication for an existing drug, can all lead to an unexpected surge in demand for a particular medicine. The increased demand can, in turn, lead to a shortage of that specific drug.

Given these challenges, the FDA is focused on doing all we can to mitigate existing shortages, and prevent them from occurring. While we help avert and minimize shortages in many ways, the FDA can have the best impact by working more closely with sponsors to help prevent shortages before they occur.

This starts with the FDA knowing about potential supply disruption well in advance of an actual shortage.

The Food and Drug Administration Safety and Innovation Act of 2012 (known as FDASIA) generally requires manufacturers to notify us of any disruptions, such as manufacturing changes, production or shipping delays, and product discontinuations likely to affect their supply of prescription drugs for serious illnesses. This vital information allows the FDA to execute other actions within our authority to help avert impending shortages or lessen their impact.

These notification requirements are critical, but there are many times manufacturers abruptly discontinue, limit, or delay production under circumstances outside those for which they are specifically required to provide advance notice to the agency. There are other times when companies notify the FDA of potential supply disruptions, but don't provide enough details to allow us to make the fullest use of our resources to address the shortage. We need to know as much as possible about these shortages.

While this information sharing can sometimes be challenging, the more information manufacturers can supply the FDA, the more we can do to help mitigate the shortage. To address these challenges and opportunities, the FDA is exploring additional ways that we can encourage companies to voluntarily share more timely information about potential supply disruptions.

We may be able to take new steps to clarify the information the agency requires to inform us better about the extent of a shortage problem. We're also looking at what additional steps we can take, under the existing law, to make the communications we receive more actionable. This includes additional information that can help the FDA develop more effective options for managing a shortage.

Our ability to help resolve shortages also relies on industry seeking approval for drugs currently in short supply. When that opportunity arises, we do what we can to prioritize these circumstances. For example, if a new production facility or supplier is needed, we have the regulatory authority to expedite facility inspections and drug application assessments so that the facility can become operational as soon as possible. We can also expedite review of a new or generic drug application that, if approved, may serve as an alternative therapy to a product facing a shortage. Even when a shortage situation is urgent, patient safety remains our top priority. We make sure that any approvals of such alternate therapies meet our standards.

Although we cannot mandate submission of applications for products in short supply, the FDA does alert other manufacturers of similar or alternative products to consider ramping up production to meet an anticipated increased demand for their product. In cases where alternative manufacturing is not available in the U.S., or the manufacturers of U.S.-marketed products are not able to expand production, we may explore importation of a product from a foreign manufacturing source until the shortage is resolved. We carefully evaluate the overseas manufacturing site and product to protect U.S. patients.

We're also taking steps to bring on new technology that can improve manufacturing, to help reduce the chance that supply disruptions will occur. The FDA has implemented an **emerging technology program (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm523228.htm)** and established an emerging technology team to engage with companies about new production technologies that could, in the long run, prevent drug shortages caused by product quality and manufacturing problems. One such technology is continuous manufacturing (CM). As with any new technology, implementing CM presents challenges, such as the initial cost of investing in new equipment. The FDA is taking steps to reduce the cost and uncertainty of adopting CM as an important, long-term solution to improve manufacturing reliability. The goal is to prevent and mitigate future drug shortages.

Finally, as we learned from our experience in responding to the devastation in Puerto Rico following Hurricane Maria last year, predicting some forces that can lead to shortages is very hard. Given the complexities involved in drug manufacturing, especially for sterile injectable drugs, problems can arise at any point in the process. When companies are proactive and have backup lines, and facilities and raw material suppliers are prepared for when things go wrong, we can more readily prevent future shortages.

Shortages are an inevitable consequence of an imperfect system. With better planning, we can minimize shortages throughout the supply chain. But, in the near term, we won't be able to fully eliminate the possibility that new shortages will arise. Meaningfully impacting the structures and market challenges that can give rise to shortages will require more coordination among public and private stakeholders.

We're evaluating our current authorities to see what more we can do to better mitigate and prevent shortages, including receiving additional, key information from industry when they notify the agency about a possible shortage and identifying all establishments where manufacturing is performed associated with listed drugs and the type of operation performed at each such establishment. It's essential that we evaluate what additional steps we can take to reduce the incidence and impact of shortages.

It may also require us to work with Congress to re-evaluate our current authorities in these areas. One consideration might be to expand the FDA's existing authority to require applicants of certain drugs to conduct a risk assessment to identify the vulnerabilities in their drug supply, including vulnerabilities that could cause a shortage, and establish risk mitigation plans to address those risks.

Anticipation, foresight and communication are keys to preventing and reducing the impact of shortages. When a manufacturer provides the FDA with advance notification before production is halted or put on hold, and a contingency plan is put in place, shortages can be more easily mitigated. Without such efforts, shortages will certainly occur at a higher rate and their impacts will be greater than necessary.

To achieve our public health goals, the FDA needs to work collaboratively with industry. The agency cannot require a company to produce a drug, even if it is medically necessary. The agency cannot require a manufacturer to increase production of a drug, and we cannot control how much of the drug is distributed or which purchasers will be given priority. And the FDA has no authority over business decisions that affect the supply of a drug made by manufacturers or other entities in the supply chain.

We must all work together to ensure that the supply chain infrastructure can withstand inevitable and unexpected disruptions. Mitigating drug shortages requires a sustained effort by industry, the FDA, and other partners to return to production levels that adequately meet the needs of patients. We're pursuing new ways to support industry efforts to identify critical facilities and products and develop such plans.

We'll continue to do all we can to address these shortages. I'll have more to share in the coming months.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information

- **FDA Drug Shortages (/Drugs/DrugSafety/DrugShortages/default.htm)**
- **FDA Drug Shortages Database (https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm)**

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Injectable Opioid Shortages
Suggestions for Management and Conservation

(Compiled by ASHP and the University of Utah Drug Information Service, March 20, 2018)

This information has been compiled using publicly available information on established best practices. ASHP and the University of Utah have provided this fact sheet for informational purposes only and are not assuming any liability for the accuracy or completeness of the information provided.

Introduction

This fact sheet provides an outline of potential actions for organizations to consider in managing the acute shortages of injectable hydromorphone, morphine, and fentanyl. Healthcare professionals should use their professional judgment in deciding how to use the information in this document, taking into account the needs and resources of their individual organizations.

Critical importance

Shortages of injectable opioids can be particularly challenging due to the range of uses in various healthcare settings, including emergency response, ambulatory surgery centers, and hospitals. Injectable opioids are used for acute, acute-on-chronic, or chronic pain that cannot be controlled by other pain management options. Some injectable opioids are used for sedation or anesthesia. Intermittent shortages of specific injectable opioids may require institutions to convert temporarily to a more available product. Not all injectable opioids are interchangeable for all indications. Improper conversion between morphine and hydromorphone caused two deaths during a similar shortage in 2010.[1]

ISMP Medication Error Reporting

ASHP encourages the reporting of any medication errors related to drug shortages to the Medication Error Reporting page on the Institute for Safe Medication Practices (ISMP) website.

What can clinicians do to mitigate the impact?

- Switch therapy to a clinically appropriate oral or enteral opioid whenever possible.
    - The Pharmacy and Therapeutics (P&T) committee should review current IV-to-oral policies; there may be an opportunity to expand policies to include drug classes affected by shortages.
- Provide multimodal pain management by using parenteral and enteral alternatives to opioids. Consider nonpharmacologic treatments, local nerve blocks, or other pharmacologic adjuncts, as appropriate.

- Engage the institution's experts in anesthesia and pain and palliative medicine to further develop guidance and formulate strategies for dealing with intermittent shortages.
- Ensure relevant institutional pain medication guidelines are up to date.
    - To reduce the risk of conversion errors, use a uniform opioid conversion tool that is approved by the anesthesia team and the P&T committee and distributed throughout the entire health system.
    - Resources like the ASHP Demystifying Opioid Conversion Calculations reference may be helpful in establishing guidelines.
- Product availability can vary by wholesaler and may change from week to week. Guiding prescribers to choose between the available injectable opioids can help institutions reserve certain opioids for specific populations or indications (for example, reserve fentanyl for operating-room use).
    - Use systemwide communications to alert all clinicians who prescribe, dispense, or administer injectable opioids.
- Ensure the electronic health record (EHR) displays opioid options that match the products currently in stock. Do not underestimate the informatics resources that will be needed during this shortage.

Inventory control strategies

- Consider reserving supplies of specific injectable opioids for specific indications and limiting the placement of those injectable opioids to locations primarily associated with those indications (for example, limiting the placement of injectable fentanyl to operating rooms, emergency departments, and intensive care units).
- Optimize the quantities of injectable opioids kept in automated dispensing cabinets after checking the usage patterns at specific locations.

Pharmacy operational strategies

- Explore all legal options for purchasing product from other wholesalers or manufacturers. There may be product available off-contract or in strengths other than normally purchased.
    - Consider the patient-controlled analgesia (PCA) pump library and syringe compatibility when making purchasing decisions.
- Limit waste by considering the doses commonly given on patient care units and then supplying those units with appropriately sized syringes or vials.
- If repackaging opioids from large vials into syringes
    - Follow the guidance in Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities, issued in January 2017 by the FDA.
    - Assign beyond-use dates as dictated by USP Chapter <797> and state rules and regulations.
    - Search the primary literature and tertiary sources for information about stability of the opioid when repackaged in specific syringes.

Infusion pumps / Informatics strategies

- Review drug records, order sets, and treatment protocols for needed changes.

    - Some examples are postoperative pain management, sedation, PCA, and epidural order sets.
    - Include equivalent opioid doses in order sets so that prescribers do not need to calculate opioid conversions without assistance.
    - Make drug information easily accessible through the medication administration record for nurses to double check dosing before administration.
- If the products available for purchase are not already on the formulary or configured in the EHR system, validate product barcodes and ensure there is information technology (IT) support to configure the products' drug files correctly.

Clinical pearls

- Morphine has an active, renally excreted metabolite.[2] In patients with renal impairment, reduce the morphine dose and extend the dosing interval on the basis of renal function.
- Morphine has a slower onset and longer duration of action than other injectable opioids commonly used in the post-anesthesia care unit (PACU). Administering morphine doses every five minutes to patients in the PACU may lead to severe sedation and respiratory depression.
- Use caution if considering meperidine as an injectable alternative for pain management. The metabolite normeperidine is neurotoxic in renally and hepatically impaired patients, including the elderly.[3]
- Avoid fentanyl in patients receiving extracorporeal therapy because the drug will bind to tubing and oxygenators.[4] If there is no alternative available, infuse fentanyl directly into an IV line through a port close to the patient. Increased dosing may be required.
- Use injectable opioids to treat pain, not to sedate patients.

Caveats / Safety information

- Use established communication channels, such as daily huddles, flyers, and product labeling, to educate staff about changes within the hospital or health system.
    - Be sure that the IT team is aware of the emergent need to make priority changes in drug files, charge description masters, and infusion pump libraries.
    - Consider having physician and nursing champions in addition to the pharmacy lead who can assist with routine communication, practice changes, and supply updates.
- Conversions between injectable opioids should be done in accordance with institutional guidelines and with input from anesthesia and pain and palliative medicine specialists, including physicians, nurse practitioners, and pharmacists.
- Most injectable opioids are available in a variety of concentrations and package sizes. Exercise extreme caution when purchasing products that are not regularly stocked in the pharmacy or automated dispensing cabinets. Do not assume that all packages of a specific opioid contain the same total dose. For example:
    - Fentanyl is available at a consistent concentration (0.05 mg/mL) but in different package sizes.
    - Hydromorphone is available as different concentrations in the same package size (1 mL).

Please contact ASHP's Center for Medication Safety and Quality at quality@ashp.org with questions.

References

1. Institute for Safe Medication Practices (ISMP). Drug Shortages: national survey reveals high level of frustration, low level of safety. ISMP Medication Safety Alert – Acute Care. Sept 2010. Accessed 2018 Mar 20 at http://www.ismp.org/Newsletters/acutecare/articles/20100923.asp
2. Osborne R, Joel S, Grebenik K, et al. The pharmacokinetics of morphine and morphine glucuronides in kidney failure. Clin Pharmacol Ther. 1993; 54(2):158-67.
3. Latta KS, Ginsberg B, Barkin RL. Meperidine: a critical review. Am J Ther. 2002; 9(1):53-68.
4. Shekar K, Roberts JA, Mcdonald CI, et al. Sequestration of drugs in the circuit may lead to therapeutic failure during extracorporeal membrane oxygenation. Crit Care. 2012; 16(5):R194.

The New York Times

Emergency Rooms Run Out of Vital Drugs, and Patients Are Feeling It

Summer is "trauma season," when emergency rooms see a rise in injuries, but a drug supply crisis has doctors scrambling to find alternatives to needed medications.

By Katie Thomas

July 1, 2018

CHICAGO — George Vander Linde tapped a code into the emergency room's automated medicine cabinet. A drawer slid open and he flipped the lid, but found nothing inside.

Mr. Vander Linde, a nurse, tried three other compartments that would normally contain vials of morphine or another painkiller, hydromorphone. Empty. Empty. Empty.

The staff was bracing for a busy weekend. Temperatures were forecast for the 90s and summer is a busy time for hospital emergency departments — the time of year when injuries rise from bike accidents, car crashes, broken bottles and gunshots.

At Norwegian American Hospital and other emergency departments around the country, doctors and nurses have been struggling for months without crucial drugs like morphine, which is used to ease the pain of injuries like broken bones, or diltiazem, a heart drug. Norwegian has been out of morphine since March, and the shortages are part of a nagging problem that has intensified this year as a rash of decades-old staples became scarce.

Hospitals small and large have been scrambling to come up with alternatives to these standbys, with doctors and nurses dismayed to find that some patients must suffer through pain, or risk unusual reactions to alternative drugs that aren't the best option.

"So many substances are short, and we're dancing every shift," said Dr. James Augustine, a doctor in Cincinnati who works for US Acute Care Solutions, a company that employs doctors who work in emergency departments for hospitals around the country.

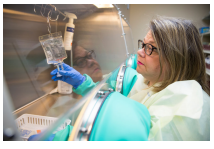
George Vander Linde checked for morphine from a dispenser at Norwegian American.
Alyssa Schukar for The New York Times

One of the main companies that makes the drugs, Pfizer, has warned that manufacturing problems at some of its plants will lower supplies of many of its products — like morphine — until next year.

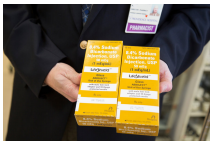
For years, drug shortages have created a behind-the-scenes scramble as pharmacists, doctors and nurses cobble together fixes that are often invisible to patients. But doctors around the country say the latest shortages are more directly affecting patient care.

More coverage of drug shortages

U.S. Hospitals Wrestle With Shortages of Drug Supplies Made in Puerto Rico Oct. 23, 2017



A Vital Drug Runs Low, Though Its Base Ingredient Is in Many Kitchens May 21, 2017



Drug Shortages Forcing Hard Decisions on Rationing Treatments Jan. 29, 2016

A survey in May of emergency doctors by their professional association, the American College of Emergency Physicians, found that 9 of 10 said they didn't have access to critical medicines, and nearly 4 in 10 said that patients had been negatively affected.

"The lack of pain medications is a huge issue," said Dr. Benjamin Savitch, who oversees the emergency room at Norwegian American for US Acute Care Solutions. He said that it can be difficult to explain to patients what is happening. "They are often disappointed and frustrated that the system is not functioning at the level it should," he said.

Like so much in health care, the roots of the drug shortage are complex and seemingly without a simple fix. The vast majority of the products in question are sterile injectable drugs, hospital workhorses that are cheaply priced even though they can be difficult to make. These low margins have led some companies to stop making the drugs, while others have failed to invest in older facilities, leading to a host of quality problems, recalls and plant shutdowns.

A recent survey of emergency doctors found that 9 out of 10 said they didn't have access to critical medicines, and 4 in 10 said patients had been negatively affected. Alyssa Schukar for The New York Times

The periodic problems were compounded last fall when Hurricane Maria hit Puerto Rico, a major center of pharmaceutical manufacturing, causing a shortage of small saline bags that are a mainstay in hospitals and worsening a yearslong problem with keeping intravenous fluids in stock.

But even as that crisis subsided, hospitals began grappling with the aftermath of another industry cataclysm — serious manufacturing problems at Pfizer, the nation's largest maker of generic injectable drugs.

In February of last year, the Food and Drug Administration issued a warning letter to the company for problems at its plant in McPherson, Kan., one of several factories Pfizer took over after it acquired the injectable maker Hospira in 2015. The agency described the plant's manufacturing process as "out of control" and, among other problems, said Pfizer had not properly investigated complaints about vials that contained particles later identified as bits of cardboard. If injected, the agency said the contaminated vials could pose a "significant risk" to patients.

PERSONAL HEALTH *Here are some strategies to navigate the emergency room.*

In September, the agency sent Pfizer another warning letter, that time for problems at its plant in a suburb of St. Louis, where the EpiPen is made.

Pfizer names hundreds of products on its list of back-ordered items as it works to fix its plants — the status of many of the drugs is described simply as "depleted," with an "estimated recovery" date of 2019. The problems have led to shortfalls of other products, including some that Pfizer makes for other companies. In May, the F.D.A. placed the EpiPen on its shortage list, as well as a competing product, Adrenaclick, which is also made by Pfizer. EpiPen is sold by Mylan, while Adrenaclick is sold by Impax Laboratories.

As Pfizer's supplies have run short, competitors have struggled to keep up with demand, depleting their own stock. The shortage of opioids like morphine has been aggravated by federal quotas that restrict the amount of narcotics any one company can manufacture; this spring, Pfizer relinquished part of its federal quota, which was then reallocated to other manufacturers.

Some of the shortages have become severe enough that the F.D.A. has allowed Pfizer to sell products that normally would have been recalled: In May, Pfizer released morphine and other drugs in cracked syringes, with instructions to health care providers to filter the drugs before injecting them.

Dr. Benjamin Savitch, right, said it can be difficult to explain to patients when the hospital lacks the drugs they need. “They are often disappointed and frustrated that the system is not functioning at the level it should,” he said. Alyssa Schukar for The New York Times

Philip J. Trapskin, the program director of Medication Use Strategy and Innovation at UW Health, the University of Wisconsin-Madison’s health system, said such actions pose a risk to patients and said he had instructed his staff to find other suppliers. Otherwise, he said, with about 2,500 nurses in his health care system who might need to use the syringes, “We’re kind of setting them up to fail if we give them something that is cracked and compromised.”

In an interview, Pfizer executives said that while the company regretted the effect the shortages were having on patients, it was investing significant resources in getting the plants up to par after taking them over from Hospira. The company plans to spend $800 million by the end of this year, and has pledged to invest at least $1.3 billion over the next five years. “We are completely aware of the essential nature of our portfolio,” said Navin Katyal, the general manager for the Pfizer Injectables unit in the United States. “The patient is truly our North Star. It’s driving our urgency to recover.”

Mr. Katyal also said that while many supplies won’t return to normal until next year, Pfizer is continuing its manufacturing — albeit at a slower pace — while the plants are being fixed and some of the most critical shortages are expected to be eased by the end of the year.

The current state of drug shortages doesn’t look that bad by the numbers. According to a recent report by the F.D.A., the agency said it had tracked just 39 new product shortages in 2017, compared with a peak of 251 in 2011. And while the F.D.A. described 2017 as a “challenging year,” it also said it had successfully prevented shortages of 145 products by taking actions such as allowing imports of certain products.

But Erin Fox, who tracks drug shortages at the University of Utah, said the figures don’t reflect the intensity of the gaps in supplies. “We’ve had all of these shortages before at different times, but what’s harder about it right now is that it’s all at once,” she said.

Dr. Scott Gottlieb, the F.D.A. commissioner, acknowledged in an interview that while the agency has made progress, it has not solved the underlying problem, where manufacturers earn a slim margin on products that are difficult to produce. “We are still in the position of trying to put a Band-Aid on a market that fundamentally hasn’t changed,” he said.

Dr. Gottlieb said he planned to act shortly on a recent request by members of Congress to look more broadly at the issue. One action, he said, could involve imposing more requirements on manufacturers, while at the same time working with programs like Medicare to increase reimbursement for certain drugs, as when they are used in outpatient clinics.

“Today it’s one drug, tomorrow is going to be another drug,” Dr. Gottlieb said. “We’ve got to think of something more holistic and comprehensive.”

UPSHOT *Here’s the company behind many surprise emergency room bills* .

On a recent weekday at Norwegian American, the emergency room had been relatively quiet. But two patients in the intensive care unit were suffering because the emergency room staff did not have the right drugs to give them.

One man, Edwin Alsina, 72, had arrived the night before complaining of a racing heart. The staff normally would have administered diltiazem, also known as Cardizem, that is used to steady an abnormal heart rate. But diltiazem was out of stock, and when two other drugs — adenosine and metoprolol — didn't work, Mr. Alsina was admitted overnight. By Thursday, he was receiving a steady drip of another drug, esmolol, but his heart rate was still 140 beats per minute.

Another man, Barbaro Gonzalez, 62, had shown up at the hospital earlier in the day with chest pains. Mr. Gonzalez said he has frequently visited the hospital to treat his pain and morphine usually does the trick. But this time, doctors had to give him another opioid, fentanyl, which Mr. Gonzalez said didn't work as well. He seemed resigned to his fate. With a nurse translating his Spanish, he said, "If they don't have the medication, you've got to live with it."

Barbaro Gonzalez was given fetanyl when Norwegian American Hospital told him they were out of the morphine he usually receives for his pain. He said it didn't work as well.
Alyssa Schukar for The New York Times

Drug shortages are often unpredictable and regional in nature. While Dr. Savitch and his staff have struggled with a lack of morphine and diltiazem, Dr. Augustine in Ohio was out of the anti-nausea drug ondansetron. An alternative medication, promethazine, treats nausea but can cause a severe and uncomfortable reaction in some patients, where the face and other muscles spasm involuntarily.

Ondansetron, also known as Zofran, has been a standard nausea treatment for so long, Dr. Augustine said, that many younger doctors have never seen the muscle spasms sometimes caused by promethazine, an older drug.

Dr. Augustine said he meets regularly with emergency physicians from overseas, and his foreign colleagues are stumped by his stories of struggles with drug shortages.

“Our compatriots are just wondering, how can this happen in America?” he said.

Katie Thomas covers the business of health care, with a focus on the drug industry. She started at The Times in 2008 as a sports reporter. @katie_thomas

A version of this article appears in print on July 1, 2018, on Page B1 of the New York edition with the headline: Bare Shelves in the Trauma Ward

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, VP Nursing & Clinical Services

SUBJECT: Medication Safety Toolkit

SUMMARY

Please review the attached Medication Safety Toolkit outline highlights for outstanding items.

ACTION REQUESTED

- How can HQI and Medication Safety Committee Toolkit combine and share resources?
- What outstanding items need to be placed into the toolkit?
- What items need to be updated?
- What new items need to be added?

Attachments: Medication Safety Toolkit

BJB:br

Medication Safety Toolkit

Resources for key medication safety topics

BJ BARTLESON, RN, MS, NEA-BC

The CHA Medication Safety Committee provides leadership within the hospital/health system and health care community to promote the highest standards of safe and effective use of medications. The committee is made up of a group of diverse multidisciplinary health care organizations who act as a source of medication safety expertise. The committee provides a venue for the coordination of medication safety activities.

This toolkit contains tools that have been developed and recommended by the CHA Medication Safety Committee for hospital and health care providers to use as they evaluate current practices and develop specific programs around these key medication safety topics. The tools are not fixed protocols that must be followed, nor are they entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results. Additional reference items and websites have been added under respective tool tabs.

Part I - Anticoagulantion Tool For Commonly Used Anticoagulants in the Inpatient Setting

This tool is intended to guide acute care facilities in the safe use of the most common anticoagulants in the inpatient setting.

Part II - Anticoagulantion Tool for Direct Oral Anticoagulants

This tool is intended to guide acute care facilities in the safe use of DOACs in the inpatient setting.

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Drug Shortages Roundtable

AJHP published information on a Drug Shortages Roundtable: Minimizing the impact on patient care.

ISMP Report an Error

Share your stories with ISMP and help prevent errors and patient harm. Healthcare practitioners and consumers report medication and vaccine errors to ISMP with the hope that future errors and patient harm will be prevented.

ASHP Injectable Opioid Shortage FAQ

This fact sheet provides an outline of potential actions for organizations to consider in managing the acute shortages of injectable hydromorphine, morphine, and fentanyl.

AHSP – Real Time Drug Shortages

Your first stop for information and resources on drug products, their availability and management.

ASHP Guidelines on Managing Drug Product Shortages in Hospitals and Health Systems

Guidelines providing a description of factors that contribute to or exacerbate shortages, describe a three-phase approach to contingency planning for management of drug products shortages and include strategies for prevention.

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Resources Forthcoming

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ISMP Medication Safety Self Assessment

This tool offers hospitals, long-term care facilities, and outpatient facilities a unique opportunity to assess the safety of systems and practices associated with up to 11 categories of high-alert medications.

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Reducing Adverse Drug Events Related to Opioids Implementation Guide

Society of Hospital Medicine released this guide to provide step-by-step instructions for hospital implementation of a successful QI program to make opioid prescribing safer, with fewer adverse events, and much less likely to result in dangerous sedation, respiratory depression and death.

Pain Management and the Opioid Epidemic

In the context of the growing opioid problem, the U.S. Food and Drug Administration (FDA) launched an Opioid Action Plan in early 2016. As part of this plan, the FDA asked the National Academies of Sciences, Engineering, and Medicine to convene a committee to update the state of the science on pain research, care, and education and to identify actions the FDA and others can take to respond to the opioid epidemic.

Medication Safety Toolkit

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Insulin Recommended Safe Practice Guidelines

These guidelines summarize the insulin safe practices that have been shown to reduce the risk of preventable harm when insulin is used to treat hospitalized patients.

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Medication List Infographic

Leveraging pharmacy staff prevents harm and increases clinician time for patient care functions.

Medication Safety Toolkit

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Replacing Old Practices with New Paradigms: Adopting Safe Practices for IV Push Medications

Webinar describes the latest changes in procedural and practice expectations and educate participants about Insitute for Safe Medication practices (ISMP) guidelines for adult IV push medications.

Medication Safety Toolkit

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SJ BARTLESON, RN, MS, NEA-BC

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2. DRUG PRODUCT SHORTAGES
3. ED MANAGEMENT
4. HIGH ALERT MEDICATION TOOLS
5. IMPROVING SAFE OPIOID USE
6. INSULIN SAFE PRACTICE
7. MEDICATION RECONCILIATION
8. NURSING STERILE COMPOUNDING
9. REDUCING ADVERSE DRUG EVENTS (ADEs)
10. REDUCING CONTROLLED SUBSTANCE DIVERSION
12. STERILE COMPOUNDING
13. TRACK AND TRACE LAW FAQS

Resources Forthcoming

Medication Safety Toolkit

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Reducing Controlled Substances Diversion in Hospitals

Roadmap for acute care settings as a plan to help navigate controlled substance diversion prevention goals.

Medication Safety Toolkit

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Perform and Assessment of Risk to Comply with USP<800>

Article by Patricia Kienle and Kate Douglass offering information such as: Definition of Terms, Handling Options, Compliance Steps, and more.

Medication Safety Toolkit

Resources for key medication safety topics

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Resources Forthcoming

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Sterile Compounding Update

SUMMARY

Recently there have been issues regarding the re-licensing of pharmacies that are dormant due to construction. A hospital system was told it needed to relicense the area, have a new room number and location room name, etc. Board of Pharmacy is working to resolve this issue.

RN Compounding will be discussed under new business.

ACTION REQESTED

- What other sterile compounding issues have surfaced since our last meeting?

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Draft Sterile Compounding Grids

SUMMARY

Please review the attached draft Sterile Compounding Grids. The CSHP Sterile Compounding Task Force has completed an enormous amount of work by updating all the tools. The grids are a hallmark example of the extraordinary collaborative work amongst the medication safety community to streamline sterile compounding efficiency and effectiveness in hospital pharmacies.

ACTION REQESTED

- CSHP has requested we review and offer revisions on the tools.

Attachments: Draft Sterile Compounding Grids

BJB:br

COMPETENCY AND TRAINING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

Competency		
Low and Medium Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Type of Competency	**Test**	**Frequency**
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure	Initially, then at least every 12 months
Process Validation	Media Fill testing	Initially, then at least every 12 months, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least every 12 months, or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU
High Risk: All training shall be completed and documented before any compounding personnel begin to prepare CSPs.		
Written Test	Pharmaceutical calculations and terminology Aseptic technique Quality Assurance procedures Skills necessary to perform the assigned tasks Sterilization technique	Initially, then at least every 12 months
Demonstration/ Observation	Hand hygiene & Garbing procedures, aseptic technique, achieving and maintaining ISO Class 5 environment, cleaning and disinfection procedure Sterilization techniques	Initially, then at least **every 6 months**
Process Validation	Media Fill Testing	Initially, then at least **every 6 months**, or whenever the QA program yields an unacceptable result
	Gloved Fingertip Testing - Garbing: Immediately after donning all garb without disinfection gloves with 70% alcohol	3 sets initially, then one set at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 0 CFU
	Gloved Fingertip Testing - Aseptic Technique: Immediately after completing the media-fill preparation	1 set initially, then at least **every 6 months,** or whenever the QA program yields an unacceptable result Action level - Greater than 3 CFU

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

Last Revised 5/1/18

COMPETENCY AND TRAINING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797> (2008) Requirements

TRAINING REQUIREMENTS	
Training	**Comments**
Hand hygiene and gloving	• Training includes theoretical principles and practical skills • Must complete didactic training, pass written competency and skills assessment (observation audit, GF testing, and media fill) before any compounding personnel begin to prepare/ handle CSPs • Media fill – simulates most challenging/ complicated condition/procedure actually encountered, and contains same amount of volume transferred. Verifies capability of compounding environment, aseptic technique and processes to produce sterile preparations
Procedure for Gloved Fingertip Sampling	
Order of Garbing procedures	
Aseptic work practices/technique (avoid touch contamination)	
Sterilization procedures for high risk compounding (if applicable)	
Pharmaceutical calculations & terminology	
Sterile compounding documentation (Compounding Log, Master Formula Record, Labelling, BUD, etc.)	
Quality assurance procedures	
Process validation using media fill tests	
General conduct in the controlled area	
Container, equipment and closure system selection	
Safe handling and compounding of CSPs (including hazardous drugs if applicable)	
Procedures for maintaining, storing, calibrating, cleaning and disinfecting equipment used in compounding	
Procedures for evaluating, maintaining, certifying, cleaning, disinfecting the facility/environment	
Achieving/maintaining ISO 5 (disinfect gloves and surfaces)	
Written training program	
Policy & Procedures	
Spill Management (pharmacy, nursing & other personnel)	
Train other support services (e.g. housekeeping) on hand hygiene, garbing, cleaning & disinfecting procedures	
Training documentation retained	

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Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Before entering the sterile compounding area, let your manager know if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

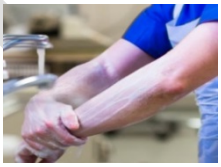
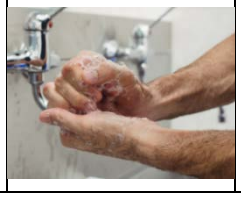
1) **Put on TWO pairs of shoe covers on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms.**

Step 5: Gowning

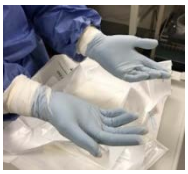
1)**Don a non-HD long-sleeved gown**
2)**Don a second long-sleeved HD gown (polypropylene or low-shedding) with closed elastic cuffs that closes in the back and covers all the way to the neck.**
NOTE: HD-gowns must be changed, at a minimum, every 3 hours OR immediately after a spill or splash

Donning, Hand Hygiene & Doffing for HAZARDOUS Sterile Compounding

STEP 6: Hand Hygiene Inside Ante Room or Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves



1) **For HD compounding, put on 2 PAIRS of sterile chemo tested gloves (ASTM 6978-05)**
   - **First pair of gloves: wear underneath the cuffs of the HD gown**
   - **Second pair of gloves: wear over the cuff of the HD gown**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

Reusing PPEs used for Hazardous Compounding?

The only PPE that can be re-used: **non-HD Gown** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of the shift

DOFFING SEQUENCE

DOFFING STEP 1:

Inside the BSC or CACI, remove the outer pair of sterile gloves and discard as hazardous waste

DOFFING STEP 2:

For facilities with HD-buffer room: perform the following steps within the HD-Buffer room doffing area. For facilities with HD-SCA: perform the following steps within the LOD of HD-SCA.
Remove and discard as hazardous waste:

1) **The outer shoe covers**
2) **The outer HD gown AND**
3) **The inner pair of sterile gloves**

DOFFING STEP 3:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Remove the non-HD gown. If non-HD gown is not soiled, hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift.**

DOFFING STEP 4:

Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Non-HD gown – if not reused**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

DONNING SEQUENCE

Step 1: Removal of Jewelry and Cosmetics

Outside the ante-room or outside the perimeter line of the Segregated Compounding Area (SCA):

1) **Remove and store in a safe place:**
   a. **Jewelry: wrist, hand and finger (including watches)**
   b. **All other visible jewelry, piercings, headphones, earbuds and personal electronic device(s)**
2) **Remove any nail polish/artificial nails**
3) **Remove all cosmetics**

Do NOT enter sterile compounding area if you are experiencing: Exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease.

Step 2: Shoe Covers

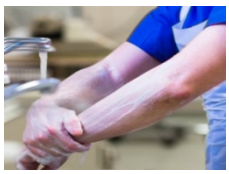
1) **Put on shoe cover on the foot closest to the line of demarcation (LOD) and place the covered foot onto the clean side of the LOD.**
2) **Repeat for 2nd foot**

Step 3: Hair Cover & Face Mask

Inside DIRTY Side of the Ante Room or outside the perimeter line of the Segregated Compounding Area (SCA)

1) **Put on Hair Cover: Cover entire head and ears**
2) **Put on beard cover (if necessary)**
3) **Put on Face Mask (over the nose and pulled all the way beneath the chin. If the mask has ties to secure: put on hair cover first then the face mask)**
4) **Validate sufficient coverage (including coverage of all facial and head hair coverage)**

Step 4: Hand Hygiene Sequence

 **Using warm water, wet hands and arms to the elbow. Apply appropriate cleaning agent.**	**Clean under nails using a one-time use disposable nail cleaning tool. Note: Do NOT use scrub brushes** 	 **Using appropriate cleaning agent, vigorously wash hands and arms (up to the elbow) for 30 seconds**	**Use warm water to rinse hands and arms to the elbow** 	 **Use non-shedding wipes to dry hands and arms**

Donning, Hand Hygiene & Doffing for NON-HAZARDOUS Sterile Compounding

Step 5: Gowning

1) **Don a non-HD long-sleeved gown**

NOTE: *All clothing must be covered

***Gown must be secured (and tied if applicable)**

STEP 6: Hand Hygiene Ante Room or Inside Buffer Area OR within the LOD if the SCA

1) **Disinfect using alcohol based product with persistent activity**
2) **Allow to dry before wearing gloves.**

STEP 7: Sterile Gloves

1) **Don sterile gloves - cuff overlapping the gown sleeve**
2) **Prior to entry into the PEC, apply sterile isopropyl alcohol to gloves and allow to dry**

What PPEs may be re-used for Non-Hazardous Sterile Compounding?

A. Booties and Hair Net: **NO.** Discard once you cross the LOD into the dirty side of the Ante Room or outside of the LOD for SCA

B. Face Mask: **NO.** Change at least every 2 hours OR whenever the mask gets wet. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA

C. Gown: **YES,** if stored for reuse on the CLEAN side of the Ante room, where possible, at least 3 feet from the sink. Reuse restricted to single user, and for the duration of a single shift

D. Gloves: **NO**. Discard once you cross the LOD into the dirty side of the Ante Room or outside the LOD for SCA

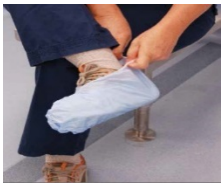
DOFFING SEQUENCE

DOFFING STEP 1:

Inside CLEAN Side of the Ante Room OR outside the LOD of the SCA:

1) **Discard the gloves**
2) **Remove the gown. Hang (where possible at least 3 feet from the sink) to reuse gown for the rest of the shift if gown is not soiled.**

DOFFING STEP 2:



Cross the LOD into the DIRTY Side of the Ante Room and remove and discard into the waste bin:

1) **Gown – if not soiled or not needed for the rest of the shift**
2) **Shoe covers**
3) **Head and face covers**

EXIT THE ANTEROOM

REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Environmental Testing Under Dynamic Conditions	Applicable Device, Room or Method	Frequency
Certification of PEC's	All BSC's, CAI's, CACI's, LAFW	Every 6 month (CCR) §1751
HEPA filter integrity testing	All BSC's, CAI's, CACI's, LAFW & ISO classified rooms	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All Buffer room/s and ante rooms. (Not required for segregated compounding rooms)	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts)	All BSC's, LAFW	Every 6 months
Volumetric air sampling by impaction (non-viable particle counts) outside of an ISO 7 cleanroom	CAI and CACI's: ▪ Particle counts sampled 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during operations ▪ Not more than 3520 particles per cubic meter during material transfer where particle probe is located as near to the transfer door as possible w/o obstructing the transfer ▪ Recovery time to achieve ISO Class 5 air quality shall be documented	Every 6 months
Viable air sampling by volumetric impaction	▪ The volume sufficient for sampling is 400-1,000 liters ▪ All ISO classified rooms and PECs ▪ Identification of any colony forming unit (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Every 6 months
Viable surface sampling	▪ Samples based on specified site map ▪ Identification of any (CFUs) to the genus level and action plan for CFUs exceeding USP action level thresholds**.	Low & medium risk compounding: Every 6 months High risk compounding: Quarterly
Air changes per hour (ACPH)	All Buffer room, Ante rooms, and segregated compounding rooms	Every 6 months
Video smoke study	▪ All BSC's, CAI's, CACI's, LAFW ▪ Unidirectional, non-turbulent airflow must be documented	Every 6 months

- Sampling locations, frequencies, and timing must be clearly described in the facility's report from the certification vendor
- Some tests may be performed by properly trained hospital staff if the CETA guidelines are followed
- Dynamic Conditions Definition: Routine staff activity during compounding-related processes must be simulated during certification
  Recertification of areas/equipment must occur is there are changes to the area such as redesign, construction, or replacement or relocation of the PEC, or alteration in the configuration of the room that could affect airflow or air quality

****USP Action Level Threshold**

Location	Viable airborne	Viable surface
ISO-5 (PEC)	>1	>3
ISO-7 (Buffer)	>10	>5
ISO-8 (Anteroom)	>100	>100

Highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count

Draft pending final approval by CSHP and CHA

REQUIRED ENVIRONMENTAL, PERSONNEL & END-PRODUCT TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Process validation: The individuals involved in the compounding of sterile drug preparation must successfully demonstrate competency on aseptic technique and aseptic area practices. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be as complicated as the most complex manipulations performed by staff with the same amount or greater amount of volume transferred during the compounding process.

Tests Required for Personnel (BOP and USP)	Risk Level	When Required
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x at least every 12 months thereafter.	Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient
	Moderate and low risk compounding – ongoing competency	At least every 12 months as part of the competency testing process
Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then at least every 6 months thereafter.	High risk compounding – initial competency	Prior to the first compound prepared for a patient
	High risk compounding – ongoing competency	At least every 6 months as part of the competency testing process

Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797>	BOP
Beyond Use Date (BUD) is the lesser of the USP<797> or the manufacturer package insert/written communication	• Meets all PEC ISO 5 requirements • Low risk: 48 hour RT, 14 days refrigeration • Medium risk: 30 hour RT, 9 days refrigeration	As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	None
Extended BUD (Greater than USP <797>)	• The USP <797> BUDs are an exemption from the USP <71> sterility testing. • BUD can only be extended if sterility tests according USP <71> are performed.	• No exemption for sterility testing for extended BUD. • Every batch of extended BUD requires sterility testing and sequestering. • In the revised USP <797> there is no extended BUD option.	BUD extension only allowable when supported by the following: Method suitability test, container closure integrity test, and stability studies. The compounded drug preparations tested and studied shall be identical in ingredients, specific and essential compounding steps, quality review, and packaging as the finished CSP.
Potency testing is the USP monograph described testing of potency	Products should have one of the following: • A manufacturer-sanctioned process • A published (refereed journal) method followed exactly • Lab data from testing of facility product	No requirements in USP <797>	Will require potency testing, schedule per the facility policy

Last Revised 5/1/18

Draft pending final approval by CSHP and CHA

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <800> Pending Requirements

BOARD OF PHARMACY REGULATIONS CCR§1735 Effective January 1, 2017				
		Beyond Use Dates		
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **HEPA filtered air** • **Negative pressure** • **Physically separate room**	**PRIMARY ENGINEERING CONTROL** • **PECs ISO Class 5 Negative Pressure unidirectional flow** • **HEPA filtered airflow** • **Non-turbulent** • **HEPA filtered exhausted air** • **External venting should be dedicated to one BSC or CACI**	**LOW RISK** • **Sterile to sterile** • **=< 3 commercial packages** **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**Comments**
• **ISO Class 7 or better** • Sink in ante area • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 30 Air Changes Per Hour (ACPH) • Ante-area ISO 7 or better CCR §1735.6(e)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent. CACI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Document daily Pressure Differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8) • Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft from PEC • Minimum of at least 3 ft line of demarcation around PEC • Emergency eye wash station acceptable • At least 0.01"-0.03" w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 12 ACPH 1735.6 (e) (1)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI must not be recirculated or turbulent CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	NA	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least q 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4) • Sink can be within 3 ft of CACI if CACI meets requirements in 1751.4 (f) (1-3)

Non-Hazardous Drugs Prepared in a Hazardous Drug Primary Engineering Control (Chemo Hood)

All drugs prepared in a Hazardous Drug Primary Engineering Control (PEC) must be labeled with HD Cautions

HAZARDOUS DRUGS : USP <800> Pending Requirements

SECONDARY ENGINEERING CONTROL Externally vented	PRIMARY ENGINEERING CONTROL C-PECs ISO class 5 Negative Pressure unidirectional flow C-PECs externally vented	BEYOND USE DATES (July 1, 2018)		Comments
		Low Risk	Medium Risk	
• **HEPA filtered air in Negative Pressure Physically Separate Room** • **ISO Class 7 or better buffer room** • **0.01" to 0.03" w.c. negative pressure** • **Minimum 30 ACPH HEPA filtered air** • **Sink placed at least 1 meter from the entrance of buffer room**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Requires negative pressure ISO 5 C-PEC • C-PEC and C-SEC externally vented • Eyewash readily available • Drug storage MUST be in a negative pressure space. Includes the refrigerator • Receiving of hazardous drugs must be in a negative or neutral pressure space. • May use the negative pressure room for non-sterile hazardous compounding BUT not at the same time. • Fixed walls

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• **Containment Segregated Compounding Area (C-SCA)** • **Must be a negative pressure separate room** • **0.01" to 0.03" w.c. negative pressure** • **Unclassified room** • **Minimum 12 ACPH** • **Sink at least 1 meter from C-PEC**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	12 hours	12 hours **(not allowed by BOP)**	

* Controlled Room Temp: 20 to 25 degrees C, 68 to 77 degrees F

**Controlled Cold Temp (Refrigerator): 2 to 8 degrees C, 35.6 to 46.4 degrees F

***Controlled Freezer Temp: (-25) to (-10) degrees C, (-13) to 14 degrees F

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Draft pending final approval by CSHP and CHA
FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (2008) Requirements

BOARD OF PHARMACY REGULATIONS -- CCR§1735 and CCR §1751 -- NON-HAZARDOUS DRUGS (Low and Medium Risk)				
SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	**PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)**	**Beyond Use Dates**		**Comments**
		LOW RISK	**MEDIUM RISK**	**APPLIES TO ALL**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**	• **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	• **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	
>ISO Class 7 clean room (clean area or buffer area) with ISO 8 or better ante-area • No sink in buffer area • Sink in ante-area • Minimum of 30 air changes per hour • 0.02-0.05" w.c. positive pressure differential relative to all adjacent spaces OR • Displacement airflow method: requires air velocity of >40 feet per minute from the clean area across the line of demarcation into the ante area, from floor to ceiling and wall to wall CCR §1735.1(m) & §1250.4 (1-4)	**Any ISO Class 5 PEC:** • Laminar Flow Hood OR • Biological Safety Cabinet with unidirectional flow OR • Compounding automated robots OR • Compounding Aseptic Isolators (CAI) with unidirectional flow. Air within the CAI shall not be recirculated or turbulent. CAI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State *** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Document **daily** pressure differential or air velocity, or use **continuous recording device**, between adjoining ISO rooms and spaces with immediate entry to ISO rooms. 1751.1(a)(8)
Segregated sterile compounding area • Any preparation area that is not ISO classed, exceeds ISO 7 limits, or does not meet pressure or air flow differentials • Sterile to sterile compounding only • PEC within demarcated area (at least 3 ft. perimeter) or separate room • Shall not have unsealed windows/doors that connect to outdoors • Not in high traffic area • Not adjacent to construction sites, warehouses or food preparation • Sink at least 3 ft. from PEC • Emergency eye wash station acceptable CCR §1735.1(af) & §1250.4 (1-4)	• CAI • Manufacturer of CAI must provide documentation for meeting requirements in 1751.4(f)(1-3) AND CAI must be certified as part of the certification process 1751.4(f)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Requires use of sterile gloves over isolator gloves 1751.4 (h) • PEC requires certification at least every 6 months CCR 1751.4(f) • Sink can be within 3 ft of CAI

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

	• Laminar Flow Hood • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	N/A	• 12 hours BUD for low-risk, non-hazardous preparations only 1751.8(d)(2) • PEC requires certification at least every 6 months CCR 1751.4(f)
Does not meet requirements for ISO Class 7 clean room or unclassified & Segregated Compounding area –	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	Labeled "Immediate Use" and shall be administered no later than 1 hour after mixing CCR §1751.8 (e)	N/A	Compounded only in limited situations where failure to administer could result in loss of life or intense suffering, and in quantity to meet immediate need

HAZARDOUS GARBING IN STERILE COMPOUNDING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Double Shoe covers	1		Don the second pair upon entering the buffer area. Remove upon leaving.
Head cover	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	For spills/decontamination of the hood: see additional garbing requirements
*Face shields & goggles	3	*Required when working outside a C-PEC	
Non Shedding/Non Hazardous Gown			
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	5	Must be changed every 2-3 hours or per manufacturer guidance. NEVER worn outside the HD handling area.	Must close in the back, long-sleeved, closed cuffs that are knit or elastic. No seams or closures that HDs could pass through.
Sterile Chemo gloves Must wear sterile gloves over any CAI gauntlet gloves	6	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA). Change every 30 minutes or when torn, punctured or contaminated.
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. The tool is not a fixed compliance assessment that must be followed and should not be construed as legal advice or used to resolve legal problems.

Last Revised 4/25/18

NON HAZARDOUS GARBING IN STERILE COMPOUNDING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<797> (2008) Requirements

Compounding attire	Order	Order of garbing in the anteroom	Information
Shoe covers	1		
Head cover (bouffant)	2		
Facial hair covers (if applicable)	2		
Face mask	3	(followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	
Hand Cleansing	4	Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.	Clean under nails using one-time use disposable nail cleaning tool Note: Do not use scrub brushes
Non-shedding gown	5		
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	6		Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS			
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails			• These items should be removed before entering the gowning area • Sanitize eye glasses (with alcohol wipes) before entering the gowning area • Cosmetics include self-removable false eye lashes
Excluded from ISO 7 and ISO 5 spaces until resolved			
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases			

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Last Revised 4/25/18

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Draft pending final approval by CSHP and CHA

TEMPERATURE REQUIREMENTS AND MONITORING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP<797>(2008) Requirements)

CSHP
CALIFORNIA SOCIETY OF HEALTH-SYSTEM PHARMACISTS
Partners in Medication Management

Temperature Description	Degrees Centigrade		Degrees Fahrenheit		Comments/Explanations Requires NIST Certified Temperature Monitoring Devices (USP <1118>	USP 39 NF 34 (2016) *(Used as a reference by the FDA for all package inserts)*	CDC Vaccine Storage (May 2014) USP <797>	Board of Pharmacy January 1, 2017
	Min	Max	Min	Max				
Controlled Freezer Temperature (USP and BOP)	-25º	-10º	-13º	14º	Check individual monographs for specific requirements outside this range	General Notices 10.20.10		No provision for excursions §1735.1 (i)
Freezer (CDC)	-50º	-15º	-58º	5º	Varicella and Zoster vaccines		See CDC Vaccine Storage and Handling Toolkit	
Controlled Cold Temperature – 2.2º	2º	8º 7.7º	35º	46º	• Transient excursions (0 ºC to 15 ºC) but the calculated MKT must be ≤ 8 ºC (46 ºF) • Transient spikes to 25 ºC (77 ºF), not to exceed 24 hours, if supported by the manufacturer's stability in writing	General Notices 10.30.40	See CDC Vaccine Storage and Handling Toolkit	No provision for excursions §1735.1 (h) Title 22 – 22 CCR § 70263 (q)(6)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15 ºC to 30 ºC (59 ºF to 86 ºF) as long as the MKT is ≤ 25 ºC (77 ºF) • Spikes to 40 ºC (104 ºF) are permitted for less than 24 hours as long as the MKT is ≤ 25 ºC (77 ºF) • Check for specific drugs with narrow ranges	General Notices 10.30.60		No provision for excursions §1735.1 (j)
Clean Room Temperatures		20º or less		68º or less	In order to compensate for the additional layers of protective garb, this is the general recommendation.		USP <797> proposed for July 1, 2018	
	20º	25º	68º	77º				Or lower required

WHAT IS MKT? Mean Kinetic Temperature approximates the effects of temperature on drug degradation. Higher temperatures result in faster degradation, lower temperatures result in less degradation. MKT calculations weight the various temperatures by their natural logs. Temperature spikes result in a greater increase in MKT than the average temperature, often by a critical 2-5 degrees. The MKT can be hand calculated, calculated by the temperature monitoring software vendor, or the manufacturer can be contacted and they have software to determine the MKT for every product.

N.B. Anytime a patient has received a vaccine or drug that is determined to have been out of range longer than allowed by the package insert, the manufacturer should be contacted immediately because all manufacturers have significant amounts of unpublished stability data by lot number, and the patient may not have to be re-dosed.

MONITORING REQUIREMENTS

Location	Comment	USP 37 NF33	CDC (Vaccines) May 2014	BOP
Freezers	Daily lapse time monitoring or continuous monitoring CDC vaccine toolkit on CDC website for more information. The vaccines for children program prohibits use of dorm refrigerators for vaccines.	Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Refrigerators		Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Ambient Room	Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

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Rev. 10/24/17

OSHPD

STERILE COMPOUNDING PHARMACIES

A2

FOR HOSPITAL FACILITIES

(OSHPD 1 Buildings)

Advisory Guide Series

December 2017

INTRODUCTION

The California State Board of Pharmacy (BoP) has changed its regulations to ensure they reflect changes in current law as a result of SB 294 (Emmerson, Statutes of 2013, Chapter 565). The regulations also address the problem of ensuring that board regulations are aligned with compounding standards of United States Pharmacopeia (USP) <797> and USP <800>, which further ensures the safety of consumers receiving compounded drugs in California.

Specifically, the California State Board of Pharmacy has recently revised Title 16 California Code of Regulations (CCR), §1735 “Compounding in Licensed Pharmacies” & §1751 “Sterile Compounding,” promulgated in July of 2016 and enforceable January 1, 2017. There is some alignment with USP <797> and <800>.

The US Pharmacopeia is currently in the process of revising Chapter <USP 797> “Pharmaceutical Compounding – Sterile Preparations” in its entirety, and has finalized the new Chapter <USP 800> “Hazardous Drugs – Handling in Healthcare Settings.”

For further information on the California State Board of Pharmacy (BoP) regulations please refer to the Board of Pharmacy web page under the following address:

http://www.pharmacy.ca.gov/

Hospital facilities not currently meeting the subject regulations covered in these guidelines will require physical construction or alteration to a hospital building or its physical environment.

The BoP regulations became effective on January 1, 2017. Any compounding facilities not currently in compliance must submit a request for delay in compliance to the BoP if they have not already done so.

Suggested submittal items include:

- BoP Application
- Functional Program (see Checklist item 3)
- Validation of OSHPD Project Submittal (Preliminary or Final)

Please email all requests to: Compounding.Waivers@dca.ca.gov

The California Office of Statewide Planning and Development (OSHPD) has drafted this Advisory Guide in consultation with the California State Board of Pharmacy (BoP) and California Department of Public Health (CDPH).

TABLE OF CONTENTS

I. STERILE COMPOUNDING ENVIRONMENT TYPES

The diagrams and checklists in this *Advisory Guide* will present information for the two types of sterile compounding environments, each of which having unique requirements:

Non-Hazardous Sterile Compounding regulations set standards for an appropriate sterile environment for mixing compounded sterile products that present no hazard to the compounding technician/pharmacy staff.

Hazardous Sterile Compounding regulations set standards for an appropriate sterile environment for mixing compounded sterile products that present a health hazard to the compounding technician/pharmacy staff, and must also limit outside environmental exposure to adjoining rooms and at all ventilation discharge locations. Refer to "Hazardous" in the definitions, below, for application of this designation.

II. CODE REFERENCE INDEX

This *Advisory Guide* is the result of a joint effort between various regulatory authorities. Consequently, references from a number of code sources are included. The items/requirements on the following pages are categorized into groups as color-coded below:

RED –Code Sections designated in red are direct code requirements supported by Title 24, CCR, California Building Standards Code (CBSC) including the California Building Code (CBC), California Electrical Code (CEC), California Mechanical Code (CMC) and California Plumbing Code (CPC).

PURPLE – Code Sections designated in purple are indirect code requirements as standards referenced by the CBSC. These include requirements associated with Board of Pharmacy regulations Title 16 §1735 & §1751 and USP <797> & <800>. Although not direct requirements, they are referenced by the CBSC and will need to be in compliance with those regulations for licensure by the Board of Pharmacy and/or for CMS Sterile Compounding Pharmacies survey compliance.

BLUE – Items designated in blue are strongly recommended items and/or practical support of submitted project programmatic requirements.

BLACK – Black text is generally provided for reference and context.

This guide is to be used for reference only. Whereas it presents code information regarding key elements of sterile compounding environments, this guide shall not be considered a complete representation of all requirements. Compliance with applicable laws, regulations and codes are the responsibility of the design professional in responsible charge, in accordance with California Administrative Code section 7-115.

III. DEFINITIONS

Ante-area: means an area with ISO Class 8 or better air quality where personnel hand hygiene and garbing procedures, staging of components, and other high-particulate-generating activities are performed, that is adjacent to the area designated for sterile compounding. It is a transition area that begins the systematic reduction of particles, prevents large fluctuations in air temperature and pressures in the cleanroom, and maintains air flows from clean to dirty areas. ISO Class 7 or better air quality is required for ante-areas providing air to a negative pressure room. [1735.1(a)]

Beyond use date (BUD): means the date, or date and time, after which administration of a compounded drug preparation shall not begin, the preparation shall not be dispensed, and the preparation shall not be stored (other than for quarantine purposes). [1735.1(b)]

> Refer to *1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations* for further information regarding determination of allowable BUDs within various environments.

Biological Safety Cabinet (BSC): means a ventilated cabinet for compounding sterile drug preparations, having an open front with inward airflow for personnel protection, downward HEPA-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection. Where hazardous drugs are prepared, the exhaust air from the biological safety cabinet shall be appropriately removed by properly designed external building ventilation. This external venting (i.e. exhaust) should be dedicated to one BSC or Compounding Aseptic Containment Isolator (CACI). [1735.1(c)]

> These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, and Type B2). See *Appendix 3* for details. [USP <800>]

Buffer Room or Buffer Area: is a term that is interchangeable with Cleanroom or Clean Area. See also definition for “Cleanroom or Clean Area”.

(1) As referenced in USP <797> an area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

(2) As referenced in USP <800> for Hazardous Compounding: A type of secondary engineering control (C-SEC) under negative pressure that meets ISO Class 7 or better air quality where the primary engineering control (C-PEC) that generates and maintains an ISO Class 5 environment is physically located. Activities that occur in this area are limited to the preparation and staging of components and supplies used when compounding HDs.

Classified space: An area that maintains an air cleanliness classification based on the International Organization for Standardization (ISO). [USP <800>]

Cleanroom or Clean Area: means a room or area with HEPA-filtered air that provides ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

[1735.1(e)] This term is interchangeable with Buffer Room or Buffer Area. See also definition for “Buffer Room or Buffer Area”.

(1) For nonhazardous compounding at least 30 air changes per hour of HEPA-filtered supply air [USP <797>] and a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

(2) For hazardous compounding at least 30 air changes per hour of HEPA-filtered supply air and a negative pressure of between 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

Compounded Sterile Preparations (CSP): A preparation intended to be sterile that is created by combining, diluting, pooling, or otherwise altering a drug product or bulk drug substance. A product produced by reconstituting a conventionally manufactured product for an individual patient strictly in accordance with the directions contained in the approved labeling provided by the product manufacturer is not considered a CSP for the purposed of this guide. [USP <797>]

Compounding Aseptic Containment Isolator (CACI): means a unidirectional HEPA-filtered airflow compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where hazardous drugs are prepared, the exhaust air from the isolator shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one Biological Safety Cabinet (BSC) or CACI. Air within the CACI shall not be recirculated nor turbulent. [1735.1(f)]

Also referenced in USP <800> as a specific type of CAI that is designed for the compounding of sterile 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.

Compounding Aseptic Isolator (CAI): means a form of isolator specifically designed for non-hazardous compounding of pharmaceutical ingredients or preparations while bathed with unidirectional HEPA-filtered air. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Air within the CAI shall not be recirculated nor turbulent. [1735.1(g)]

Also referenced in USP <800> as an isolator specifically designed for compounding sterile, non-hazardous pharmaceutical ingredients or preparations. The CAI is designed to maintain an aseptic compounding environment throughout the compounding and material transfer processes.

Compounding Workstation: is a term used to describe the Primary Engineering Control. Terms are interchangeable. See definition for “Primary Engineering Control (PEC)”.

Controlled room temperature: means 20 degrees to 25 degrees C (68 degrees to 77 degrees F). [1735.1(j)]

Displacement airflow method: means a concept which utilizes a low pressure differential, high airflow principle to maintain segregation from the adjacent ante-area by means of specific pressure differentials. This principle of displacement airflow shall require an air velocity of 40 ft per minute or more, from floor to ceiling and wall to wall, from the clean area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain clean area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, or for hazardous compounds. [1735.1(m)]

Doff: to remove personal protective equipment (PPE). [USP <800>]

Don: to put on personal protective equipment (PPE). [USP <800>]

Equipment: means items that must be calibrated, maintained or periodically certified. [1735.1(o)]

First air: means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free. [1735.1(p)]

Hazardous: see also "Hazardous Drug". Means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge. [1735.1(r)] See also "Hazardous Drug".

Hazardous Drug (HD): see also "Hazardous". Any drug identified by at least one of the following criteria: [USP <800>]

- Carcinogenicity, teratogenicity, or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low dose in humans or animals

Laminar Air Flow Workbench (LFW or LAFW): a Primary Engineering Control (PEC) that is a type of laminar airflow system that provided an ISO Class 5 or better environment for sterile compounding. The device provides a unidirectional HEPA-fileted airflow. An LAFW shall not be used for the manipulation of hazardous drugs (HD's). [USP 797 & USP 800]

Parenteral: means a preparation of drugs administered in a manner other than through the digestive tract. It does not include topical, sublingual, rectal or buccal routes of administration. [1735.1(w)]

Personal protective equipment (PPE): means clothing or devices that protect the employee from exposure to compounding ingredients and/or potential toxins and minimize the contamination of compounded preparations. These include shoe covers, head and facial hair covers, face masks, gowns, and gloves. [1735.1(x)]

Preparation: means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile. [1735.1(z)]

Primary Engineering Control (PEC or C-PEC): means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators. [1735.1(ab)]

Also referenced in USP <800> as Containment Primary Engineering Control (C-PEC). 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

Product: means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA. [1735.1(ad)]

Secondary Engineering Control (SEC or C-SEC): also known as Containment Secondary Engineering Control (C-SEC)**.** The room with fixed walls in which the PEC is placed. It incorporates specific design and operational parameters required to contain the potential hazard within the compounding room. [USP <797>, USP<800>]

Segregated Sterile Compounding Area (SCA or S-SCA): means a designated space for sterile-to-sterile compounding where a PEC is located within either a demarcated area (at least three-foot perimeter) or in a separate room. Such area or room shall not contain and shall be void of activities and materials that are extraneous to sterile compounding. The segregated sterile compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation. The segregated sterile compounding area shall not have a sink, other than an emergency eye-washing station, located within one meter of a PEC. The segregated sterile compounding area shall be restricted to preparation of sterile-to-sterile compounded preparations. [1735.1(af)]

(1) The BUD of a sterile drug preparation made in a segregated sterile compounding area is limited to 12 hours or less as defined by section 1751.8(d).

(2)) When the PEC in the segregated sterile compounding area is a CAI or a CACI and the documentation provided by the manufacturer shows it meets the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d).

Unclassified space: A space not required to meet any air cleanliness classification based on the International Organization for Standardization (ISO). [USP <800>]

IV. TITLE 16, DIVISION 17 CODE REFERENCES – SELECT EXCERPTS

ARTICLE 4.5

1735.6. COMPOUNDING FACILITES AND EQUIPMENT

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations. This shall include records of maintenance and cleaning of the facilities and equipment. Where applicable, this shall also include records of certification(s) of facilities or equipment.

(b) Any equipment used to compound drug preparations shall be stored, used, maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug preparations for which calibration or adjustment is appropriate shall be calibrated prior to use, on a schedule and by a method determined by the manufacturer's specifications, to ensure accuracy. Documentation of each such calibration shall be recorded in a form which is not alterable and these records of calibration shall be maintained and retained in the pharmacy.

(d) Any pharmacy engaged in any hazardous drug compounding shall maintain written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs.

(e) Hazardous drug compounding shall be completed in an externally vented physically separate room with the following requirements:

(1) Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when products are assigned a BUD of 12 hrs or less or when non sterile products are compounded; and

(2) Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

(3) Each PEC in the room shall also be externally vented; and

(4) All surfaces within the room shall be smooth, seamless, impervious, and non-shedding.

(f) Where compliance with the January 1, 2017 amendments to Article 4.5 or Article 7, requires physical construction or alteration to a facility or physical environment, the board or its designee may grant a waiver of such compliance for a period of time to permit such physical change(s). Application for any waiver shall be made by the licensee in writing, and the request shall identify the provision(s) requiring physical construction or alteration, and the timeline for any such change(s). The board or its designee may grant the waiver when, in its discretion, good cause is demonstrated for such waiver.

ARTICLE 7. STERILE COMPOUNDING

1751. STERILE COMPOUNDING; COMPOUNDING AREA; SELF-ASSESSMENT

(a) Any pharmacy engaged in compounding sterile drug preparations shall conform to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding.

(b) Any pharmacy compounding sterile drug preparations shall have a compounding area designated for the preparation of sterile drug preparations that is in a restricted location where traffic has no impact on the performance of the PEC(s). The cleanroom, including the walls, ceilings, and floors, shall be constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. The pharmacy shall be ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations. The environments within the pharmacy shall meet the following standards:

(1) Each ISO environment shall be certified at least every six months by a qualified technician in accordance with Section 1751.4. Certification records must be retained in the pharmacy.

(2) Items related to the compounding of sterile drug preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

(3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within one meter of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

(4) There shall be a refrigerator and, where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

1751.4. FACILITY and EQUIPMENT STANDARDS for STERILE COMPOUNDING

(a) No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations.

(b) During the compounding of sterile drug preparations, access to the areas designated for compounding must be limited to those individuals who are properly attired.

(c) All equipment used in the areas designated for compounding must be made of a material that can be easily cleaned and disinfected.

(d) Cleaning shall be done using a germicidal detergent and sterile water. The use of a sporicidal agent is required to be used at least monthly.

(1) All ISO Class 5 surfaces, worktable surfaces, carts, counters, and the cleanroom floor shall be cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, worktable surfaces, carts, and counters.

(2) Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment shall be cleaned at least monthly.

(3) Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.

(4) All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

(e) Disinfection, using a suitable sterile agent, shall also occur on all surfaces in the ISO Class 5 PEC frequently, including:

(1) At the beginning of each shift;

(2) At least every 30 minutes when compounding involving human staff is occurring or before each lot;

(3) After each spill; and

(4) When surface contamination is known or suspected.

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic

containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following criteria:

(1) Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

(2) Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations. Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The negative pressure PEC must be certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

(h) If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals that use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again.

(i) Compounding aseptic isolator and compounding aseptic containment isolator used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns.

(j) Viable surface sampling shall be done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. Viable air sampling shall be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and shall be done at least once every six months. Viable surface and viable air sampling shall be performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling. Viable air sampling is to be performed under dynamic conditions that simulate actual production. Viable surface sampling is to be performed under dynamic conditions of actual compounding. When the environmental monitoring action levels are exceeded, the pharmacy shall identify the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation shall include, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

(k) The sterile compounding area in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb.

(l) A licensee may request a waiver of these provisions as provided in section 1735.6(f).

1751.5. STERILE COMPOUNDING ATTIRE

(a) When compounding sterile drug preparations the following standards must be met:

(1) Personal protective equipment consisting of a non-shedding gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times. For hazardous compounding double shoe covers are required.

(2) Personal protective equipment must be donned and removed in an ante-area or immediately outside the segregated compounding area. (Note: Per USP 800, for HD compounding, the outermost gown, glove and booties should be removed before exiting the Clean/Buffer Room and before entering the Ante Area/Room.)

(3) Personnel shall don personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. The following order is to be followed unless the pharmacy has a procedure in place that documents a method equivalent to or superior to the method described here: The donning of shoe covers or dedicated shoes, head and facial hair covers and face masks shall be followed by the washing of hands and forearms up to the elbows for 30 seconds with soap and water, drying hands, and then the donning of a non-shedding gown.

(4) Compounding personnel shall not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic device.

(5) Sterile gloves that have been tested for compatibility with disinfection with isopropyl alcohol are required. Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom. Gloves are to be routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects. Gloves shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.

(6) Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails shall be excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

(b) When preparing hazardous agents, appropriate gowns and personal protective equipment shall be worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator).

V. TITLE 24, PARTS 2, 3, 4 and 5 CODE REFERENCES – SELECT EXCERPTS

PART 2: CALIFORNIA BUILDING CODE

1224.19 PHARMACEUTICAL SERVICE SPACE
…The pharmacy room or service space shall conform to the requirements of §1751, Article 7, Division 17, Title 16, California Code of Regulations as enforced by the California Board of Pharmacy.

1224.19.1.1 Handwashing fixture. *Handwashing fixture(s) shall be provided within each separate room where open medication is handled, or in an anteroom, or immediately outside the room where open medication is handled, still within the pharmaceutical service space.*

> ***Exception:*** *ISO Class 5 sterile preparation areas (e.g. chemotherapy and intravenous solutions) and their ISO Class 7 buffer area(s) shall not contain sources of water (sinks) or floor drains. However, the anteroom to the buffer area shall have a hand-washing fixture regardless of its intended ISO Classification (i.e. Class 7 or Class 8). Reference: U.S. Pharmacopeia (USP) 797 Pharmaceutical Compounding – Sterile Preparations.*

1224.19.1.2 Location. *Provide for immediate accessibility to staff toilet rooms and lockers (toilet room is not required in satellite pharmacy if other staff facilities are available nearby).*

1250 PHARMACIES

1250.1 Application. *This section applies to pharmacies listed in Section 1.4.1 regulated by the Department of Consumer Affairs.*

1250.2 Restrooms. *A pharmacy shall maintain a readily accessible restroom. The restroom shall contain a toilet and washbasin supplied with running water.*

1250.3 Sink. *All pharmacies shall be equipped with a sink within the pharmacy for pharmaceutical purposes. The sink shall be supplied with hot and cold running water.*

1250.4 Compounding area for parenteral solutions. *The pharmacy shall have a designated area for the preparation of sterile products for dispensing which shall:*

1. *1. In accordance with Federal Standard 209 (b), Clean Room and Work Station Requirements, Controlled Environment as approved by the Commission, Federal Supply Service, General Service Administration meet standards for Class 100 HEPA (high efficiency particulate air) filtered air such as laminar airflow hood or clean room.*

2. *Have nonporous and cleanable surfaces, ceilings and ceiling tiles, walls, floors and floor coverings.*

3. *The pharmacy shall be arranged in such a manner that the laminar-flow hood is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral solutions.*

4. *A sink with hot and cold running water must be within the parenteral solution compounding area or adjacent to it.*

5. *Any pharmacy that compounds sterile injectable products from one or more nonsterile ingredients must compound the medication in one of the following environments:*

   5.1 An ISO class 5 laminar airflow hood within an ISO class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.

   5.2 An ISO class 5 cleanroom.

   5.3 A barrier isolator that provides an ISO class 5 environment for compounding.

   Note: For additional pharmacy mechanical standard requirements, see Chapter 5, California Mechanical Code.

PART 3: CALIFORNIA ELECTRICAL CODE

517.33 Critical Branch.

(A) Task Illumination and Selected Receptacles. *The critical branch of the essential electrical system shall supply power for task illumination, fixed equipment, selected receptacles, and special power circuits serving the following areas and functions related to patient care:*

(3) Patient care areas - task illumination and selected receptacles in the following:

b. Medication preparation areas
c. Pharmacy dispensing areas

517.34 Equipment Branch Connection to Alternate Power Source. *The equipment branch shall be installed and connected to the alternate power source such that the equipment described in 517.34(A) is automatically restored to operation at appropriate time-lag intervals following the energizing of the essential electrical system. Its arrangement shall also provide for the subsequent connection of equipment described in 517.34(B). [99:6.4.2.2.5.2]*

(B) Equipment for Delayed Automatic or Manual Connection. *The following equipment shall be permitted to be arranged for either delayed automatic or manual connection to the alternate power source:*

(1.1) [OSHPD 1 & 4] Heating, ventilating and cooling equipment as required by the California Mechanical Code.

(7) Controls for equipment listed in 517.34.

PART 4: CALIFORNIA MECHANICAL CODE

321.4 *All supply, return, and exhaust fans required to maintain the positive and negative air balances as required in Table 4-A.*

321.5 *All control components and control systems necessary for the normal operation of equipment required to have essential electrical power.*

407.4.1 *Design of the ventilation system shall provide air movement that is generally from clean to less clean areas.*

502.2.1 *Environmental Air Ducts. Environmental air duct exhaust shall terminate not less than 3 feet (914 mm) from a property line, 10 feet (3048 mm) from a forced air inlet, and 3 feet (914mm) from openings into the building. Environmental exhaust ducts shall not discharge onto a public walkway.*

502.2.2 *Product Conveying Ducts. Ducts conveying explosive or flammable vapors, fumes, or dusts shall terminate not less than 30 feet (9144 mm) from a property line, 10 feet (3048 mm) from openings into the building, 6 feet (1829 mm) from exterior walls or roofs, 30 feet (9144 mm) from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet (3048 mm) above adjoining grade.*

Other product-conveying outlets shall terminate not less than 10 feet (3048 mm) from a property line, 3 feet (914mm) from exterior walls or roofs, 10 feet (3048 mm) from openings into the building, and 10 feet (3048 mm) above adjoining grade.

505.0 Product-Conveying Systems.

505.1 General. *A mechanical ventilation or exhaust system shall be installed to control, capture, and remove emissions generated from product use or handling where required in accordance with the building code or fire code and where such emissions result in a hazard to life or property. The design of the system shall be such that the emissions are confined to the area in which they are generated by air currents, hoods, or enclosures and shall be exhausted by a duct system to a safe location or treated by removing contaminants. Ducts conveying explosives or flammable vapors, fumes, or dusts shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums.*

Exception: Ducts conveying vapor or fumes having flammable constituents less than 25 percent of their Lower Flammability Limit (LFL) shall be permitted to pass through other spaces.

505.1.1 Incompatible Materials*. Incompatible materials shall not be conveyed in the same exhaust system. | [NFPA 91:4.1.2]*

505.1.2 Flammability Limit. *In systems conveying flammable vapors, gases, or mists, the concentration shall not exceed 25 percent of the lower flammability limit (LFL).*

Exception: Higher concentrations shall be permitted where the exhaust system is designed and protected in accordance with the Standard on Explosion Prevention Systems in Chapter 1 7, using one or more of the following techniques:

(1) Combustible concentration reduction
(2) Oxidant concentration reduction
(3) Deflagration suppression
(4) Deflagration pressure containment [NFPA 91:4.1.3, 4.1.3. 1]

Contaminated air shall not be recirculated to occupied areas unless contaminants have been removed. Air contaminated with explosive or flammable vapors, fumes, or dusts; flammable or toxic gases; or radioactive material shall not be recirculated.

***505.1.3 Mechanical Ventilation**. A mechanical ventilation system shall be interlocked to operate with the equipment used to produce vapors, fumes, or dusts that are flammable or hazardous.*

***505.2 Penetrations**. Fire dampers shall not be installed where the material being exhausted is toxic and where a risk evaluation indicates that the toxic hazard is more than the fire hazard. Exhaust ducts shall not pass through fire walls. [NFPA 91:4.1.10, 4.1.11]*

***505.3 Product-Conveying Ducts Classification.** Product-conveying ducts shall be classified according to their use, as follows:*

> *Class 1 - Ducts conveying nonabrasives, such as smoke, spray, mists, fogs, noncorrosive fumes and gases, light fine dusts, or powders.*
>
> *Class 2 - Ducts conveying moderately abrasive particulate in light concentrations, such as sawdust and grain dust, and buffing and polishing dust.*
>
> *Class 3 - Ducts conveying Class 2 materials in high concentrations and highly abrasive materials in low concentrations, such as manganese, steel chips, and coke.*
>
> *Class 4 - Ducts conveying highly abrasive material in high concentrations.*
>
> *Class 5 - Ducts conveying corrosives, such as acid vapors.*

***505. 7 Pharmacies** - CompoundingArea ofParenteral Solutions. [CA - Board ofPharmacy] The pharmacy shall have a designated area for the preparation ofsterile products for dispensing which shall he ventilated in a manner not interfering with laminar airflow.*

Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.

> ***505. 7.1 Pharmacies** - Laminar Flow Biological Safety Cabinet. [CA - Board of Pharmacy] In all pharmacies preparing parenteral cytotoxic agents, all compounding shall be conducted within a certified Class II TypeA or Class II TypeB vertical laminar airflow hood with bag in - bag out*

design. The pharmacy must ensure that contaminated air plenums that are underpositive air pressure are leak tight. Note: For additional pharmacy building standard requirements, see Chapter 12, California Building Code.

512.1 Dampers. *Dampers shall not be installed in exhaust ducts or exhaust duct systems. [NFPA 96:9.1.1]*

PART 5: CALIFORNIA PLUMBING CODE

416.0 Emergency Eyewash and Shower Equipment.

416.1 Application. *Emergency eyewash and shower equipment shall comply with ISEA Z358. 1.*

416.2 Water Supply. *Emergency eyewash and shower equipment shall not be limited in the water supply flow rates. Flow rate, discharge pattern, and temperature of flushing fluids shall be provided in accordance with ISEA Z358.1 based on the hazardous material.*

416.3 Installation. *Emergency eyewash and shower equipment shall be installed in accordance with the manufacturer's installation instructions.*

416.4 Location. *Emergency eyewash and shower equipment shall be located on the same level as the hazard and accessible for immediate use. The path of travel shall be free of obstructions and shall be clearly identified with signage.*

416.5 Drain. *A drain shall not be required for emergency eyewash or shower equipment. Where a drain is provided, the diseharge shall be in accordance with Section 811.0.*

VI. USP <797> – SELECT REQUIREMENTS for STERILE COMPOUNDING

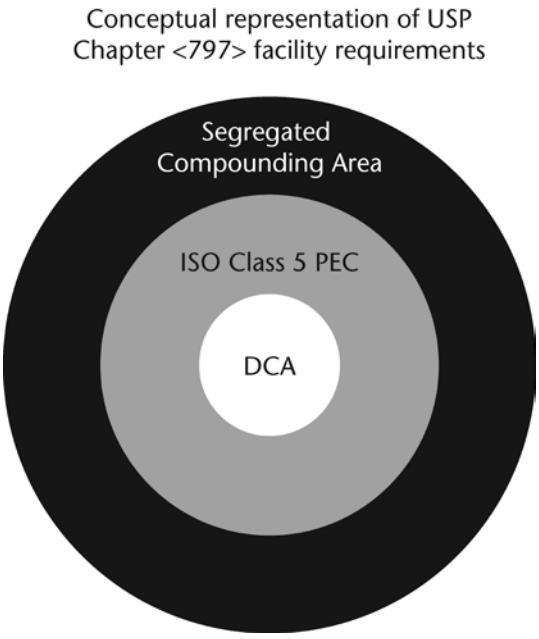


Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

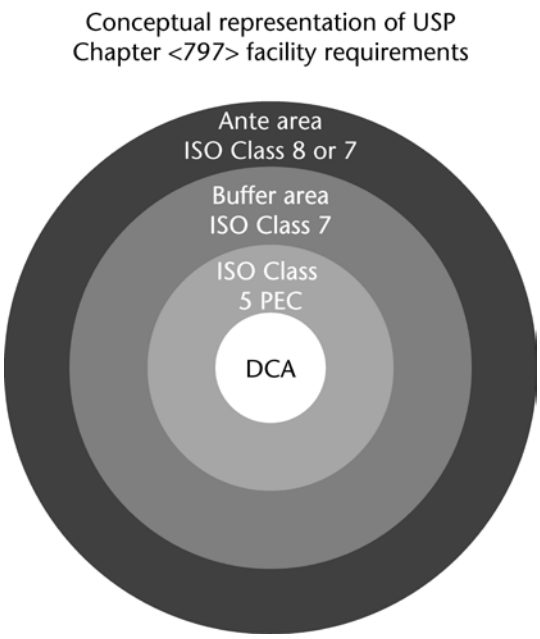


Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

DCA = Direct Compounding Area

VII. USP <800> – SELECT REQUIREMENTS for HAZARDOUS DRUG STERILE COMPOUNDING

5.2 HD STORAGE

HDs must be stored in a manner that prevents spillage or breakage if the container falls. Do not store HDs on the floor. In areas prone to specific types of natural disasters (e.g., earthquakes) the manner of storage must meet applicable safety precautions, such as secure shelves with raised front lips.

Antineoplastic HDs requiring manipulation other than counting or repackaging of final dosage forms and any HD API must be stored separately from non-HDs in a manner that prevents contamination and personnel exposure. These HDs must be stored in an externally ventilated, negative-pressure room with at least 12 air changes per hour (ACPH). Non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic HDs may be stored with other inventory if permitted by entity policy.

Sterile and nonsterile HDs may be stored together, but HDs used for nonsterile compounding should not be stored in areas designated for sterile compounding to minimize traffic into the sterile compounding area.

Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH [e.g., storage room, buffer room, or containment segregated compounding area (C-SCA)]. If a refrigerator is placed in a negative pressure buffer room, an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator should be considered.

5.3 COMPOUNDING

Sterile hazardous drugs (HD) must be compounded within a C-PEC located in a C-SEC. The C-SEC used for sterile compounding must:

- Be externally vented
- Be physically separated (i.e. a different room from other preparation areas)
- Have minimum air exchange rate of at least 30 ACPH / 12 ACPH for segregated environment
- Have a negative pressure between 0.01 and 0.03 inches of water column relative to all adjacent areas

The C-PEC must operate continuously if it supplies some or all of the negative pressure in the C-SEC, or if it is used for sterile compounding. Refer to USP <800> regarding loss of power or shut-down.

A sink and eyewash must be readily available, however, restrictions regarding water sources and drains apply if placed within the C-SEC. Their placement must prohibit interference with required ISO classifications.

All water sources and drains must be located at least 1 meter away from the C-PEC.

(Refer to to USP <800> for further requirements regarding environments that compound both nonsterile and sterile HDs.)

5.3.2 STERILE COMPOUNDING

In addition to the requirements of USP <800>, sterile compounding must also meet the requirements of USP <797>.

All C-PECs used for sterile HDs must be externally vented and provide an ISO Class 5 or better air quality. Refer to USP <800> for specific types of allowable and prohibited C-PECs.

The C-PEC must be located in a C-SEC, which is to also be externally vented and may be either:

- An ISO Class 7 buffer room with an ISO Class 7 ante-room:
    - The buffer room must have fixed walls, HEPA-filtered supply air, and meet the C-SEC requirements in Table 3, below. It shall be negative pressure relative to the ante-room.
    - The ante-room must have fixed walls, HEPA-filtered supply air and maintain a positive pressure of at least 0.02 inches of water column relative to all adjacent unclassified areas. It shall meet air quality of ISO Class 7 or better, with a minimum of 30 ACPH. A required sink capable of hand-washing up to the elbows must be placed a minimum of one meter away from the entrance to the HD buffer room.
- An unclassified containment segregated compounding area (C-SCA) with limitations on the BUDs per USP <797>:
    - Must have fixed walls, and meet the C-SCA requirements in Table 3, below.
    - A hand-washing sink capable of washing up to the elbows must be placed at least one meter from the C-PEC and may be either inside the C-SCA or directly outside the C-SCA.
    - Only applicable to low-risk and medium-risk HD CSPs, and must not exceed the BUDs described in USP <797> for CSPs prepared in a segregated compounding area.

Table 3. Engineering Controls for Sterile HD Compounding

Configuration	C-PEC	C-SEC	Maximum BUD
ISO Class 7 buffer room with an ISO Class 7 ante-room	*Externally Vented * Examples: Class II BSC or CACI	*Externally vented * 30 ACPH * Negative pressure between 0.01 and 0.03 inches of water column relative adjacent areas	As described in USP <797>
Unclassified C-SCA	*Externally Vented * Examples: Class II BSC or CACI	*Externally vented * 12 ACPH * Negative pressure between 0.01 and 0.03 inches of water column relative adjacent areas	As described in USP <797> for CSPs prepared in a segregated compounding area

VIII. OSHPD SUBMITTAL INSTRUCTIONS

1. In addition to code citations listed in this document, pharmacy projects, as with all construction, remodeling, and alteration of hospital buildings and structures, are required to be designed in conformance with applicable codes as noted in OSHPD CAN-1.

2. For those projects which are affected by local planning and zoning, evidence of approval is required as part of the submittal to OSHPD.

3. The *Checklist* portion of this guide in the following Appendix is provided to assist the design professional in responsible charge [CAC 7-115], in the preparation and submission of project documents. Inclusion of this checklist with all OSHPD submittals for sterile compounding projects will facilitate a more expeditious review.

4. *Appendix B - Pharmacy Summary Checklist* is required to assist CDPH in their review of pharmacy projects. This checklist is required for all OSHPD submittals for sterile compounding projects.

5. OSHPD projects that were created with an open project number via the eServices Portal must have a functional program, as described in *Checklist* item 3, and either a preliminary or final submittal received by the Office within 10 days. Open OSHPD project numbers without an accompanying submittal within 10 days of the creation of that number will be cancelled. The Board of Pharmacy will be notified of project number cancellations.

6. Facilities intending to use **mobile units** as an interim solution to maintaining compounding operations during construction must submit:

    a. An application to the Board of Pharmacy with an accompanying functional program, in order to confirm that the intended mobile unit has been assessed for conformance with applicable requirements for licensure, and that the mobile unit is acceptable for use at that facility in its proposed location.

    b. Construction documents to OSHPD per the guidelines listed in PIN 34 Review of Mobile Units Used for Outpatient Hospital Services, with an accompanying Alternate Method of Compliance (AMC) request for Program Flexibility (preliminary) for use of a mobile unit for inpatient sterile compounding. The AMC application shall be in accordance with the California Administrative Code (CAC) section 7-104, and include a functional program.

        i. BoP requires a ramp or lift to the trailer to provide for taking pharmaceutical products into and out of the trailer in a safe

manner. Based on Title 24, Part 2, Section 1224.19 it is incumbent to require this as a condition of AMC approval.

ii. A means for emergency power shall be available for the mobile unit for up to 72 hours of use due to loss of power. This may be integral to the unit, external or connected to Hospital system.

c. Functional programs shall address the following specific items in addition to the general information required by CAC section 7-119:
   i. Make and model of the mobile clean room unit and a brochure showing the interior design of the mobile unit.
   ii. A diagram of the intended site placement that includes path of travel from the mobile unit to the proposed destination of the compounded sterile products (CSP's) within the hospital. This could be either the hospital's Pharmacy Department, or the staff/service elevators intended for direct disbursement to the various patient care areas. Departmental boundaries along the CSP's interior path of travel must also be shown.
   iii. A statement of reason regarding use of the mobile unit, and the intended duration.

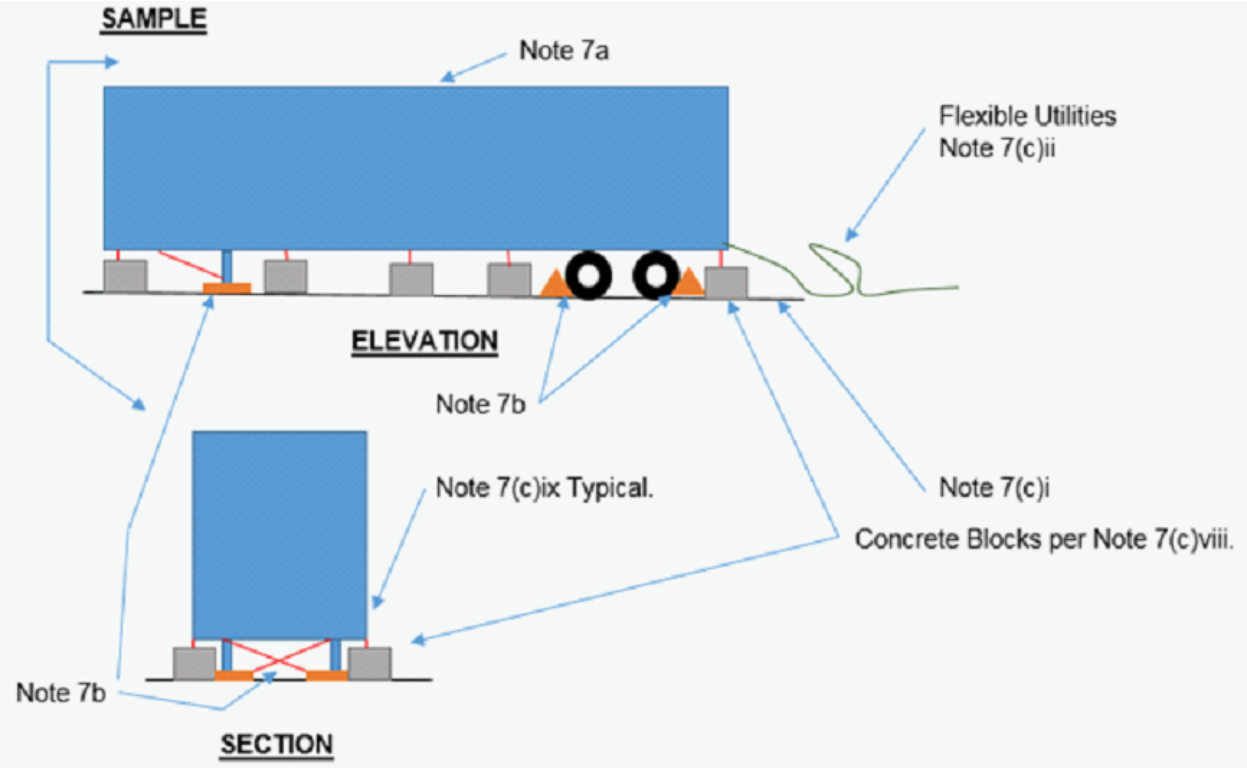
Please note that OSHPD approval is for construction identified in PIN 34. The Owner is to secure additional **separate** approvals as follows:

- The Board of Pharmacy for licensure of the mobile unit, based upon their initial application and subsequent onsite inspection and certification process at the end of construction.

- The California Department of Public Health for final Program Flexibility approval, which will be subject to prior approval processes by both OSHPD and the Board of Pharmacy. An onsite inspection by CDPH may be required prior to final approval for use. Program Flexibility may only be granted for a maximum of 12 months.
  CA Code of Regulations, Title 22, § 70267 (a)

7. Guideline for Mobile Units Used for Temporary Pharmacy Relocation
   a. Trailer design shall comply with State and National design standards for highways.
   b. Trailer is assumed to consist of 8 wheels in the back of trailer blocked to resist rolling, and two steel support legs in front connected to rubber or concrete pads capable of limiting punching shear of bearing surface when overturning loads are applied. Legs shall be braced and/or strengthened as necessary to resist forces as calculated in (c) below.
   c. Trailer tethered anchorage shall be designed to resist overturning and sliding forces from wind or seismic as follows:
      i. Trailer shall be parked on an engineered concrete or asphalt surface that is relatively flat for 10 feet around trailer.
      ii. Utility connections are flexible allowing for 10 feet of movement.

iii. Seismic horizontal and vertical demands may be based on ASCE 7-10 Chapter 13 at ASD force level using 50% Fp for temporary installations per CAN 2-108, page 4 of 8 Seismic Design (Long Term Temporary Permit – 180 day max*). *Extensions may be granted.
iv. Wind Load horizontal and vertical demands may be based on ASCE 7-10 Chapter 29.5 (Other structure) at ASD force level using Risk Category II map. Demand/Capacity to be <= 1.0.
v. Sliding may be resisted using friction between (1) trailer tires (rubber) and asphalt or concrete (parking lot surface), and (2) jack stands and asphalt or concrete.
vi. Friction between any combination of rubber, concrete and asphalt may be used to resist sliding using a static coefficient of friction equal to 0.5.
vii. Friction resisting force may be calculated by multiplying the static coefficient of friction by the operating weight of trailer plus the least weight of counter weights on one side of the trailer.
viii. Overturning may be resisted utilizing counter weights such as concrete blocks. Connections shall not be slack wires.



8. Facilities intending to use modular unit(s) for either interim or final placement of sterile compounding must ensure that the modular units meet all the requirements listed in this *Advisory Guide* as well as all applicable codes related to construction, remodeling and alteration of hospital buildings and structures as noted in OSHPD CAN-1.

9. Hospitals with less than 100 beds operating under a Hospital Pharmacy Permit Exemption shall provide all basic pharmaceutical services and be licensed by the Board of Pharmacy. Exempt hospitals shall have less than 100 licensed beds, and may not have a full-time pharmacist, nor be eligible for a sterile compounding license. See *Appendix C.*

APPENDIX A

OSHPD PROJECT #: _____ **DATE** _____

FACILITY NAME: _____ **FACILITY #** _____

[OSHPD-1]

STERILE COMPOUNDING PHARMACIES

CHECKLIST

CLEAR FORM

Compliance Guide for CBSC Requirements
Title 16 §1735 & §1751, and UPS <797> & <800>
ARCHITECTURAL, MECHANICAL & ELECTRICAL COMMENTS

PROJECT SCOPING			
		Compliance	
			Sheet/Det
1.	**Purpose:** The project is required to achieve compliance with the BoP requirements.	☐	
2.	**Basic Service:** Pharmaceutical Service is a Basic Service for licensure of a General Acute Care Hospital. Sterile compounding must be located within a compliant licensed hospital building. This means, such service(s) shall be located in a "Hospital Building" with a rating of SPC-2 or higher. Although it is preferred to locate the compounding facilities within the Pharmacy Department, existing hospitals may locate them elsewhere within the hospital when existing conditions make placement within the department infeasible. Refer to 1751(B) and/or 1735.1(af) for restrictions regarding placement. Remote placement will be subject to BoP and CDPH approval.	☐	
3.	**Functional Program:** Projects associated with alterations to existing pharmacies and creation of new pharmaceutical service space must include a clear and thorough Functional Program per California Administrative Code (CAC) section 7-119. The Functional Program must additionally include:	☐	
	a) Description of Interim Provisions for maintaining operations during construction, when applicable for renovation of existing compounding facilities in their present location. Interim placement must also meet required standards for that specific use as defined by code and noted in this advisory guide. Indicate if construction is required to prepare interim space prior to use.	☐	

b) Project Timeline to include all phases of project implementation including all interim provisions and final scope of work. Timeline shall indicate for each phase:

i) Plan review and permitting

ii) Construction duration

iii) Licensing and Acceptance

4. Pharmacy Summary Checklist: Projects associated with alterations to existing sterile compounding pharmacies and creation of new sterile compounding pharmaceutical service space must include a Pharmacy Summary Checklist (see *Appendix B*). The Pharmacy Summary Checklist must be a standalone PDF and also include:

a) Overall floorplan identifying all department boundaries and the location of the project on the floor.

b) Enlarged floorplan of the compounding spaces/areas and HD storage if provided. This plan shall identify all provided components in the Pharmacy Summary Checklist.

Mechanical Systems: Mechanical support of these spaces must include intended International Standards Organization (ISO) air quality rating (e.g. ISO 5, ISO 7, and ISO 8), laminar airflow, pressure differential in relation to adjacent spaces, inches of water column, and air changes per hour. Identification of components must include any, and all, HEPA filtration, source of supply air, routing of return air, routing of required dedicated exhaust and roof termination at all impacted levels, duct material, etc.

GENERAL REQUIREMENTS – ALL ENVIRONMENT TYPES

	Compliance	
		Sheet/Det
5. Compounding Work Station *or* **"Primary Engineering Control" (PEC):**		
a) Coordinate with Pharmacist for specific type of PEC. All are to provide a minimum ISO Class 5 environment and provide ventilation/exhaust per the specific requirements of intended use. Type of PEC's to be identified later in the *Specific Environment Type* sections.		
b) Finishes – Subject to wet cleaning [1751.4(d) & (e)]		
(i) If not built against the wall, all sides of the work station must be accessible for cleaning and will require space to allow for reach behind the unit. If built against the wall, seal unit against wall to prevent intrusion of moisture, contaminants and bacteria growth.		
c) Accessibility – Employee Work Station [CBC *11B-203.9*]		
d) Electrical Power - Provide critical branch power source for engineering controls such as hoods, laminar airflow workbenches, biological safety cabinets, barrier isolators. [CEC 517.33(A)(3) & (4]		

e) Subject to certification and testing requirements. [1751.4(f)] ☐

f) All PEC stands/bases are required to be anchored and braced per ASCE 7-10, Sections 13.3, 13.4 and CBC Part 2, Section 1616A. Such anchorage and bracing shall be substantiated by engineering calculations and shall be submitted with the design/construction documents. ☐

Alternatively, OSHPD OPM(s) for the PEC Stand/bases may be referenced on the design documents in order to satisfy this requirement.

g) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7-10, Sections 13.3 , 13.4 and CBC Part 2, Section 1616A. ☐

6. Buffer Room / Cleanroom (SEC) *and* Buffer Area / Clean Area (SCA):

a) Mechanical Equipment and Ventilation - ISO Class, pressure differentials, and additional ventilation/exhaust per the requirements of the specific environment types, indicated later in this document. ☐

(i) Laminar Air Flow - Designated area for the preparation of sterile products shall be ventilated in a manner not interfering with laminar airflow. [CMC 505.7 & 1751(b)] ☐

a. Air Supply - Air must be introduced through ceiling HEPA units. [USP <797> *Facility Design and Environmental Controls*] ☐

b. Low Return/Exhaust – Return and exhaust grilles should be low on the wall, creating a top-down dilution of area air with HEPA-filtered make-up air. Ceiling mounted returns are not recommended. [USP <797> *Facility Design and Environmental Controls*] ☐

i. One return/exhaust should be placed near the refrigerator's compressor. ☐

(ii) Electrical Power – Provide equipment branch power source for delayed automatic or manual connection. ☐

a. Fans [CEC 517.34(B)(1.1), CMC 321.4 (Table 4A for IV Prep, Pharmacy/Medicine)] ☐

b. Controls [CEC 517.34(B)(7), CMC 321.5] ☐

(iii) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7-10, Sections 13.3, 13.4 and CBC Part 2, Section 1616A. ☐

b) Controlled room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to be maintained for personnel. [1751.4(k)] ☐

c) Sealed-tight room with automatic/self-closing doors, similar to an Airborne infection isolation room [*1224.4.4.1.3*], except for Segregated Buffer Areas. ☐

(i) Controlled door operators shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [1010.1.9] ☐

a. Doors opening forces shall comply with the requirements of CBC 1010.1.3 and 11B-404.2.9. ☐

(ii) Power operated doors shall comply with the requirements of CBC 1010.1.4.2 and 11B-404.3. ☐

(iii) Special purpose horizontal sliding, accordion or folding doors shall comply with the requirements of CBC 1010.1.4.3 and 11B-404.2.9. ☐

d) Finishes – Non-porous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning [1751.4(d)] – The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and non-shedding. The surfaces shall be resistant to damage by disinfectant agents. [USP <797>] Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc. ☐

(i) 1250.4(2), 1735.6(e)(4), 1751.4(d) – Smooth, seamless, impervious, and non-shedding ☐

(ii) *1224.4.11.1.3 [Floor finishes] Wet Cleaning – not affected by cleaning solutions*. ☐

(iii) *1224.4.11.2.2 [Floors and Wall Bases] Wet Cleaning – coved. monolithic without joints (similar to Operating Room).* ☐

(iv) *1224.4.11.3 Wall finishes (similar to Sterile Supply) – washable, smooth, and able to withstand cleaning with chemicals.* ☐

(v) *1224.4.11.4.1 Ceiling finishes (restricted area) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals.* [USP <797>] Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. ☐

(vi) [USP <797>] Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. ☐

(vii) [USP <797>] Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility. ☐

(viii) [USP <797>] Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection. ☐

(ix) [USP <797>] The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. ☐

e) Sources of water (sinks) or floor drains are not permitted in the Buffer Room/Area. [1224.19.1.1, 1250.4, 1751(b)(3), USP <797>] ☐

f) Eyewash station - Required wherever there is compounding and mixing. May either be placed in Buffer Room or Ante-area. When placed in the Buffer Room, it should be located just inside the door and at least one meter from the rim of the sink to the (PEC). No drains are permitted within the Buffer Room/Area, thus the eyewash must be "dry", unless in use. (PEC). [CPC 416.0, 1735, 1751(b)(3), USP <800>, & OSHA 1910.151(c)] ☐

(i) When considering placement of eyewash within the Buffer Room, consideration should be given to weekly testing requirements. ☐

(ii) Water temperature to be tepid. ☐

(iii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach – refer to ISEA Z358.1.

g) Refrigerator on Essential Power required within the Buffer Room or Ante-area [1751(b)(4)]. ☐

(i) Provide critical branch power source. [517(A)(9)] ☐
(ii) If used for HD storage, refrigerator must be in negative pressure room [USP 800, 5.2]. ☐
(iii) Pass-through refrigerators are not permitted between a HD Buffer Room and any adjacent space. ☐

h) Dedicated environmental services (cleaning materials & supplies for Buffer Room & Anteroom) [1751.4(d)(4)] All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic microfibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. [USP <797>] ☐

i) Accessibility – Employee Work Station [11B-203.9] – Provide common use circulation, turning area & door clearance. ☐

j) Egress through intervening spaces [CBC 1016.2] - Sterile compounding pharmaceutical spaces located within "I-2" Occupancies are not considered "habitable rooms" and not subject to the requirements of CBC Section 407.4.1 regarding direct corridor access. [OSHPD CAN 2-407.4.1] ☐

7. Ante-area:

a) Mechanical Equipment and Ventilation - ISO Class, pressure differentials, and additional ventilation/exhaust per the requirements of the specific environment types, indicated later in this document.

(i) Electrical Power – Provide equipment branch power source for delayed automatic or manual connection. ☐

a. Fans [CEC 517.34(B)(1.1), CMC 321.4 (Table 4A for IV Prep, Pharmacy/Medicine)] ☐

b. Controls [CEC 517.34(B)(7), CMC 321.5] ☐

(ii) Equipment Anchorage – all roof mounted ventilation equipment must be anchored per ASCE 7-10, Sections 13.3, 13.4 and CBC Part 2, Section 1616A. ☐

b) Controlled room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to be maintained for personnel. [1751.4(k)] ☐

c) Donning and Doffing Area

(iii) Refer to processes in 1751.5 *Sterile Compounding Attire*, and USP <797> *Garb and Glove Requirements* for non-Hazardous environment donning and doffing. ☐

(iv) Refer to processes in 1751.5 *Sterile Compounding Attire*, USP <797>, and USP <800>, *Section 6 Personal Protective Equipment* for Hazardous environment donning and doffing. ☐

- Seating and/or other provisions for gowning at Demarcation Line to restricted area ☐
- Storage for sterile gowns, gloves & booties ☐
- Storage for contaminated gown, gloves & booties ☐

d) Finishes – Non-porous and cleanable surfaces, ceilings, walls, and floors, subject to wet cleaning. Organic material or plastic laminate over organic core not acceptable on counters, casework, doors, etc.

(i) 1250.4(2), 1735.6(e)(4), 1751.4(d) – Smooth, seamless, impervious, and non-shedding ☐

(ii) *1224.4.11.1.3 [Floor finishes] Wet Cleaning – not affected by cleaning solutions* ☐

(iii) *1224.4.11.2.2 [Floors and Wall Bases] Wet Cleaning – coved. monolithic without joints (similar to Operating Room).* ☐

(iv) *1224.4.11.3 Wall finishes (similar to Sterile Supply) – washable, smooth, and able to withstand cleaning with chemical* ☐

(v) *1224.4.11.4.1 Ceiling finishes (restricted area) – monolithic, scrubbable, and able to withstand cleaning and/or disinfecting chemicals.* ☐

e) Scrub Sink (or handwashing fixture capable for scrubbing to elbows) [1224.19.1.1, 1751.(b)(3), & 797-3.2] ☐

f) Eyewash Station – Required wherever there is compounding and mixing. May either be placed in Buffer Room with restrictions as noted above, or Ante-area. [1751(b)(3), 797-5.3, CPC 416.0, OSHA 1910.151(c)] ☐

(i) Water temperature to be tepid. ☐

(ii) Eyewash location to be in an accessible location that requires no more than 10 seconds to reach – refer to ISEA Z358.1. ☐

g) Refrigerator on Essential Power required within the Buffer Room or Ante Room [1751(b)(4)]. Refrigerator to be in Ante area for Segregated environment. ☐

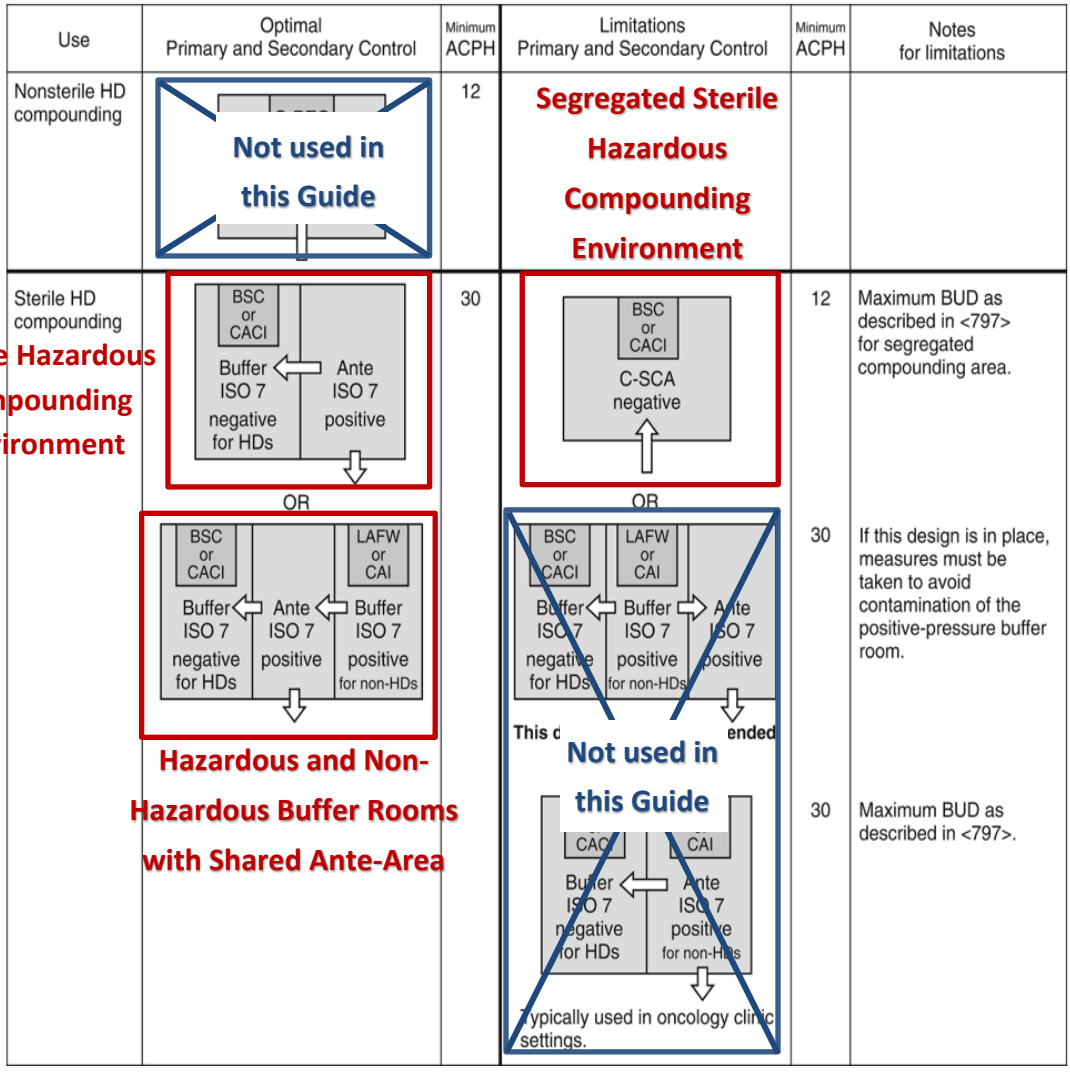
(i) Provide critical branch power source. [CEC 517(A)(9)] ☐
(ii) If used for HD storage, refrigerator must be in negative pressure room [USP 800, 5.2]. ☐
(iii) Pass-through refrigerators are not permitted between a HD Buffer Room and any adjacent space. ☐

h) Dedicated environmental services (cleaning materials & supplies for Buffer Room & Anteroom). All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic microfibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for ☐

	disposal. [1751.4(d)(4)] Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. [USP <797>]		
i)	Accessibility – Employee Work Station [CBC 11B-203.9] – Common use circulation, turning area & door clearance.	☐	
j)	Egress through intervening spaces [CBC 1016.2] - Sterile compounding pharmaceutical spaces located within "I-2" Occupancies are not considered "habitable rooms" and not subject to the requirements of CBC Section 407.4.1 regarding direct corridor access. [OSHPD CAN 2-407.4.1]	☐	
	(v) Controlled door operators, if provided, shall be readily openable in the egress direction without the use of a key or special knowledge or effort. [CBC 1010.1.9]	☐	
	(vi) Exit travel distance limitations shall apply. Travel distance shall be in compliance with CBC Section 1017.	☐	
k)	Automatic/self-closing doors, if provided, shall meet the requirements listed in *Checklist* item 6c.	☐	

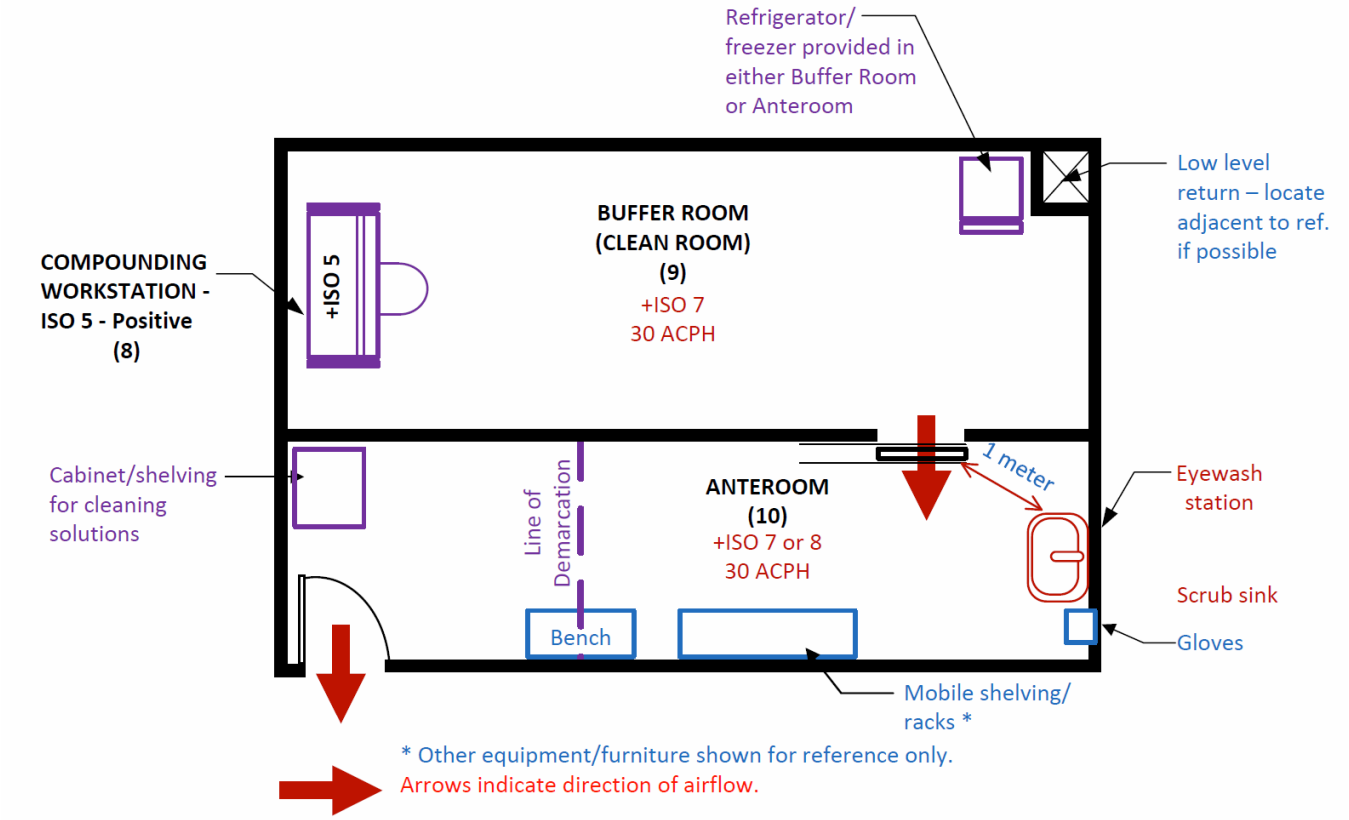
GENERAL ROOM RELATIONSHIPS – VARIOUS ENVIRONMENT TYPES

The following chart, referenced from <USP 800> regulations, provides a high-level overview of the required relationships between the various environments, and their associated allowable Beyond Use Dates (BUDs).



The illustrations on the following pages represent specific environment types to highlight unique requirements pertinent to the each. Illustrations are diagrammatic and for reference purposes only. The actual design is the responsibility of the design professional in responsible charge, to be developed in coordination with their client under the advisement of pharmacy staff.

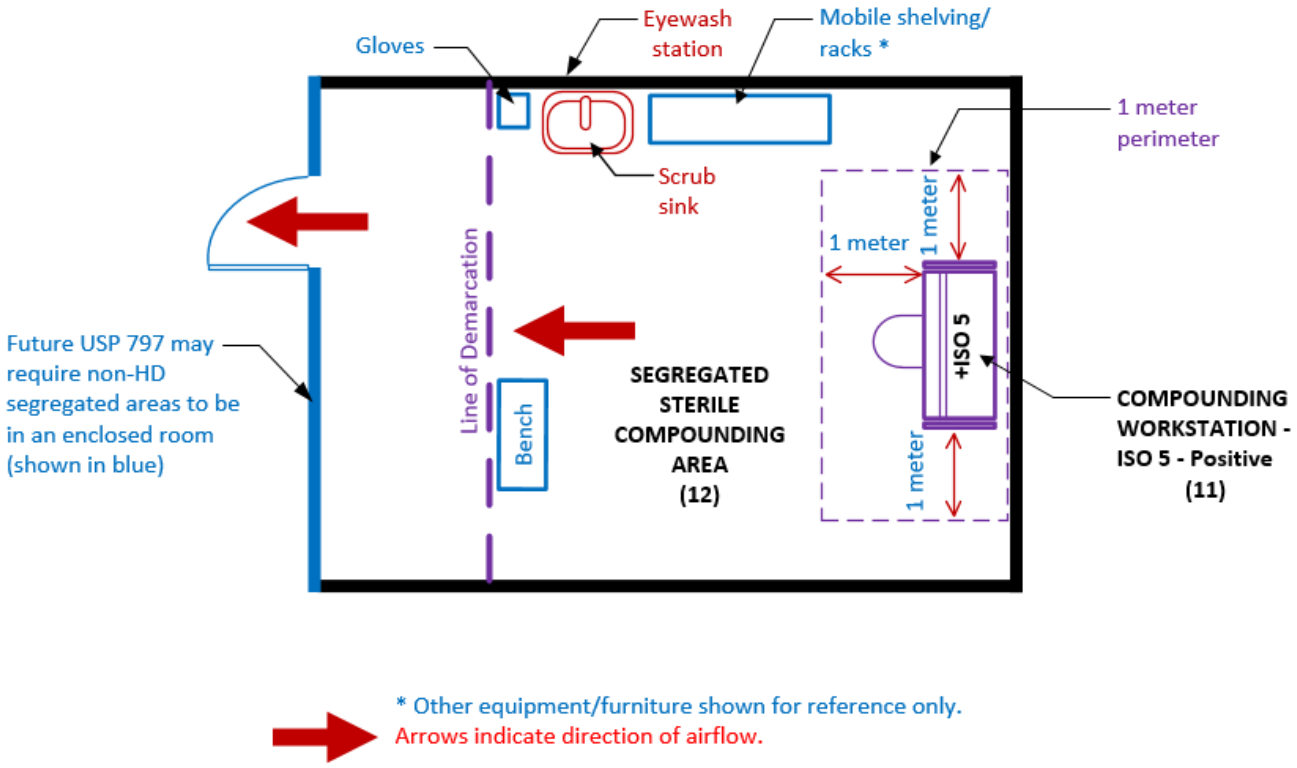
SPECIFIC ENVIRONMENT TYPE – STERILE NON-HAZARDOUS



	Compliance	
		Sheet/Det
8. Compounding Work Station (PEC):		
a) Meets the general requirements of *Checklist* Item 5, above.	☐	
b) ISO Class 5 - Positive Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." [USP 797-4.1]. Coordinate with Pharmacist for specific type of PEC.	☐	
(i) LAFW [USP <797>]	☐	
(ii) CAI [1735.1(g)]	☐	
9. Buffer Room / Cleanroom (SEC):		
a) Meets the general requirements of *Checklist* Item 6, above.	☐	
b) ISO 7 - Positive Pressure HEPA-filtered [USP <797>4.1].	☐	
(i) Supply air to room to be minimum of 50% (i.e. 15 ACPH) HEPA-filtered air. Total ACPH may be augmented by the ISO Class 5 PEC not to exceed 50% (i.e. 15 ACHP). [USP <797> Facility Design and Environmental Controls]	☐	

(ii)	30 ACPH minimum [USP <797> Facility Design and Environmental Controls]	☐	
(iii)	Positive 0.02 to 0.05 in water column (w.c.) vs. all adjacent areas/spaces. [1735.1(e)(1), USP <797> Pressure Differential Monitoring]	☐	
(iv)	Continuous monitoring. [USP <797> Pressure Differential Monitoring]	☐	
10.	**Ante-area:**		
a)	Meets the requirements of *Checklist* Items 6a and 7, above.	☐	
b)	ISO Class 8 or better - <u>Positive Pressure</u> HEPA-filtered [1735.1(a) & USP <797> Facility Design and Environmental Controls]	☐	
(i)	30 ACPH minimum [USP <797> Facility Design and Environmental Controls]	☐	
(ii)	Continuous monitoring [USP <797> Pressure Differential Monitoring]	☐	

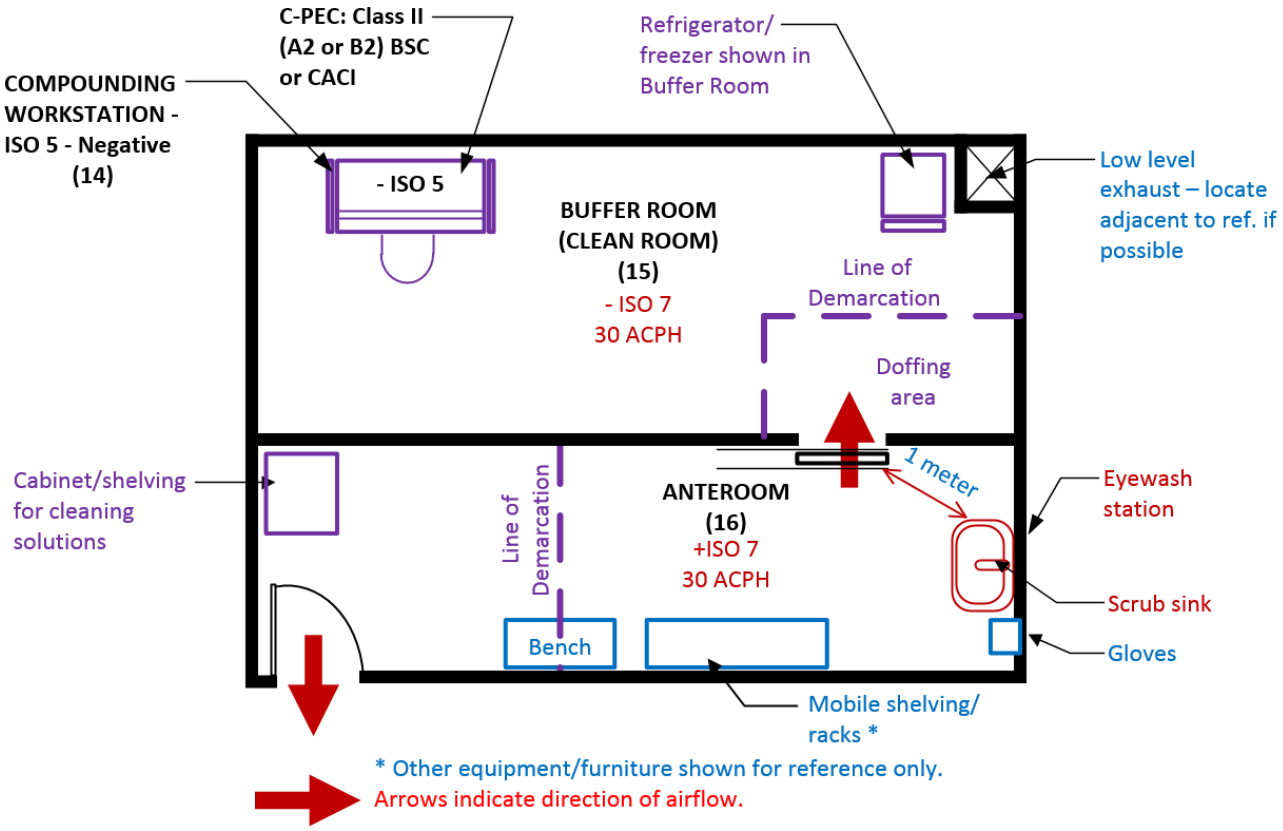
SPECIFIC ENVIRONMENT TYPE - SEGREGATED STERILE NON-HAZARDOUS (Limited to Beyond Use Date BUD < 12 hours)



	Compliance	
		Sheet/Det
11. Compounding Work Station (PEC):		
a) Meets requirements of *Checklist* Item 8, above.	☐	
(iii) LAFW [USP <797>]	☐	
(iv) CAI [1735.1(g)]	☐	
12. Segregated Sterile Compounding Area (SCA):		
a) Meets the general requirements of *Checklist* Item 6 & 7, above, except as noted herein.	☐	
b) No ISO Class required - Unclassified.		
(i) Maintain airflows from clean to less clean areas. [CMC 407.4.1]	☐	
c) Line of Demarcation shall be established to define Segregated Compounding Area if this area is not separated by a wall with a door. [1735.1(af), USP<797>]	☐	

d) The 1 meter perimeter around PEC shall not contain the sink. [1735.1(af), USP<797>] See item 6f for eyewash requirements.	☐	
e) Location shall not be in a location that has unsealed windows or doors that connect to the outdoors, in a location with high traffic flow, or in a location that is adjacent to construction sites, warehouses, or food preparation.	☐	
f) Item 6a)(i)a not required.	☐	
g) Item 6c not required.	☐	
h) Item 6d applicable within designated Segregated Compounding Area only.	☐	

SPECIFIC ENVIRONMENT TYPE – STERILE HAZARDOUS



	Compliance	
		Sheet/Det
14. Compounding Work Station (PEC):		
a) Meets the general requirements of *Checklist* Item 5, above.	☐	
b) All compounding shall be conducted within a certified Class II Type A or Class II Type B vertical laminar airflow hood with bag in – bag out design. The pharmacy must ensure that contaminated air plenums that are under positive air pressure are leak tight. [CMC 505.7.1]	☐	
c) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." [1735.6(e), 1751.4(g), USP <800> Appendix "A"] Must operate continuously. [USP <800>5.3]	☐	
(i) Biological Safety Cabinet (BSC) [1735.1(c)]	☐	
(ii) Containment Aseptic Compounding Isolator (CACI) [1735.1(f)]	☐	
d) Exhaust – 100% dedicated direct exhaust to exterior. Recommended one dedicated exhaust per each PEC. [1735.1(c), 1735.1(f) & 1735.6(e)(3), 1751.4(g) & USP 800-5.3].	☐	

(i) Termination of exhaust duct from HD PEC or HD buffer room shall be not less than 3 feet from a property line, 10 feet from a forced air inlet, and 3 feet from openings into the building. They shall not discharge onto a public walkway. [CMC 502.2.1] If the duct is conveying explosive or flammable vapors, fumes, or dusts it shall terminate not less than 30 feet from a property line, 10 feet from openings into the building, 6 feet from exterior walls or roofs, 30 feet from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet above adjoining grade. Other product-conveying outlets shall terminate not less than 10 feet from a property line, 3 feet from exterior walls or roofs, 10 feet from openings into the building, and 10 feet above adjoining grade. [CMC 502.2.2] ☐

(ii) Ducts conveying fumes shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums. [CMC 505.1] ☐

(iii) Air contaminated with fumes, toxic gasses, or radioactive materials shall not be recirculated. [CMC 505.1.2] ☐

(iv) Exhaust fans shall be interlocked with PECs. [CMC 505.1.3] ☐

(v) Fire dampers shall not be installed where the material being exhausted is toxic. Exhaust ducts shall not pass through fire walls. [CMC 505.2] ☐

(vi) Class 5 ductwork required if corrosive vapors are being exhausted. [CMC 505.3] ☐

(vii) Dampers shall not be installed in exhaust ducts or exhaust duct systems. [CMC 512.1] ☐

15. Buffer Room / Cleanroom (SEC):

a) Hazardous drug compounding shall be completed in an externally vented physically separate room with fixed walls. [1735.6(e), USP <800>5.3, USP <800>5.3.2 for ISO Class 7 buffer room with ISO Class 7 ante-room] ☐

b) Meets the general requirements of *Checklist* Item 6, above. ☐

c) ISO 7 – <u>Negative</u> HEPA-filtered [USP 800-5.3.2]. ☐

(i) 30 ACPH minimum [1735.6(e)(1), USP <797>, USP <800>] ☐

(ii) <u>Negative</u> 0.01 to 0.03 in water column (w.c.) relative to the ante-room. [1735.6(e)(2), USP<797>, USP<800>5.3.2] ☐

(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring] ☐

d) Exhaust – 100% exhaust to exterior. [USP <800>, 1735.6(e)] ☐

(i) Termination of exhaust duct from HD PEC or HD buffer room shall be not less than 3 feet from a property line, 10 feet from a forced air inlet, and 3 feet from openings into the building. They shall not discharge onto a public walkway. [CMC 502.2.1] If the duct is conveying explosive or flammable vapors, fumes, or dusts it shall terminate not less than 30 feet from a property line, 10 feet from openings into the building, 6 feet from exterior walls or roofs, 30 feet from combustible walls or openings into the building that are in the direction of the exhaust discharge, and 10 feet above adjoining grade. Other product-conveying outlets shall terminate not less than 10 feet from a property line, 3 feet from exterior walls or roofs, 10 feet from openings into the building, and 10 feet above adjoining grade. [CMC 502.2.2] ☐

(ii) Ducts conveying fumes shall extend directly to the exterior of the building without entering other spaces and shall not extend into or through ducts and plenums. [CMC 505.1] ☐

(iii) Air contaminated with fumes, toxic gasses, or radioactive materials shall not be recirculated. [CMC 505.1.2] ☐

(iv) Exhaust fans shall be interlocked with PECs. [CMC 505.1.3] ☐

(v) Fire dampers shall not be installed where the material being exhausted is toxic. Exhaust ducts shall not pass through fire walls. [CMC 505.2] ☐

(vi) Class 5 ductwork required if corrosive vapors or being exhausted. [CMC 505.3] ☐

(vii) Dampers shall not be installed in exhaust ducts or exhaust duct systems. [CMC 512.1] ☐

16. Ante-area:

a) Must have fixed walls. [USP <800>5.3.2] ☐

b) Meets the requirements of *Checklist* Items 6a and 7, above. ☐

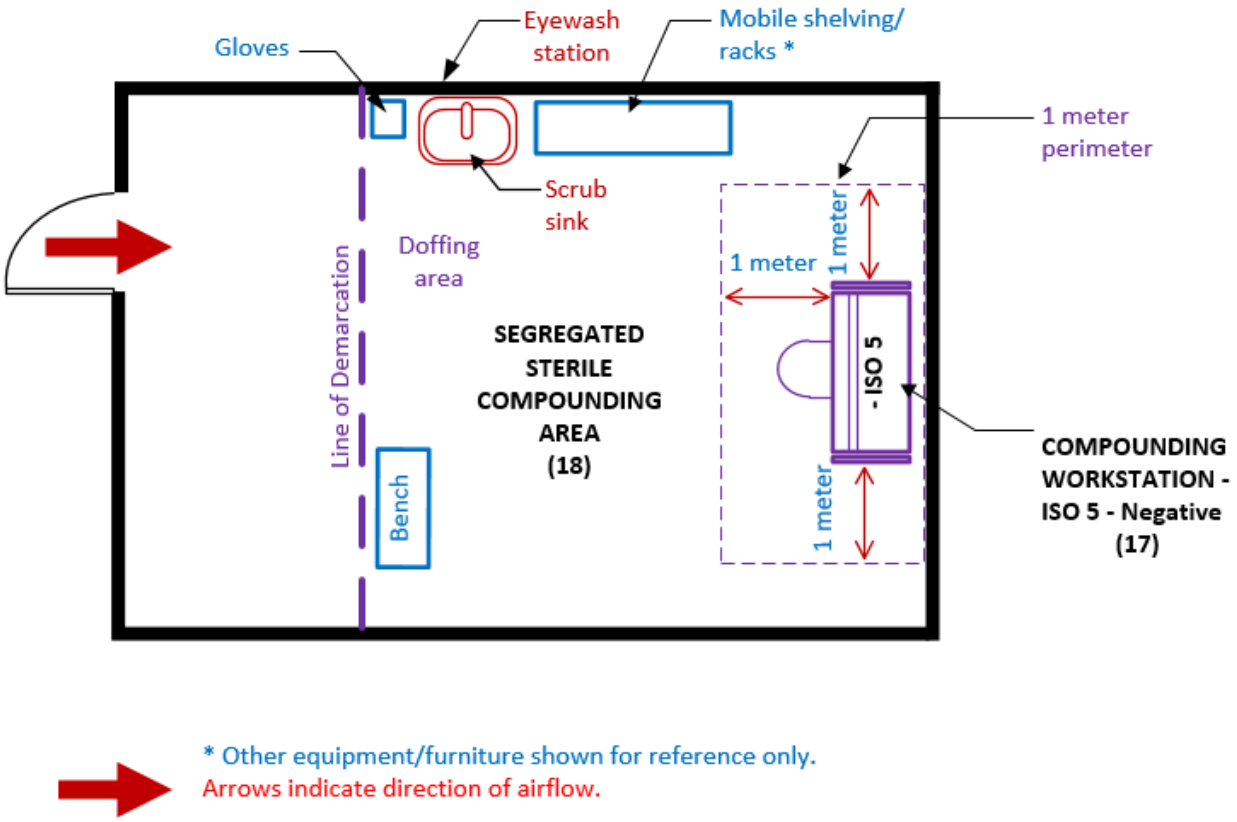
c) ISO Class 7 - Positive Pressure HEPA-filtered [1735.1(a), USP <800>5.3.2] ☐

(i) 30 ACPH minimum [USP <800>5.3.2] ☐

(ii) Positive at least 0.02 in water column (w.c.) relative to all adjacent unclassified areas. [USP<800>5.3.2] ☐

(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring]	☐	
d) Handwash sink capable of washing up to elbows shall be at least one meter away from the door to the Buffer Room. [USP <800>5.3.2]	☐	

SPECIFIC ENVIRONMENT TYPE - SEGREGATED STERILE HAZARDOUS (Limited to Beyond Use Date BUD < 12 hours)



	Compliance	
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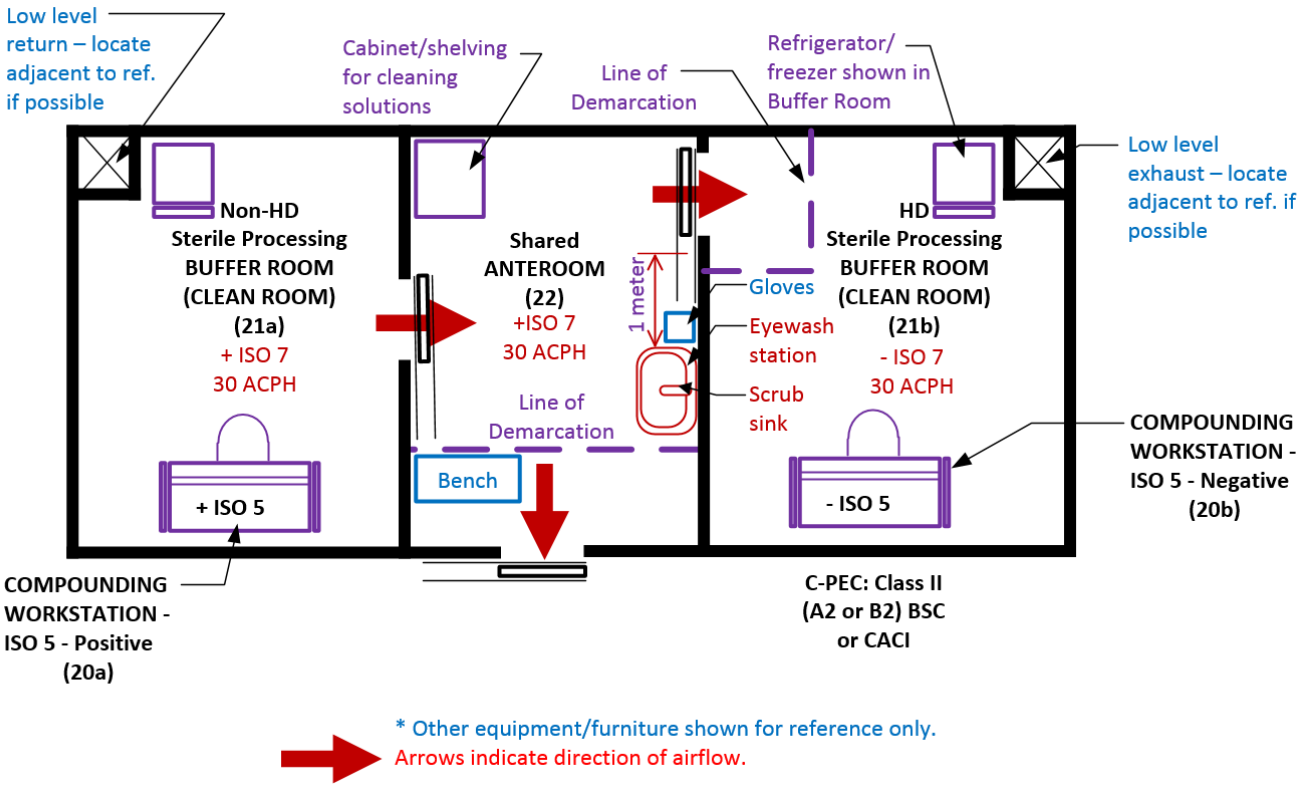
17. Compounding Work Station (PEC):		
a) Meets the requirements of *Checklist* item 14, above, except as noted herin.	☐	
b) ISO Class 5 - Negative Pressure through non-turbulent, laminar-flow, HEPA-filtered "first air." [USP 797-4.1]. Must operate continuously. [USP <800>5.3]	☐	
(i) Biological Safety Cabinet (BSC) [1735.1(c)]	☐	
(ii) Containment Aseptic Compounding Isolator (CACI) [1735.1(f)]	☐	
18. Segregated Sterile Compounding Area (SCA):		
a) Hazardous drug compounding shall be completed in an externally vented physically separate room with fixed walls. [1735.6(e), USP <800>5.3, USP <800>5.3.2 for C-SCA]	☐	

b) Meets the requirements of *Checklist* item 15, above, except as noted herein.	☐	
(i) Item 15 c) not required.	☐	
(ii) Item 6 a)(i)a not required.	☐	
(iii) Item 6 c) not required.	☐	
c) Unclassified – Negative pressure. [USP <800>5.3.2]	☐	
(i) 12 ACPH minimum [1735.6(e)(1), USP <797>, USP <800>]	☐	
(ii) Negative 0.01 to 0.03 in water column (w.c.) relative to all adjacent spaces. [1735.6(e)(2), USP<797>, USP<800>5.3]	☐	
(iii) Continuous monitoring. [USP <797> Pressure Differential Monitoring]	☐	
(iv) Maintain airflows from clean to less clean areas. [CMC 407.4.1]	☐	
d) Line of Demarcation shall be established to define Segregated Compounding Area if this area is not separated by a wall with a door. [1735.1(af), USP<797>]	☐	
e) The 1 meter perimeter around PEC shall not contain the sink. [1735.1(af), USP<797>] See item 6f for eyewash requirements.	☐	

SPECIFIC ENVIRONMENT TYPE - HAZARDOUS & NON-HAZARDOUS BUFFER ROOMS WITH SHARED ANTEROOM



	Compliance	
		Sheet/Det
20. Compounding Work Station (PEC):		
a) For non-hazardous compounding refer to *Checklist* item 8, above.	☐	
b) For hazardous compounding refer to *Checklist* item 14, above.	☐	
21. Buffer Room / Cleanroom (SEC):		
a) For non-hazardous compounding refer to *Checklist* item 9, above.	☐	
b) For hazardous compounding refer to *Checklist* item 15, above.	☐	
22. Ante-area:		
a) Consideration should be given to separate dedicated Ante-areas for HD and Non-HD Buffer Rooms, so that contamination affecting one Ante-area allows the other to remain in use.	☐	

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Provide simplified overall plan identifying all department boundaries and location of project on the floor ❑
Provide diagram (see sample attached) identifying all compounding components below ❑

General

Intended Compounded Sterile Products (CSP's) - check all that apply:

Non-Hazardous CSP's
❑ Low risk CSP's
❑ Medium risk CSP's
❑ High risk CSP's

Hazardous CSP's
❑ Low risk CSP's
❑ Medium risk CSP's
❑ High risk CSP's

❑ Radiopharmaceutical CPS's

Beyond Use Date (BUDs)

❑ Equal to or less than 12 hours
❑ Greater than 12 hours

Design supports the BUDs to be assigned? No Yes NR
Room names identified? No Yes NR
Pressure arrows (negative/positive). NA No Yes NR

Ante-area NA
Positive pressure to general environment (0.02 min)? NA No Yes NR
ISO 8 unless connected to HD buffer, then ISO 7. NA No Yes NR
ISO 7 then 30 ACPH. NA No Yes NR
Sink type and location (greater than 1 meter from entrance to HD buffer area). NA No Yes NR
Line of Demarcation. NA No Yes NR
Refrigerator(s). NA No Yes NR
Pass through's (if applicable). NA No Yes NR

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Buffer Area NA
ISO 7 or better. NA No Yes NR
Positive pressure to ante-area (0.02 min). NA No Yes NR
30 ACPH minimum (no more than half from hoods). NA No Yes NR
Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)? NA No Yes NR
Pressure monitoring devices noted. NA No Yes NR

Hazardous buffer area (C-SEC) NA
Externally vented, room and C-PEC. NA No Yes NR
ISO 7 or better. NA No Yes NR
Negative pressure to ante-area (-0.01 to -0.03). NA No Yes NR
30 ACPH minimum. NA No Yes NR
Type(s) of Primary Engineering Control (PEC) Workstations (include cut sheets)? NA No Yes NR
Does not include a pass-through refrigerator (not allowed). NA No Yes NR
Chemo PPE don/doff area inside the room, next to the entrance. NA No Yes NR
Refrigerator(s). NA No Yes NR
Pressure monitoring devices noted. NA No Yes NR

Segregated compounding area (non-hazardous) NA
Placed in an appropriate area of the hospital. NA No Yes NR
Area is defined. NA No Yes NR
Sink (greater than 1 meter from hood). NA No Yes NR

Segregated compounding area (C-SCA) (hazardous) NA
Enclosed by walls and a door. NA No Yes NR
Externally vented room and hood. NA No Yes NR
12 ACPH minimum. NA No Yes NR
Negative pressure to general area (-0.01 to -0.03). NA No Yes NR
Chemo PPE don/doff area inside the room, next to the entrance. NA No Yes NR
Sink (greater than 1 meter from hood). NA No Yes NR

One room with ante and buffer area, no dividing wall and door NA
Line of demarcation. NA No Yes NR
AF 40 ft/min, wall to wall and ceiling to floor, across the line. NA No Yes NR

CAI located in worse than ISO 7 NA
Does the hood meet the bullet points for location outside an ISO 7 buffer? NA No Yes NR

Pharmacy Summary Checklist

Appendix B

Facility:
OSHPD Number:
Date:

Hazardous drug storage area NA
Externally vented room. NA No Yes NR
Negative pressure. NA No Yes NR
12 ACPH. NA No Yes NR

NA=not applicable, No=does not meet standard, Yes=meets standard, NR=insufficient information to review

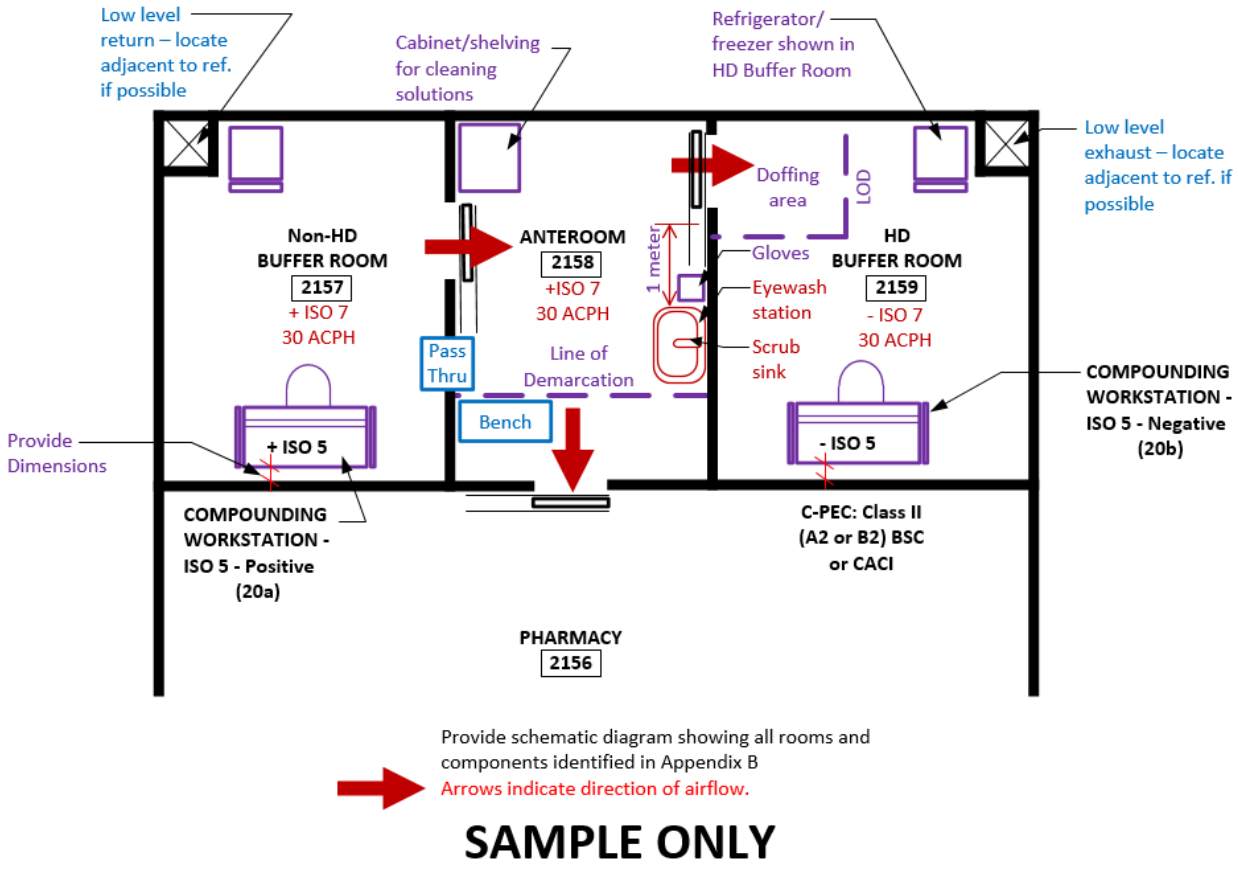
Pharmacy Summary Checklist

Appendix B

Facility:

OSHPD Number:

Date:



Provide schematic diagram showing all rooms and components identified in Appendix B

Arrows indicate direction of airflow.

SAMPLE ONLY

Appendix C

- ***Less than 100-bed Pharmacy Permit Exemption.*** *Hospitals under a Hospital Pharmacy Permit Exemption shall provide all basic pharmaceutical services and be licensed by the Board of Pharmacy. Exempt hospitals shall have less than 100 licensed beds, and may not have a full-time pharmacist, nor be eligible for a sterile compounding license. Exempt hospitals may purchase drugs at wholesale for administration and shall provide the following pharmacy service space:*
    - *Drug Room: Licensed pharmaceutical space with drug distribution under the supervision of a physician and be monitored by a pharmacist consultant. The drug room shall include the following:*
        - *A room or area for receiving, breakout, and inventory control of drugs used in the hospital.*
        - *Cleanable work counters and space for automated and/or manual dispensing activities.*
        - *Reserved*
        - *An area for reviewing and recording*
        - *An area for storage, exchange, and restocking of carts*
        - *Security provisions for drugs and personnel in the dispensing counter area*
    - *A hand-washing station shall be provided immediately accessible to the area where medication(s) are handled.*
    - *Cabinets, shelves, and/or separate rooms or closets shall be provided for the following:*
        - *Bulk storage*
        - *Active storage*
        - *Refrigerated storage*
        - *Storage for volatile fluids and alcohol in accordance with applicable fire safety codes for the substances involved.*
        - *Secured lockable storage for controlled drugs*
        - *Equipment and supply storage for general supplies and equipment not in use*

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: 7-11-18

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Sterile Compounding FAQs

SUMMARY

To find them at www.pharmacy.ca.gov:

1. Click on the **Licensees** tab at top of the homepage.
2. Click on **Important Information for Licensees**.
3. Click on **Compounding**.
4. Click on **Compounding Regulation FAQs**.

OR click on **Compounding** in the Important Information box on the homepage.

OR enter **compounding faqs** in search box at top of homepage.

A quick link is here.

ACTION REQUESTED

- Information only.

Attachment: Sterile Compounding FAQs

BJB:br

Compounding Regulations Guidance
Title CCR section 1735 et seq. and CCR section 1751 et seq.

Regulation Effective January 1, 2017

This guidance is not nor is it a substitute for legal advice. It is intended solely to assist pharmacists and pharmacies with understanding the requirements for compounding drug preparations for patients in California. References are provided to aid the users of this document. Licensees are strongly encouraged to read the regulations to have a full understanding of the requirements. All references to California Code of Regulations (CCR) sections are in Title 16 of the California Code of Regulations.

1. What is a "copy or essentially a copy" of a commercially available product?

   CCR section 1735.1(k) specifies that this includes all preparations that are comparable in active ingredients to commercially available products EXCEPT when the following conditions are met

   - The preparation has been changed for an identified patient AND
   - The preparation produces for that patient a clinically significant difference as determined by the prescribing practitioner.

   NOTE: The FDA currently has pending guidance in this area.

2. Who determines whether there is a "clinically significant difference" between a compounded preparation and the comparable commercially available drug product?

   As stated in CCR section 1735.1(k), the prescribing practitioner determines whether there is a "clinically significant difference".

3. Are there requirements for the maintenance of equipment used in compounding including minimum standards for such equipment as well as record keeping requirements?

   Yes, CCR section 1735.6 states compounding facilities and equipment requirements for all compounding (general and sterile). Included in this section are the record keeping requirements for the maintenance and cleaning of equipment, calibration requirements and specific requirements for hazardous drug compounding. In addition, CCR section 1751.4 establishes additional requirements for facilities and equipment used in sterile

compounding. An entity performing sterile compounding must comply with the requirements in both of these sections.

4. Are there requirements for the establishment of beyond use dates (BUDs)? Are the requirements the same for sterile preparations?

   There are several provisions regarding assignments of BUDs:
   - CCR section 1735.2(i) establishes general requirements for all compounded preparations.
   - For sterile drugs preparations, sections 1735.2(i)(2) and 1751.8 address BUD assignment.

5. Under what conditions can a BUD be extended?

   As specified in CCR section 1735.2(i)(3), a BUD can be extended if it is supported by the following:
   - Method Suitability Test, AND
   - Container Closure Integrity Test, AND
   - Stability Studies

6. Is a master formula required for compounded preparations made for an inpatient of a hospital?

   Yes, as stated in CCR section 1735.2(e) a master formula is required in all settings and for all compounding. Under the provisions of CCR section 1735.2(f), if a preparation is not routinely compounded, the master formula may be recorded on the prescription document.
   Note: As with all pharmacy compounding records, the master formula may be maintained in an electronic form that is readily retrievable. Records recorded or stored electronically, on magnetic media, or in any other computerized form shall be maintained as specified in B&PC section 4070(c). (CCR section 1735.3(d))

7. What are the requirements for a compounding log?

   As provided in CCR 1735.3(a)(2), a compounding log shall be a single document containing all of the following:
   - Name and strength of the compounded drug preparation;
   - The date the drug preparation was compounded;

- The identity of any pharmacy personnel engaged in compounding the drug preparation;
- The identity of the pharmacist reviewing the final drug preparation.
- The quantity of each ingredient used in compounding the drug preparation.
- The manufacturer, expiration date and lot number of each component.
- A pharmacy-assigned unique reference or lot number for the compounded drug preparation;
- The beyond use date or beyond use date and time of the final compounded drug preparation, expressed in the compounding document in a standard date and time format;
- The final quantity or amount of drug preparation compounded for dispensing;
- Documentation of quality reviews and required post-compounding process and procedures.

8. What are expectations with regards to the training of environmental services staff?

   As required by CCR section 1735.7(a), the environmental services, housecleaning, maintenance or any other staff in the compounding area must have the skills and training required to properly and accurately perform their assigned responsibility. As required in this section, there must be documentation of this training in or retrievable from the pharmacy.

9. May a sterile compounding pharmacy use a continuous monitoring or recording device to monitor and document air pressure differentials as required under CCR section 1751.1(a)(8) ?

   Yes, so long as daily documentation is maintained and readily retrievable.

10. Can a CAI be used outside an ISO Class 7 environment?

    Yes, according to CCR section 1751.4(f) a CAI may be used outside an ISO Class 7 environment if certain conditions specified in the section are met.

11. Am I allowed to wear any kind of makeup in a clean room?

    No, CCR section 1751.5(a)(6) prohibits cosmetics in ISO Class 5 and ISO Class 7 compounding areas.
    Note: Nail polish and artificial nails are prohibited as well.

12. What are the training requirements for sterile compounding staff?

    CCR section 1751.6 details training requirements for sterile compounding staff, responsibilities for ensuring training and documentation requirements.

13. Is a nonresident compounding pharmacy held to the same requirements for a drug recall as a compounding pharmacy in California?

    Yes, both resident and nonresident sterile compounding pharmacies must notify the board within 12 hours of initiating a recall involving California. (See B&PC section 4127.9(a)(2) and 4127.2(e)(3).)

14. Can I use a stability study done by a third party to assign the BUD of my compounded preparation?

    The pharmacist performing or supervising the compounding is responsible for exercising his or her professional judgment with regard to beyond use dating. CCR section 1735.2(i)(4) does not prohibit reliance on third-party stability studies, if all of the following conditions are met:

    - The drugs or compounded drug preparation tested and studied are identical in ingredients.
    - The specific and essential compounding steps and quality reviews are identical.
    - The packaging of the finished drug or compounded drug preparation is identical.

15. How long will a pharmacy have to get in compliance with the new building requirements for hazardous compounding?

    The revised regulation will go into effect January 1, 2017. As provided in CCR section 1735.6(f), a pharmacy may seek a compliance delay for a defined section for requirements that require physical construction or alteration to a facility or physical environment. The process and forms to request such a compliance delay can be found at the following link:
    http://www.pharmacy.ca.gov/licensees/facility/compliance_delay.shtml

16. If the hospital pharmacy is located in the basement and there are challenges to venting hoods to outside and ceiling air filter/exchanges are there exemptions are available?

There are no exemptions available. If a facility anticipates it will not be compliant with the physical requirements by the effective of January 1, 2017, a compliance delay may be requested to allow additional time for the necessary structural changes to be made (see CCR section 1735.6(f)). The process and forms to request such a compliance delay can be found at the following link: http://www.pharmacy.ca.gov/licensees/facility/compliance_delay.shtml

17. Under CCR section 1735.1(l), "daily" is defined as "occurring every day the pharmacy is operating." What happens to monitoring and maintenance requirements when the compounding area is not open on a day the retail area of the pharmacy is open?

    If the pharmacy is open, then activities requiring daily monitoring or maintenance are required. There are no exemptions if the compounding area(s) is/are not in use but the pharmacy is open. For instance, a refrigerator and freezer still need to be monitored at least every 24 hours to ensure they are storing dangerous drugs at the correct temperature. Please see required policies and procedures under CCR section 1735.5(c)(9).

18. What drugs are required to be treated as "hazardous drugs?

    As specified in CCR section 1735.1(r), hazardous drugs include all anti-neoplastic agents identified by NIOSH as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

19. The facility's scales are new and have internal calibration. Staff records performance of the daily calibration by signing an individual's initials on an online form. Is this acceptable?

    According to CCR section 1735.6(c), this is acceptable if the calibration is done prior to use, done per manufacturer's specification, the records are not alterable and the records are retrievable for 3 years.

20. Is it required that each BSC and Compounding Aseptic Containment Isolator (CACI) have a dedicated external vent?

    No, CCR section 1735.1(c) and 1735.1(f) state external venting should be dedicated to one BCS or CACI.

Acronyms:
ACPH: air changes per hour
B&PC: Business and Professions Code
BOP: The California State Board of Pharmacy
BUD: beyond use date
CCR: California Code of Regulations.
CETA: Controlled Environment Testing Association
CFUs: colony-forming units
CSP: Compounded Sterile Preparations
EPA: Environmental Protection Agency
FD&C act: Food Drug and Cosmetic act
FDA: Food and Drug Administration
NIOSH: National Institute for Occupational Safety and Health
P&P: policy and procedure
PIC: Pharmacist- in-Charge
USP <1150>: United States Pharmacopeia Chapter 1150
USP <1207>: United States Pharmacopeia Chapter 1207
USP <797>: United States Pharmacopeia Chapter 797
USP <800>: United States Pharmacopeia Chapter 800

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: AFL 18-20 – Sterile Compounding Clean Rooms

SUMMARY

In January 2017, the California Board of Pharmacy (BoP) established new regulatory requirements for hospitals performing sterile compounding. The California Department of Public Health (CDPH) last month released the attached All Facilities Letter 18-20, which clarifies requirements for new or remodeled pharmacy clean rooms and use of mobile sterile compounding units in general acute care hospitals. According to the letter, hospitals must obtain CDPH approval for all new or remodeled pharmacy clean rooms under the hospital's license. Hospitals must also obtain CDPH approval — including program flexibility approval — to temporarily use mobile sterile compounding units.

CDPH reminds hospitals that, because of the multiple levels of review by state entities, they must allow sufficient time for all required approvals. CDPH advises hospitals to submit applications to the Centralized Applications Unit 120 days prior to when the new or remodeled pharmacy is anticipated to be completed, and clearly mark that the application is for sterile compounding. In addition, CDPH advises hospitals to contact the CDPH Pharmacy Consultant Unit at LNCPharmCleanRoom@cdph.ca.gov 90 days prior to anticipated completion.

ACTION REQESTED

- Information only.

Attachments: AFL 18-20

BJB:br

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

State of California—Health and Human Services Agency
California Department of Public Health

EDMUND G. BROWN JR.
Governor

May 25, 2018

AFL 18-20

TO: General Acute Care Hospitals (GACH)

SUBJECT: New or Remodeled Pharmacy Clean Rooms and Use of Mobile Sterile Compounding Units (MSCU)

AUTHORITY: Title 22 California Code of Regulations (CCR) sections 70105, 70267, 70803, and 70805

All Facilities Letter (AFL) Summary

This AFL clarifies the California Department of Public Health (CDPH) application process for new or remodeled pharmacy clean rooms in a GACH, and the CDPH application and program flexibility request process for GACHs to temporarily use MSCUs.

On January 1, 2017, the California Board of Pharmacy updated CCR Title 16 pertaining to Sterile Compounding, including clean room requirements. Additionally, the U.S. Pharmacopeia (USP) is revising its compounding standards with an anticipated effective date of December 1, 2019. CDPH recommends facilities visit and monitor USP's website to stay apprised of developments regarding compounding requirements.

This AFL is a reminder that GACHs must obtain CDPH approval for new or remodeled pharmacy clean rooms. CDPH approval is required for all pharmacy clean rooms under the hospital's license, including projects the Office of Statewide Health Planning and Development (OSHPD) identifies as subject to Title 24, California Building Standards Code for licensed clinics ("OSHPD 3"). For example, a GACH must apply for CDPH approval for a new or remodeled clean room in an infusion clinic that operates under the GACH's license.

GACHs opting to temporarily use a MSCU to provide pharmaceutical services during the construction or remodel of pharmacy clean rooms must obtain CDPH approval. The CDPH application process for using a MSCU includes obtaining a program flexibility approval. CDPH Licensing and Certification (L&C) Program has the authority to grant program flexibility from regulatory requirements as long as the facility meets statutory requirements.

Pharmacy clean room and MSCU projects involve multiple state entities, including OSHPD, the California Board of Pharmacy, and CDPH. CDPH recommends that hospitals plan ahead to allow sufficient time to obtain all required approvals.

CDPH Application Process for New or Remodeled Pharmacy Clean Rooms

Facilities seeking approval for a new clean room must:

1. Apply for CDPH approval by submitting the required forms to the Centralized Applications Unit (CAU). The application requirements are located on the General Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List.
    - CDPH recommends facilities apply 120 days prior to the new pharmacy clean room's anticipated construction completion date.
    - Submit documents via mail to:
      California Department of Public Health
      Centralized Applications Unit
      Attn: Licensing and Certification Program
      Pharmacy Clean Room and Sterile Compounding Projects
      PO Box 997377, MS 3207
      Sacramento, CA 95899-7377
2. Contact the CDPH Pharmaceutical Consultant Unit (PCU) to initiate the administrative review of the clean room, by emailing: LNCPharmCleanRoom@cdph.ca.gov.
    - CDPH recommends contacting PCU 90 days prior to the anticipated construction completion date.
    - To expedite the CDPH administrative review of the new clean room, please review the Examples of Documentation.

CDPH Application Process for the Use of MSCUs

Facilities seeking approval for the temporary use of a MSCU must:

1. Apply for CDPH approval for the temporary use of a MSCU by submitting the required forms to CAU. The application requirements are located on the General Acute Care Hospital Pharmacy Clean Room and Sterile Compounding Applicant Check List.
    - CDPH recommends applying for approval of a MSCU 120 days prior to the date of intended use.
    - Submit documents via mail to:
      California Department of Public Health
      Centralized Applications Unit
      Attn: Licensing and Certification Program
      Pharmacy Clean Room and Sterile Compounding Projects
      PO Box 997377, MS 3207
      Sacramento, CA 95899-7377
2. Apply for a program flexibility by submitting a Program Flexibility Request form to the appropriate District Office (DO). Requests for program flexibility must include justification for the flexibility request and adequate supporting documentation that the proposed alternative does not compromise patient care. CDPH reviews requests for program flexibility on a case-by-case basis.
    - CDPH recommends submitting the program flexibility request concurrently with CAU MSCU documents, 120 days prior to the date of intended use.
    - The CDPH review process for a MSCU program flexibility request includes an administrative review by the PCU.
    - If you have any questions regarding program flexibility requests, please contact your local DO.

To facilitate the MSCU application process, CDPH requests that GACHs contact PCU prior to the delivery of the MSCU to the GACH by emailing: LNCPharmCleanRoom@cdph.ca.gov.

For questions regarding this AFL, please contact the Centralized Applications Unit by email at CAU@cdph.ca.gov or by telephone at (916) 552-8632.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Deputy Director

Center for Health Care Quality, MS 0512 . P.O. Box 997377 . Sacramento, CA 95899-7377
(916) 324-6630 . (916) 324-4820 FAX
Department Website (cdph.ca.gov)

Page Last Updated : May 25, 2018

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, VP Nursing & Clinical Services
Amber Ott, VP Strategic Finanical Initiatives

SUBJECT: 340B Drug Discount Program Update

SUMMARY

CHA is pleased to report that the Administration's proposal to eliminate the 340B drug discount program in Medi-Cal was rejected by the Legislature and, therefore, is not included in the budget. The Administration had proposed trailer bill language to prohibit hospitals from purchasing discounted drugs through the 340B program for Medi-Cal managed care and fee-for-service patients, in order to eliminate duplicate discounts of drugs purchased through the 340B program. The proposal would have completely eliminated the savings hospitals currently achieve through the 340B program.

On June 12, Rep. Doris Matsui (D-Sacramento) introduced House Resolution 6071, known as the Stretching Entity Resources for Vulnerable (SERV) Communities Act, which clarifies the intent of the 340B Drug Pricing Program and provides for enhanced program integrity. The bill text, a one-page summary, a section-by-section summary and CHA's support letter, which was submitted yesterday, are attached. CHA also issued a news release today in support of the legislation.

The bill would improve the program's integrity and transparency by requiring the Secretary of Health and Human Services to audit both providers and drug manufacturers. Manufacturers would also be required to disclose critical pricing information.

The bill would reverse the cut in Medicare reimbursement to 340B hospitals for their purchases of Part B drugs set forth in the calendar year 2018 outpatient prospective payment system final rule. In December 2017, CHA joined 31 state and regional hospital associations in an ongoing litigation effort to overturn cuts to the 340B program.

CHA supports the SERV Communities Act, and thanks Rep. Matsui for her recognition of the 340B program's important role in preserving vital health care programs and services for seniors, children and others across California.

ACTION REQUESTED

- Information Only

Attachments: CHA News Release
Final Rule Summary
CHA Summary
CHA Joins Litigation

BJB:br

CHA News Release

For Immediate Release

Contact:
Jan Emerson-Shea
(916) 552-7516 – Office
(916) 804-0663 – Cell
@jemersonshea – Twitter

California Hospital Association Supports New Federal Legislation to Protect 340B Drug Discount Program

Rep. Doris Matsui (D-Sacramento) Introduces Stretching Entity Resources for Vulnerable (SERV) Communities Act

SACRAMENTO (June 12, 2018) – The California Hospital Association (CHA) has announced its support for new federal legislation that would protect and enhance the long-standing 340B drug discount program, which allows safety-net hospitals, community clinics and other providers that serve low-income and vulnerable patients to purchase outpatient medications at a discount from drug manufacturers.

The Stretching Entity Resources for Vulnerable (SERV) Communities Act, is sponsored by Rep. Doris Matsui (D-Sacramento). The act will ensure that hospitals and other safety-net providers can continue to stretch limited financial resources to best serve their patients and communities.

"The savings gleaned from the 340B program allow hospitals to make critical, cost-effective investments to improve the health and well-being of their communities," said CHA President & CEO Carmela Coyle. "This legislation will improve the integrity and transparency of the program, while enabling hospitals to continue to be exemplary stewards of these vital resources."

With bipartisan support, Congress created the 340B drug discount program in 1992 to offer financial relief from high prescription drug costs to health care providers who care for low-income and indigent populations. No state or federal dollars are involved with this program. Drug manufacturers provide the discounts directly to eligible hospitals and other providers.

Among the key components of the SERV Communities Act is the requirement that the Secretary of Health and Human Services (HHS) audit 340B health care providers as well as drug manufacturers,

— more —

and mandates that drug manufacturers publicly disclose drug pricing information. Additionally, the act will reverse a January cut in Medicare payments to 340B hospitals for their purchase of outpatient drugs.

"Hospitals and clinics doing life-saving work rely on the 340B program to help them provide inclusive and affordable care in their communities," said Rep. Matsui.

In California, 175 hospitals qualify for the 340B program and use the subsequent savings to fund such vital patient care services as behavioral health programs, mobile health care clinics, chemotherapy infusion centers, Hepatitis C treatment and inner-city primary care centers. Additionally, many hospitals provide free or discounted drugs and therapies to low-income patients with chronic diseases.

As one of the largest health care trade associations in the nation, CHA represents more than 400 hospitals and health systems in California. The association advocates for patients and hospitals, promotes public health policy and is hospitals' voice at the state and federal levels. CHA has offices in Sacramento and Washington, D.C.

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CY 2018 Medicare Outpatient Prospective Payment System

Final Rule Summary
November 2017

On November 1, the Centers for Medicare & Medicaid Services (CMS) released its final rule addressing rate updates and policy changes to the Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgery center (ASC) prospective payment system (PPS) for calendar year (CY) 2018. The final rule is available at www.calhospital.org/cy2018-opps-final and was published in the November 13 *Federal Register*.

Policies in the final rule are effective for discharges on or after January 1, 2018, unless otherwise noted. Until December 31, CMS is accepting comments on the payment classifications assigned to Healthcare Common Procedure Coding System (HCPCS) codes identified in Addenda B, AA and BB with the comment indicator "NI." Other resources related to the final rule are available on the CMS website at www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS-1678-FC.html?DLPage=1&DLEntries=10&DLSort=2&DLSortDir=descending.

Provisions related to the ASC PPS are not addressed in this summary. Member hospitals that would like additional information on the policy and payment provisions related to the CY 2018 ASC PPS final rule should contact Alyssa Keefe, CHA vice president, federal regulatory affairs, at akeefe@calhospital.org or (202) 488-4688.

Upcoming CHA Member Forum on OPPS Final Rule – Registration is Now Open!

CHA will review the provisions of the OPPS final rule as well as key provisions in the physician fee schedule in a member forum on **Friday**, **December 8 from noon-1:30 p.m. (PT).** Please register for this call by no later than noon on December 7 at www.surveymonkey.com/r/NPW35HP. Registered participants will be notified of materials posted to the regulatory calendar section of the CHA website on December 8. This forum will be recorded.

SUMMARY OF CHANGES FOR CY 2018

The final rule:

- Drastically cuts Medicare payments for drugs that are acquired under the 340B Drug Pricing Program. Specifically, CMS will pay separately payable, non-pass-through drugs (other than vaccines) purchased through the 340B program at the average sales price (ASP) minus 22.5 percent, rather than ASP plus 6 percent. CHA estimates a loss of $85 million in OPPS payments for 340B hospitals for CY 2018.
- Reinstates the non-enforcement moratorium for critical access hospitals and small rural hospitals with 100 or fewer beds for CYs 2018 and 2019. CMS believes this will give those hospitals more time to comply with supervision requirements and submit specific services for evaluation by the Advisory Panel on Hospital Outpatient Payment for a recommended change in supervision level.
- Removes total knee arthroplasty (TKA) from the inpatient-only (IPO) list, which would allow for Medicare coverage of TKA in either an inpatient or an outpatient setting. In addition, CMS will

prohibit recovery audit contractor (RAC) review of patient status for TKA procedures performed in the inpatient setting for a two-year period.
- Continues its policy of two separate ambulatory payment classifications (APCs) for partial hospitalization services: one for community mental health centers (CMHCs) and one for partial hospitalization programs (PHPs).
- Removes the exception for certain drug administration services and conditionally packages payment for low-cost drug administration services.
- Removes six quality measures from the Hospital Outpatient Quality Reporting (OQR) program beginning with CY 2020, and delays the Outpatient and Ambulatory Surgery (OAS) Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey measures (OP-37-a-e) indefinitely.

Discussed in more detail below, but included in the CY 2018 physician fee schedule (PFS) final rule, CMS will implement changes to payments for non-excepted off-campus hospital-based outpatient departments. Section 603 of the Bipartisan Budget Act of 2015 requires that, with the exception of dedicated emergency department services, services furnished in off-campus provider-based departments (PBDs) that began billing under the OPPS on or after November 2, 2015 (referred to as "non-excepted" services), would no longer be paid under the OPPS, but rather under another applicable Part B payment system. For CY 2017, CMS finalized the PFS as the applicable payment system for most of these items and services and set payment for most non-excepted services at 50 percent of the OPPS rate. In the PFS final rule, CMS pulled back from its original proposal of 25 percent and finalized its policy to pay hospitals at 40 percent, rather than 50 percent, of the OPPS rate for non-excepted services beginning January 1, 2018.

The details of these provisions, as well as others, are noted below.

MARKET BASKET UPDATE AND FINANCIAL IMPACT OF CY 2018 OPPS PROPOSED RULE

CMS estimates a conversion factor update of 1.35 percent, based on a market basket of 2.7 percent less a 1.6 percentage point adjustment for multifactor productivity and a 0.75 percent mandatory reduction — both mandated by the Affordable Care Act (ACA). After considering all other policy changes finalized under the OPPS, including estimated spending for pass-through payments and budget neutrality adjustments, CMS estimates a 1.4 percent, or approximately $5.8 billion, payment increase for hospitals paid under the OPPS in CY 2018 compared to CY 2017.

Hospitals that fail to meet the OQR Program requirements will be subject to a 2 percent market basket reduction in OPPS payments for CY 2018. The table below includes CMS' projected impact of the proposed rule by major provider type.

CMS' Estimated Impact of OPPS Final Rule for CY 2018 (by major provider type)	
All Hospitals	1.5%
Urban Hospitals (Pacific Region)	0.9%
Rural Hospitals (Pacific Region)	3.1%
Non-Teaching	2.9%
Minor Teaching	1.7%
Major Teaching	-0.9%

Below is a summary of the CHA DataSuite analysis for California providers. CHA estimates that hospital outpatient payments will increase 1.1 percent overall and by 1.61 percent for rural hospitals and 1.08 percent for urban hospitals, compared to CY 2017.

California

Impact Analysis	Dollar Impact	Percent Change
Estimated CY 2017 OPPS Payments	*$4,847,281,200*	
Marketbasket Update	$111,036,300	2.29%
ACA-Mandated Marketbasket Reductions	($55,518,100)	-1.15%
340B Drug Payment Reduction BN Adjustment	$132,958,600	2.74%
Other BN Adjustments	$10,837,800	0.22%
Wage Index	($1,723,100)	-0.04%
APC Factor/Updates (Includes 340B Reduction)	($144,388,000)	-2.98%
Estimated CY 2018 OPPS Payments	*$4,900,484,700*	
Total Estimated Change CY 2017 to CY 2018	***$53,203,500***	***1.10%***

The impact shown above does not include the impact of the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress through FFY 2025. It is estimated that the impact of sequestration on CY 2018 OPPS PPS-specific payments would be: -$98,009,700

ALTERNATIVE PAYMENT METHODOLOGY FOR DRUGS PURCHASED UNDER THE 340B DRUG DISCOUNT PROGRAM

All hospitals paid under the OPPS are currently paid the same rate for separately payable drugs; this rate does not vary based on the differing prices at which hospitals may acquire the drugs. Medicare beneficiaries are liable for 20 percent of the OPPS payment rate, which is currently average sales price (ASP) plus 6 percent — regardless of whether the hospital purchased the drug at a discounted rate.

The 340B Drug Discount Program allows eligible hospitals — those with a Medicare disproportionate share hospital (DSH) percentage above 11.75 percent — to purchase certain "covered outpatient drugs" at discounted prices from drug manufacturers. The ACA expanded 340B eligibility to other hospitals paid under the OPPS, including sole community hospitals with a DSH adjustment percentage of 8 percent or higher, rural referral centers with a DSH adjustment percentage of 8 percent or higher and freestanding cancer hospitals with a DSH adjustment percentage above 11.75 percent. The ACA also expanded the 340B program to critical access hospitals (CAHs), which are not paid under the OPPS. To be 340B program-eligible, DSH hospitals must be owned by a state or local government or be a nonprofit hospital under contract with a state or local government to provide services to low-income patients who are not eligible for Medicare or Medicaid.

CMS reiterates its stated rationale for this policy in the final rule, including its assertions that several recent studies and reports on Medicare Part B payments for 340B purchased drugs highlight a difference in drug spending between 340B hospitals and non-340B hospitals, as well as varying differences in the amount by which the Part B payment exceeds the drug acquisition cost and some instances where the patient copayment exceeds the price at which the hospital acquired the drug. The final rule provides excerpts from Medicare Payment Advisory Commission (MedPAC), Office of the Inspector General and General Accountability Office reports on:

- The magnitude of discounts hospitals receive under the 340B program
- The profitability to hospitals of furnishing 340B drugs
- Differential utilization and Medicare spending for oncology drugs and other drugs between 340B hospitals and other hospitals
- Differential Medicare drug spending per beneficiary between 340B hospitals and other hospitals

CMS believes its policy of paying 340B hospitals for separately payable drugs under the OPPS at ASP plus 6 percent is inappropriate, given that hospitals acquire those drugs at significantly discounted rates. CMS expresses particular concern about the rising prices of certain drugs and the effect on Medicare beneficiary coinsurance, especially on low-income seniors. It is also concerned that the current payment methodology may lead to unnecessary utilization — and potential overutilization — of separately payable drugs. Therefore, CMS has adopted its policy as proposed with some slight modifications. The table below compares the proposed and final rule policies.

Summary Comparison of Proposed and Final Rule Policies

Issue	Proposed Rule	Final Rule
Payment Rate for 340B Drugs	ASP minus 22.5%	Unchanged
Modifier	Required for drugs NOT purchased under the 340B program	Required ONLY for drugs purchased under the 340B program and may be used for packaged drugs and drugs on pass-through status without triggering the payment adjustment
Drug Exclusions	Drugs on pass-through status, vaccines	Unchanged
Biosimilars	Included, but only the first biosimilar to a given reference product can receive pass-through	Included. Final rule modifies pass-through policy, allowing all biosimilars to receive pass-through.
Rural sole community hospitals, children's hospitals and PPS-exempt cancer hospitals	Included	Exempt, but hospitals are required to submit information-only modifier when billing for a drug acquired under the 340B program. Modifier will NOT trigger a payment at ASP minus 22.5%.
Non-excepted off campus provider based HOPDs	Excluded	Excluded. While CMS finalized its policy in the PFS to pay non-excepted off campus HOPDs at 40 percent of the OPPS rate, it notes that the applicable payment system is the PFS. Therefore, CMS does not apply the 340B payment policy to these sites. CHA is seeking clarity regarding the application of the modifier to the existing modifiers already required under this separate payment policy.
Budget Neutrality	$900 million savings estimate applied to the OPPS conversion factor (not modeled in payment impact or applied to the proposed rule conversion factor). Solicited comments on alternatives.	$1.6 billion savings estimate applied to the OPPS conversion factor

OPPS Payment Rate for 340B Purchased Drugs

CMS' goal in making changes to the OPPS payment for separately payable drugs is to align Medicare payment for those drugs more closely to the resources hospitals expend to acquire such drugs. CMS notes that the intent of the 340B program is to allow covered entities, including eligible hospitals, to stretch scarce resources while continuing to provide access to care. CMS proposed to limit its policy to separately payable drugs under the OPPS; thus, the policy would not apply to CAHs that are paid based on 101 percent of reasonable costs under a separate provision of the statute. CMS would also exclude drug s on pass-through status and vaccines, which are excluded from the 340B program.

CMS finalized proposals to exclude drugs on pass-through status and vaccines. In the final rule, CMS also excludes rural sole community hospitals (SCHs), children's hospitals and inpatient prospective payment system (IPPS)-exempt cancer hospitals from the policy. CMS solicited comment on whether other types of drugs, such as blood clotting factors, should be excluded from the reduced payment. The final rule does not exempt any specific type of drug product from the policy.

To address current data limitations that inhibit identification of which drugs were acquired under the 340B program in Medicare OPPS claims data, CMS proposed to establish a modifier, to be effective January 1, 2018, for hospitals to report with separately payable drugs that were **not** acquired under the 340B program. In response to commenters, CMS is not adopting its proposed policy and instead will only require this modifier when billing for drugs that **are** acquired under the 340B program. Rural SCHs, children's hospitals and IPPS-exempt cancer hospitals will be required to use an information-only modifier when billing for drugs acquired under the 340B program. The modifier will not trigger the ASP minus 22.5 percent adjustment for these hospital types.[i] **Further details about the modifier are noted below and in the final rule. In addition, CMS is currently developing sub-regulatory guidance, including guidance related to billing for dually eligible beneficiaries for whom covered entities do not receive a discount under the 340B program, and hopes to issue the guidance before the end of the year. A recent hospital open door forum outlined a number of the outstanding provider questions about how to appropriately apply the modifiers in light of the many operational challenges. CHA is in communication with CMS and continues to solicit questions from hospitals related to the appropriate application of the modifiers.**

- Hospitals paid under the OPPS (other than CAHs, hospitals paid under the Maryland waiver, children's hospitals and PPS-exempt cancer hospitals) are required to report modifier "JG" on the same claim line as the drug HCPCS code to identify a drug purchased under the 340B drug subject to payment at ASP minus 22.5 percent. This only applies to those drugs with status indicator K.
- Rural SCHs, children's hospitals and IPPS-exempt cancer hospitals will be required to report informational modifier "TB" for 340B-acquired drugs beginning January 1, 2018. Modifier "TB" is informational only and will not trigger a payment adjustment.
- Part B drugs or biologicals excluded from the 340B payment adjustment include vaccines (assigned status indicator "L" or "M") and drugs with OPPS transitional pass-through payment status (assigned status indicator "G").

CMS cites section 1833(t)(14)(A)(iii)(II) of the Act as its authority for making payment at ASP minus 22.5 percent for drugs acquired under the 340B program. This section of the law allows the Health and Human Services Secretary to pay separately payable drugs under the OPPS at ASP plus 6 percent when hospital acquisition cost data are not available "as calculated and adjusted by the Secretary as necessary for purposes of this paragraph." CMS is applying section 1833(t)(14)(A)(iii)(II) of the Act to all

separately payable drugs and biologicals, as it has in past years. However, it is exercising the Secretary's authority to adjust the applicable payment rate as necessary for separately payable drugs and biologicals (other than drugs on pass-through status and vaccines) acquired under the 340B program by reducing ASP by 22.5 percent, which the agency believes better represents the average acquisition cost for these drugs and biologicals.

CMS believes that using an average discount to set payment rates for separately payable drugs will achieve the dual goals of (1) adjusting payments to better reflect resources expended to acquire such drugs while (2) protecting the confidential nature of discounts applied to a specific drug. CMS does not believe that Medicare beneficiaries should be liable for a copayment rate that is tied to the current methodology of ASP plus 6 percent when the actual cost to the hospital to purchase the drug is much lower.

To the extent that blood clotting factors and radiopharmaceuticals are covered outpatient drugs purchased under the 340B program, CMS believes that the OPPS payment rate for these drugs should account for the discounted rate at which they were purchased. CMS believes that it is not necessary to phase in the reduced payment rates and said it would take the comments related to acquisition cost billing into account for future policymaking. It noted that several state Medicaid programs require reporting of actual acquisition cost for 340B drugs, so the magnitude of implementation challenges may be less than the comments suggest.

CMS is exempting rural SCHs, children's hospitals and IPPS-exempt cancer hospitals from the policy. In response to comments, CMS indicated that more study is needed before applying the adjustment to rural SCHs that receive a special 7.1 percent adjustment to their OPPS payments for higher costs. Unlike rural SCHs, rural referral centers do not receive any special payments and will be subject to the policy.

Children's hospitals and IPPS-exempt cancer hospitals are being exempted from the policy because these hospitals receive transitional outpatient payments (TOPs). As these hospitals are permanently held harmless to their "pre-BBA amount," any reduction in payment for 340B drugs would potentially be paid back to these hospitals at cost report settlement through TOPs. While CMS is exempting rural SCHs, children's and IPPS-exempt cancer hospitals from the 340B drug payment reduction, these hospitals are still being required to report informational modifier "TB" for tracking and monitoring purposes when they furnish drugs under the 340B program because CMS believes it is important to collect information on which drugs being billed to Medicare were acquired under the 340B Program.

General Policy Comments

Organizations representing physician oncology practices, pharmaceutical research and manufacturing companies, a large network of community-based oncology practices and several individual Medicare beneficiaries supported the proposal, indicating that the policy will:

- Help address the growth of the 340B program
- Stem physician practice consolidation with hospitals that has resulted in a 30 percent shift in the site of service for chemotherapy administration from the physician office setting to the more-costly hospital outpatient setting
- Preserve patient access to community-based care and reduce drug costs for seniors
- Control prices for drugs as drug manufacturers must offset the cost of the discounts with higher drug prices
- Continue to allow substantial savings for hospitals to use to provide direct and indirect patient benefits

The Community Oncology Alliance supported the proposal and provided a report showing that some 340B hospitals offered little charity care and turned away some patients in need because those patients were uninsured.[ii] Some commenters urged the Department of Health and Human Services, specifically CMS and the Health Resources and Services Administration (HRSA), to work with Congress to reform the 340B program. One commenter requested greater transparency and accountability on how 340B savings are being used, as well as a specific definition of the "340B patient," which the commenter noted would require a legislative change.

Other comments provided various opinions as to whether the proposal would achieve CMS' goal of lowering drug prices and reducing beneficiary out-of-pocket costs:

- Some commenters stated that the proposal has the potential to alleviate the financial burden that high-cost drugs place on patients.[iii]
- Other commenters stated that, because the proposal does not address the issue of expansion of 340B entities, the volume of 340B-discounted drugs and the affordability of drugs, especially oncology drugs, CMS should not finalize the proposal.
- One commenter said that it is imperative to ensure that an across-the-board reduction actually reflects the size of the 340B discount to avoid creating barriers to access, should both physician practices and the hospital outpatient departments be unable to cover actual acquisition costs.

Comments, including those from CHA and other organizations representing 340B-eligible safety-net hospitals in urban and rural areas and teaching hospitals, opposed the policy because:

- The Secretary lacks statutory authority to impose such a large reduction in the payment rate for 340B drugs.
- The proposal will effectively eviscerate the 340B program by taking money intended for services to low-income patients and giving it to hospitals that do not share that mission.
- Medicare payment cuts of this magnitude would greatly "undermine 340B hospitals' ability to continue programs designed to improve access to services — the very goal of the 340B Program."
- Rather than "punitively targeting" 340B safety-net hospitals serving vulnerable patients, including those in rural areas, CMS should instead redirect its efforts to halt the "unchecked, unsustainable increases" in the price of drugs.
- Commenters disputed that 340B hospitals may be unnecessarily prescribing more drugs and/or more expensive drugs relative to non-340B hospitals. These commenters cited other studies in an effort to refute the evidence presented in the proposed rule.[iv] [v]
- Medicare beneficiaries, including dually eligible Medicare beneficiaries, would not directly benefit from a lowered drug copayment amount. The commenters noted that many beneficiaries have supplemental insurance that covers their out-of-pocket drug costs, in whole or in part.

CMS' general response to comments was to acknowledge them, thank those supporting the proposal and reiterate its justification for adopting the policy — the current OPPS payment rate of ASP plus 6 percent significantly exceeds the discounts received for covered outpatient drugs by hospitals enrolled in the 340B program. The evidence it presented in the proposed rule supports that hospitals receiving 340B discounts bill for more drugs than hospitals that do not receive these discounts.

In response to comments about beneficiary liability, CMS said, while many Medicare beneficiaries may have supplemental coverage that covers some or all of their out-of-pocket expenses, not all beneficiaries have such coverage. This policy will lower both the amount that a beneficiary is responsible to pay as well as the amount that any supplemental insurance, including the Medicaid program, will pay on the beneficiary's behalf. It further added that beneficiaries may pay more in the hospital setting as

beneficiaries are liable both for cost-sharing for drugs they receive and for a hospital "facility fee" that they do not have to pay when the service is provided outside the hospital.

Comments on the Statutory Authority for the 340B Payment Proposal

Many commenters challenged the statutory authority of various aspects of the proposal. This summary highlights several key arguments:

Arguments on Whether There is Statutory Authority for the Adjustment

Section 1833(t)(14)(A)(iii)(II) of the Act authorizes CMS to "calculate and adjust" ASP. The plain and ordinary meaning of the terms "calculate" and "adjust" express a limited and circumscribed authority to set the payment rate, which restricts the agency to mathematically determining "an appropriate, slight alteration."

- The Secretary's limited adjustment authority under section 1833(t)(14)(A) (iii)(II) of the Act is an "explicit statutory directive" that the Secretary must follow. The Secretary does not have authority to rewrite the statute. *Pettibone Corp. v. United States*, 34 F.3d 536, 541 (7th Cir. 1994) (an agency's authority to interpret a statute "must not be confused with a power to rewrite").
- Subclause (I) of section 1833(t)(14)((A)(iii) establishes that the payment rate be set to the average acquisition cost of the drug taking into account hospital acquisition cost survey data found in other parts of paragraph (14). Considered in its entire context, the statute does not provide the adjustment authority the Secretary proposes to use. The comment refers the agency to *Roberts v. Sea-Land Servs., Inc.*, 566 U.S. 93, 101 (2012) (Statutory provisions "…cannot be construed in a vacuum. It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme").

CMS' general response to these arguments is that it has broad discretion to adjust payments for drugs, including taking into account when certain drugs are acquired at a significant discount under section 1833(t)(14)(A)(iii)(II) of the Act. The agency disagrees that the Secretary's authority under section 1834(t)(14)(A)(iii)(II) of the Act to "calculate and adjust" drug rates as necessary is limited to minor changes. CMS' response further indicated that hospitals have their own data on acquisition costs, as well as data related to OPPS payment rates for drugs, yet did not suggest an alternative minimum discount. This gives CMS confidence that the 22.5 percent discount appropriate that the community does not believe there is some alternative discount that would be more accurate. CMS used this point to further argue that its policy does not "eviscerate" the 340B program as some commenters asserted because hospitals will continue to retain a portion of the discount to furnish services to low-income patients.

Authority to Vary Payment by Hospital Group

- Only subparagraph (I), and not subparagraph (II), of section 1833(t)(14)(A)(iii) of the Act permits CMS to vary payment "by hospital group." By including "by hospital group" in subparagraph (I) and omitting it in subparagraph (II), Congress expressed its intent that CMS may not vary prices by hospital group under subparagraph (II).
- The subparagraph (II) methodology must apply to "the drug," and CMS may not vary payment for the same drug based upon the type of hospital that furnishes it.

CMS acknowledged that explicit authority to vary payment rates by hospital group is in subclause (I) of section 1833(t)(14)(A)(iii) of the Act, not subclause (II), but stated authority under subclause (II) to "calculate and adjust" drug payments "as necessary for purposes of this paragraph" giving the Secretary

broad discretion to adjust payments for drugs according to whether or not certain drugs are acquired at a significant discount for Medicare beneficiaries. Further, the policy is not adjusting payment by hospital group but by whether the drug itself is acquired under the 340B program. CMS further argued that "it would be odd" for the statute to give the Secretary broad discretion throughout section 1833(t)(14) to determine prices for separately payable drugs and then assume the Secretary is foreclosed from taking into account considerations specified through section 1833(t)(14) from being applied in section 1833(t)(14)(A)(iii)(II).

Authority to Establish Payment Rates in the Absence of Acquisition Cost Survey Data and Authority to Base Payment on an Average Discount

- The Secretary ignored the statutory directive in section 1833(t)(14) of the Act to set payment rates at the average acquisition cost for specific drugs and not to use averages for all drugs.
- The Secretary impermissibly discards Congress' requirement that any survey data used in setting payment rates must be derived from statistically rigorous surveys by using MedPAC's estimate of average discounts as a proxy or replacement for the surveys required under subsection (iii)(I).

CMS indicated that unlike subclause (I), subclause (II) does not require taking survey data into account for determining average price for the drug in the year. Section 1833(t)(14)(A)(iii)(II) of the Act grants the Secretary the authority to calculate and adjust rates as necessary in the absence of acquisition cost. Because CMS is not using authority under subclause (I), CMS disagrees with the commenter's suggestion that the Secretary is using the MedPAC analysis to stand in the place of the survey requirement under subclause (I).

Current Agency View Contrasts with Longstanding Practice

Public comments argued the proposal contrasts sharply with the agency's previous view and longstanding practice under section 1833(t)(14) of the Act that the statutory default of ASP plus 6 percent "requires no further adjustment" because it "represents the combined acquisition and pharmacy overhead payment for drugs and biologicals." CMS responded that the fact that the agency has not historically utilized its authority under section 1833(t)(14)(A)(iii)(II) of the Act to adjust payment amounts for separately payable 340B-acquired drugs does not mean the agency is permanently barred from adjusting these payments where it has a reasoned explanation for doing so.

Violation of Section 340B of the Public Health Service Act

The proposed policy would transfer 340B discounts from hospitals eligible for the program to hospitals ineligible for the 340B program. By granting 340B eligibility only to Medicare hospitals that serve large numbers of low-income or other underprivileged patients, Congress did not intend for non-340B hospitals to benefit from 340B drug discounts as is occurring under CMS' proposed policy. Congress has had ample opportunity to amend the Medicare statute governing Part B payments and/or the 340B statute to expressly permit CMS to reduce Medicare payments to 340B hospitals, but has not done so. The proposed cut to 340B hospitals is contrary to Congress' intent for the 340B program to enable safety-net providers to reach more patients and furnish more comprehensive services.

CMS responded that there are no references in section 1833(t) of the Act that govern Medicare OPPS payments and section 340B of the Public Health Service Act to each other — each statute stands on its own and neither is hindered or rendered null and void by the other. Congress' silence on this issue should not be viewed as a constraint on the broad authority conferred to the Secretary under section 1833(t) of the Act to establish payment rates under the OPPS. CMS remains interested in exploring ways to better

target 340B savings to hospitals that serve low-income and uninsured patients to address concerns that 340B discounts are increasing payments for non-drug OPPS services for all hospitals.

Proposal is Procedurally Defective and Inconsistent with HOP Recommendations

Commenters argued that the Secretary acted contrary to the statute by not consulting with the Hospital Outpatient Panel in accordance with section 1833(t)(9)(A) of the Act prior to making the proposal. Nevertheless, at the August 21, 2017 meeting of the HOP, the panel recommended CMS not finalize the proposal. Further, the proposal was "procedurally defective" because it was solely articulated through preamble and did not propose to amend the Code of Federal Regulations (CFR) when altering the substantive standards for payment.[vi]

CMS responded that section 1833(t)(9)(A) of the Act does not impose an obligation on the Secretary to consult with the HOP panel *prior* to issuing a notice of proposed rulemaking, nor does it require the Secretary to adopt the panel's recommendation(s). The HOP did meet after the proposed rule publication and did make recommendations on this issue, which were taken into consideration in the development of the final rule. CMS disagreed that it is out of compliance with section 1871 of the Act and the Administrative Procedures Act, noting that it is going through notice and comment rulemaking procedures to adopt its policy. As the rates for separately payable drugs have not been established in the CFR, there are no CFR provisions to modify.

Comments in Other Areas

Biosimilar Biological Products. One commenter requested that CMS use its equitable adjustment authority to apply the 340B policy to biosimilars on pass-through. The commenter indicated that CMS' proposed policy will disadvantage a reference product relative to a biosimilar if a biosimilar is paid ASP plus 6 percent of the reference product's ASP, while the reference product is paid ASP minus 22.5 percent. Further, CMS' policy of only making pass-through payment for the first biosimilar will apply the payment reduction to the reference product and all subsequent biosimilars, favoring the first biosimilar to the detriment of the reference product and subsequent biosimilars. The commenter estimated that if the 340B drug policy is implemented as proposed, up to $50 million of any savings could be lost due to hospitals switching to the biosimilar biological product receiving pass-through payment. Another commenter requested that CMS exclude biosimilar biological products from the proposed payment adjustment until such time as the biosimilar biological product market is better established.

CMS rejected comments requesting that it apply the 340B policy to biosimilars receiving pass-through payment because section 1833(t)(6)(D)(i) of the Act provides for an explicit payment for drugs and biologicals eligible for pass-through payment. However, CMS is adopting a change in policy to allow pass-through payment for each FDA-approved biosimilar instead of only the first biosimilar for a particular reference product. Biosimilar biological products that are not on pass-through payment will be paid ASP minus 22.5 percent of the reference product.

Nonexcepted Off-Campus Hospital Outpatient Departments. Commenters requested that CMS also apply the alternative payment methodology for 340B drugs furnished in nonexcepted off-campus PBDs to avoid creating financial incentives for hospitals to reallocate services to the site of care that pays the highest rate for an item or service. CMS responded that it will continue to monitor the billing patterns of claims submitted by nonexcepted off-campus outpatient PBDs, noting that its policy only applies to covered outpatient department services and does not include services furnished in non-excepted off-campus HOPDs, which are paid for separately payable drugs at ASP plus 6 percent in accordance with section

1847A of the Act. CMS may consider adopting the requested policy in 2019 notice-and-comment rulemaking.

Payment Impact. Based on 2016 claims data, the total OPPS Part B drug payment is approximately $10.2 billion. For the final rule, CMS uses the HRSA covered entity database to identify 1,338 OPPS hospitals participating in the 340B program. Of these, 270 were rural SCHs, 47 were children's hospitals and three were IPPS-exempt cancer hospitals. CMS does not assume any changes in the number of 340B hospitals or changes in volume of drugs purchased using a 340B discount. Using assumptions outlined in the final rule, CMS estimates OPPS payments for separately payable drugs, including beneficiary copayments, will decrease by approximately $1.6 billion under the final rule policy.

CHA estimates 129 340B hospitals in California are subject to this policy, resulting in a cut of approximately $85 million in outpatient payments in CY 2018 as compared to CY 2017.

The final rule indicates that there are potential offsetting factors, including possible changes in provider behavior and overall market changes, that would likely lower the impact of the payment reduction. As a result, CMS indicates that it may need to make an adjustment in future years to revise the conversion factor once it has more accurate data on drugs purchased with a 340B discount within the OPPS — similar to the adjustment it made for the clinical diagnostic laboratory test packaging policy in the 2016 OPPS/ASC final rule with comment period.

SECTION 603 OF THE BALANCED BUDGET ACT OF 2015 (CY 2018 PFS) PROPOSED PAYMENT RULES UNDER THE PFS FOR NONEXCEPTED ITEMS AND SERVICES FURNISHED BY NONEXCEPTED OFF-CAMPUS PROVIDER-BASED DEPARTMENTS OF A HOSPITAL

Section 603 of the Bipartisan Budget Act of 2015 (Public Law 114–74) excludes from the definition of covered HOPD services "applicable items and services" furnished on or after January 1, 2017, by certain off-campus outpatient departments of a provider (generally those that did not furnish covered HOPD services before November 2, 2015) and provides for payment for those services furnished by off-campus provider-based departments (PBDs) under a Part B payment system other than the hospital OPPS ("applicable payment system" under Part B).

In the 2017 OPPS interim final rule with comment (81 FR 79720 through 79729), CMS established initial payment policies under the PFS for nonexcepted items and services furnished on or after January 1, 2017. CMS finalized that the PFS would be the applicable payment system and established payment policies under the PFS for off-campus PBDs to bill and be paid for nonexcepted items and services. CMS' finalized payment policies under the PFS for nonexcepted items and services furnished during 2018 are discussed below.

OPPS Payment Adjustments
For 2018, CMS will continue the policies finalized in 2017. Specifically, CMS adopted the packaging payment rates and multiple procedure payment reduction percentage that apply under the OPPS to establish the PFS payment rates for nonexcepted off-campus PBDs furnishing nonexcepted items and services that are billed by hospitals. The claims processing logic that is used for OPPS payment for comprehensive APCs, conditionally and unconditionally packaged items and services, and major procedures is incorporated into the newly established PFS rates.

For 2018, CMS will continue its 2017 policy and not adopt OPPS payment adjustments for outlier payments, the rural SCH adjustment, the cancer hospital adjustments, transitional outpatient payments,

the hospital outpatient quality reporting payment adjustment and the inpatient hospital deductible cap to the cost-sharing liability for a single hospital outpatient service.

After consideration of comments, CMS finalizes a PFS Relativity Adjuster of 40 percent for 2018. CMS agrees with commenters' concerns, including those from MedPAC, about the proposed change to the PFS Relativity Adjuster for 2018 based on a single code level comparison. In addition, CMS acknowledges that the proposed PFS Relativity Adjuster of 25 percent may overcorrect for the possibility that the 2017 PFS Relativity Adjuster of 50 percent was an overestimate of the relativity between the OPPS and the PFS. CMS also agrees with commenters who stressed the need to account for packaging rules that apply under the OPPS, but notes it is unable to fully calculate the effect of packaging under the OPPS.

CMS believes the methodology it used for determining the 2017 PFS Relativity Adjuster addresses many of the concerns and comments it received. Thus, CMS updated the list of the 25 major codes billed by off-campus hospital departments using the "PO" modifier and included a full year of 2016 claims data. This analysis included all the parameters used for the 2017 interim final rule except HCPCS code G0463 (Hospital outpatient clinic visit), which was included for the 2018 analysis. Due to payment policies, CMS removed HCPCS code 36591 (Collection of blood specimen from a completely implantable venous access device), HCPCS code G0009 (Administration of pneumococcal vaccine) and HCPCS code G0008 (Administration of influenza vaccine) from the list. Table 10 in the final rule shows data for the OPPS rates, the analogous PFS rates and the full year utilization for the codes used in the analysis. The resulting utilization-weighted average comparison between the PFS and the OPPS is 35 percent; the applicable payment amount under the PFS is 35 percent of the amount that would have been paid under the OPPS. Because it is unable to fully calculate the effects of packaging under the OPPS, CMS believes that a 40 percent PFS Relativity Adjuster is an appropriate upward adjustment to the 35 percent calculation.

In response to comments requesting clarification about the policy for drugs that are packaged under the OPPS, CMS states that drugs and biologicals that are unconditionally packaged under the OPPS will continue to be packaged when furnished in a nonexcepted off-campus PBD. Drug administration services subject to conditional packaging (identified by status indicator Q1 under the OPPS) will be packaged under the OPPS if the relevant criteria are met; otherwise, they will be separately paid. Drugs and biologicals that are separately payable under the OPPS (identified by status indicator "G" or "K" under the OPPS) will be paid consistent with payment rules in the physician office setting. In addition, drugs that are acquired under the 340B program and furnished by non-excepted off-campus PBDs will be paid under the PFS and are not subject to the OPPS drug payment policies.

CMS disagrees with commenters that the total PFS non-facility rate should be used to assess relativity between the PFS and OPPS. CMS believes the most appropriate code-level comparison between the PFS and the OPPS would reflect the technical component of each HCPCS code under the PFS. A technical component is not calculated for all HCPCS codes and for those HCPCS codes where there is a different payment for facility and non-facility settings; CMS believes it is appropriate to compare the difference under the PFS between the non-facility and facility rate with the OPPS rate.

Commenters suggested that the PFS rate for services should be established as a payment floor for nonexcepted items and services furnished by nonexcepted off-campus PBDs, or alternatively some items and services should be excluded from the PFS Relativity Adjuster. In response, CMS states it will consider whether it would be appropriate to set a floor using the PFS or otherwise address codes subject to statutory payment reductions, such as the DRA of 2005, in future rulemaking.

CMS disagrees with comments that its implementation of section 603 has restricted access to care for rural populations. CMS also disagrees that statements in the 2017 interim final rule reflected a promise not to change the PFS Relativity Adjuster until CMS had the required data to determine a more precise calculation.

Several commenters questioned why CMS had not responded to comments on the 2017 OPPS interim final rule, which implemented the 2017 PFS Relativity Adjuster of 50 percent. Commenters also questioned whether CMS' proposal to reduce the PFS Relativity Adjuster to 25 percent might be a violation of rulemaking obligations under the Administrative Procedure Act (APA) (U.S.C. 533) as CMS had indicated its intention to develop a revised PFS Relativity Adjuster based on claims data when it becomes available. Some commenters suggested that CMS' policies made in the absence of specific data to support them as explained in the 2017 interim final rule are arbitrary and capricious.

In response to these comments, CMS acknowledges that to meet rulemaking obligations, it generally responds to comments on an interim final rule at the time that it adopts the final policies relating to the interim final rule. CMS notes that the public comments on the 2017 interim final rule and the 2018 PFS proposed rule express many of the same views and concerns about how CMS determines the PFS Relativity Adjuster. In addition, CMS discusses the analysis for the 2018 proposed PFS Relativity Adjuster of 25 percent and the final PFS Relativity Adjuster of 40 percent, including responding to public comments. CMS believes given the limitations related to data availability, it is moving as judiciously as possible, providing public transparency into policy considerations, and is in full accordance with notice and comment rulemaking obligations.

CMS acknowledges it received several comments on topics related to policies addressed in prior rulemaking or outside the scope of this final rule. In response to comments requesting that CMS move all of the rulemaking related to implementation of section 603 from the PFS rule to the OPPS rule, CMS states it is appropriate that these issues be addressed in the PFS rulemaking because the policies relate to payments that are made under the PFS to nonexcepted off-campus PBDs furnishing nonexcepted items and services.

Partial Hospitalization Programs (PHPs)

For 2018, CMS proposed to continue the policies finalized in 2017 for PHP services furnished by nonexcepted off-campus PBDs. Specifically, CMS proposed to continue to pay PHP services at the CMHC rate for APC 5853, for providing three or more PHP services per day. CMS believes that adopting the CMHC rate is appropriate since CMHCs are freestanding entities that are not part of a hospital but provide the same services as hospital-based PHPs. CMS reiterates that an off-campus PBD may still enroll as a CMHC if it chooses to do so and meets the relevant requirements.

After consideration of public comments, CMS finalizes its proposal and sets the PFS payment rate for these PHP services as the per diem rate that would be paid to a CMHC in 2018. The final 2018 CMHC per diem rate is 68.8 percent of the final 2018 hospital-based per diem rate under the OPPS. (The final 2018 PHP APC geometric mean per diem costs for hospital-based PHP APC 5863 is $208.09.)

Many commenters believed that this payment policy does not compensate for financial viability, would hinder expansion of PHPs and jeopardize access to critically needed mental health services. A few commenters suggested alternatives including exempting PHP APC codes or paying at the hospital-based PHP rate. CMS believes that the CMHC per diem rate provides appropriate payment for PHPs. CMHCs are freestanding providers that are not part of a hospital and have lower cost structures than

hospital-based PHPs. In response to the alternatives suggested, CMS states it is unable to pay nonexcepted off-campus PBDs that are PHPs at the same rate that hospital-based PHPs are paid under the OPPS or to except PHP APC codes from the requirements of section 603 of the Bipartisan Budget Act of 2015. CMS will consider other payment methodologies for PHP services in determining whether to propose a different methodology for PHP services in future rulemaking.

Supervision Rules

CMS notes that the amendments made by section 603 did not change the status of off-campus PBDs as provider-based departments; rather, the amendments only changed the manner in which these provider-based departments are reimbursed for their nonexcepted items and services. Thus, the supervision rules under 42 CFR 410.27 continue to apply to off-campus PBDs that furnish nonexcepted items and services.

Beneficiary Cost-Sharing

CMS specifies that all beneficiary cost-sharing rules that apply under the PFS pursuant to sections 1848(g) and 1866(a)(2)(A) of the Act will continue to apply for all nonexcepted items and services furnished by off-campus OPDs, regardless of the cost-sharing obligation under the OPPS.

2019 and Subsequent Years

CMS states it continues to believe that section 603 of the Bipartisan Budget Act of 2015 intended to eliminate the payment incentive for hospitals to purchase physician offices, convert them to off-campus PBDs, and bill under the OPPS for items and services furnished in these PBDs.

CMS expects to use the 2017 claims data reported using the "PN" modifier for use in PFS rate setting for 2019. Using the current methodology, CMS expects to use that data to determine the relative resources involved in furnishing non-exempted items and services in nonexcepted off–campus PBDs relative to other PFS services. CMS acknowledges that, based on the current methodology, payment rates are not equal on a procedure-by-procedure basis but instead work towards equalizing payment rates in the aggregate between physician offices and nonexcepted off-campus PBDs.

CMS discusses its concerns that, depending on the mix of services of particular off-campus PBDs, specialty-specific patterns in payment differentials could result in continued incentives for hospitals to buy specific physician offices and convert them to non-excepted off-campus PBDs. For 2019 and future years, CMS intends to examine the claims data to determine the PFS relativity adjuster and whether additional adjustments to the methodology are necessary.

Regulatory Impact
For 2018, nonexcepted items and services furnished by nonexcepted off-campus PBDs will be paid under the PFS at a rate that is 40 percent of the OPPS rate. CMS estimates that this change will result in total Medicare Part B savings of $12 million for 2018 relative to maintaining the 2017 PFS Relativity Adjuster of 50 percent for 2018.

ENFORCEMENT INSTRUCTION FOR THE SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES IN CAHS AND CERTAIN SMALL RURAL HOSPITALS

Currently, CMS requires direct supervision for hospital outpatient therapeutic services covered by Medicare that are furnished in hospitals and hospital PBDs, including CAHs. Due to the difficulty of meeting this standard, CMS created an interim non-enforcement ("enforcement instruction") period,

through December 31, 2016, that allowed Medicare administrative contractors not to evaluate or enforce supervision requirements for CAHs and small rural hospitals with 100 or fewer beds.

In response to continued comments, including CHA's, CMS finalized its proposal to reinstate this moratorium for CYs 2018 and 2019, allowing more time for CAHs and small rural hospitals to comply with the supervision requirements and for providers to submit specific services for evaluation by the Advisory Panel on Hospital Outpatient Payment to determine changes in supervision level. These hospitals will continue to be subject to conditions of participation for hospitals and other Medicare rules related to supervision.

RECALIBRATION OF APC WEIGHTS

CMS recalibrates the APC relative payment weights for CY 2018 with the same basic methodology used for many years. CMS did, however, finalize changes for pathogen reduced platelets and rapid bacterial testing of platelets, brachytherapy insertion procedures, blue light cystoscopy and packaging low-cost drug administration services. For this final rule, CMS uses hospital final action claims for services furnished from January 1, 2016, through December 31, 2016. Cost data are from the most recently filed cost reports, in most cases for cost reporting periods beginning in 2015.

COMPREHENSIVE APCS

For CY 2018, CMS did not create any new comprehensive APCs (C-APCs) or any extensive changes to the established methodology used for C-APCs. There is a total of 62 C-APCs.

A C-APC is defined as payment for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. C-APCs provide all-inclusive payments for certain procedures and cover payment for all Part B services that are related to the primary procedure — including items currently paid under separate fee schedules. The C-APC encompasses diagnostic procedures, lab tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; coded and un-coded services and supplies used during the service; outpatient department services delivered by therapists as part of the comprehensive service; durable medical equipment and the supplies to support that equipment; and any other components reported by HCPCS codes that are provided during the comprehensive service. The costs of blood and blood products are included in the C-APCs.

The C-APCs do not include payments for services that are not covered by Medicare Part B or are not payable under the OPPS, such as certain mammography and ambulance services, brachytherapy sources, pass-through drugs and devices, and charges for self-administered drugs. A full list of excluded services is available in Addendum J to the final rule.

For C-APC 5627 (Level 7 Radiation Therapy): Stereotactic Radio Surgery (SRS), CMS will continue to make separate payments for the 10 planning and preparation services adjunctive to the delivery of the SRS treatment using either the Cobalt-60-based or LINAC-based technology when furnished to a beneficiary within 30 days of the SRS treatment. Additionally, the data collection period for SRS claims with modifier "CP" is set to conclude on December 31, 2017; CMS will then delete and discontinue the required use of this modifier.

COMPOSITE APCS

Since 2008, CMS has used composite APCs to make a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. CMS is continuing composite policies for mental health services and multiple imaging services and finalized its proposal to delete the low dose rate (LDR) prostate composite APC and assign

CPT code 55875 (Transperineal placement of needs or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to a C-APC.

More specifically, CMS will delete composite APC 8001 (LDR Prostate Brachytherapy Composite) and instead assign HCPCS code 55875 (transperineal placement of needles or catheters into prostate for interstitial radioelement application, with or without cystoscopy) to status indicator "J1" and C-APC 5375 (Level 5 Urology and Related Services). However, CMS does not finalize a code edit for claims with brachytherapy services, proposed to be effective January 1, 2018, that would have required brachytherapy application HCPCS code 77778 (Interstitial radiation source application; complex) to be added on the claim with the brachytherapy insertion procedure (HCPCS code 55875). CHA opposed this code edit in comments on the proposed rule and is pleased that CMS did not finalize it. Finally, Table 7 in the final rule shows the proposed HCPCS codes that would be subject to the multiple imaging procedure composite APC policy and their respective families.

CHANGES TO PACKAGING POLICIES

Packaging of Low-cost Drug Administration Services

In the CY 2015 OPPS final rule, CMS conditionally packaged payment for low-cost ancillary services assigned to APCs with a geometric mean cost of less than or equal to $100. The packaged ancillary services are primarily minor diagnostic tests and procedures that are often performed with a primary service, although there are instances wherein hospitals provide such services without another primary service during an encounter. Under this policy, the agency assigns the conditionally packaged services to status indicator "Q1," which indicates that the service is separately payable when not billed on the same claim as certain other primary services. Among the exclusion to this packaging policy were certain low-cost drug administration services.

However, for CY 2018, CMS examined drug administration billing patterns and payments under the OPPS in CY 2016 to establish a more consistent approach to packaging services under its current categories. The agency found that APC 5691 (Level 1 Drug Administration) and APC 5692 (Level 2 Drug Administration) had geometric mean costs of less than $100 and were often reported on the same claim with other separately payable services, such as an emergency department or clinic visit. Accordingly, the agency finalized its proposal to conditionally package payment for these low-cost drug administration services, except for add-on codes and vaccine administrations other than preventive services. Table 8 of the final rule lists the drug administration services included in APCs 5691 and 5692, along with their proposed status indicators.

Comment Solicitation on Unconditionally Packaging Drug Administration Add-on Codes

In 2014, CMS finalized a policy to unconditionally package procedures described by add-on codes, which represent an extension or continuation of a primary procedure and are typically supportive, dependent or adjunctive to a primary service. Commenters expressed concern that the policy would disadvantage providers of longer drug administration services, which are often protocol-driven and are not necessarily dictated by the hospital, but rather by the characteristics of the specific drug or biological being administered to the patient. In the proposed rule, CMS solicited public comment on whether conditionally or unconditionally packaging drug administration add-on codes for 2018 would negatively impact access to care or result in other unintended consequences.

Many commenters raised concerns about the appropriateness of packaging drug administration services add-on codes. Without explicit incremental payment for additional hours of infusion, some commenters suggested that hospitals might discontinue offering the infusion. CMS indicated that it would take these comments into consideration for future rulemaking.

CONVERSION FACTOR AND OUTLIER THRESHOLD

Applying all of the changes outlined in the final rule results in a conversion factor of $78.636 for CY 2018, an increase of 4.85 percent from CY 2017's conversion factor of $75.001.

To maintain total outlier payments at 1 percent of total OPPS payments, CMS finalized a CY 2018 outlier fixed-dollar threshold of $4,325 — an increase over the current threshold of $3,825. Outlier payments will continue to be paid at 50 percent of the amount by which the hospital's cost exceeds 1.75 times the APC payment amount, when both the 1.75 multiple threshold and the fixed-dollar threshold are met.

AREA WAGE INDEX

CMS continues its policy of adopting the final federal fiscal year (FFY) inpatient prospective payment system (IPPS) post-classified wage index as the OPPS calendar year wage index for adjusting standard payment amounts for labor market differences. The 2018 OPPS final rule wage index is based on the FFY 2018 IPPS proposed post-classified wage index. Minor changes finalized in the FFY 2018 IPPS final rule impacted the area wage index; for more details, review CHA's final rule summary at www.calhospital.org/ffy2018-ipps-final-summary.

ADJUSTMENT FOR RURAL SOLE COMMUNITY HOSPITALS AND ESSENTIAL ACCESS COMMUNITY HOSPITALS

CMS will continue to apply a 7.1 percent payment increase for rural sole community hospitals and essential access community hospitals. This payment add-on excludes separately payable drugs and biologicals, devices paid under the pass-through payment policy and items paid at charges reduced to costs.

OPPS PAYMENTS TO CANCER HOSPITALS

CMS will continue its policy to provide payment increases to the 11 hospitals identified as exempt cancer hospitals. Previously, CMS did this by providing a payment adjustment such that the cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals; thus, the adjustment was budget-neutral. However, beginning in CY 2018, the 21st Century Cures Act requires that the weighted average PCR for other OPPS hospitals be reduced by one percentage point. Therefore, CMS finalized its proposal to set the target PCR to 0.88 instead of 0.89, in order to determine the CY 2018 cancer hospital payment adjustment using the most recent data available. CMS states that this required reduction does not significantly impact the budget neutrality adjustments for this policy.

CMS will calculate a budget neutrality factor as if the cancer hospital adjustment target PCR was 0.89, not 0.88 as finalized in this rule. Therefore, CMS adopted a 0.08 percent adjustment to the CY 2018 conversion factor to account for this policy.

NEW TECHNOLOGY APCS

CMS assigns new technology services that are ineligible for transitional pass-through payments and for which the agency has insufficient clinical information and cost data for appropriate assignment to a clinical APC group to new technology APCs. These new technology APCs are designated by cost bands, which allow CMS to provide appropriate and consistent payment for designated new procedures that are not yet reflected in claims data. Assignment to a new technology APC is temporary; the service will be assigned to a clinically appropriate APC group when CMS acquires sufficient data. Currently, there are 51 levels of new technology APC groups with two parallel status indicators: one set with the status indicator of "S" and the other set with the status indicator of "T." These APCs have the same payment levels, but only the "T" set is subject to the multiple procedure payment reduction.

To improve its ability to more closely match payments for services over $100,000 to the cost of the service, for CY 2018 the agency finalized its proposal to narrow the increments for new technology APCs 1901 through 1906 from $19,999 cost bands to $14,999 cost bands. It also finalized its proposal to add new technology APCs 1907 and 1908 and New Technology Level 52 ($145,001-$160,000), which will allow for an appropriate payment of retinal prosthesis implantation procedures. Table 15 in the final rule includes the complete list of the modified and additional new technology APC groups for CY 2018. The payment rates for these new technology APCs are included in Addendum A to the final rule.

PAYMENT FOR MEDICAL DEVICES WITH PASS-THROUGH STATUS

CMS finalized that the pass-through payment status of the three device categories eligible for pass-through payments will expire on December 31, 2017:

- C1822 – Generator, neurostimulator (implantable), high frequency, with rechargeable battery and charging system
- C2613 – Lung biopsy plug with delivery system
- C2623 – Catheter, transluminal angioplasty, drug-coated, non-laser

Because all the devices in these categories were approved prior to 2017, CMS applied its policy to expired device categories at the end of this year, after at least two years of pass-through payments have been made. For 2018, CMS will package the costs of the device described by HCPCS codes C2623, C2613 and C1822 into the costs related to the procedures with which the device is reported in hospital claims data.

DEVICE-INTENSIVE PROCEDURES

Beginning in CY 2017, CMS defined device-intensive APCs as procedures that require the implantation of a device and are assigned an individual HCPCS code-level device offset of more than 40 percent, regardless of APC assignment.

Additionally, for new HCPCS codes describing device implantation procedures that do not yet have associated claims data, CMS applies a device offset of 41 percent until claims data are available to establish an offset for the procedure.

As finalized in the CY 2017 final rule, CMS applies the CY 2016 device coding requirements to newly defined device-intensive procedures. In addition, any device code would satisfy this edit when it is reported on a claim with a device-intensive procedure. CMS did not finalize any changes to this policy for CY 2018.

PAYMENT ADJUSTMENT FOR NO COST/FULL CREDIT AND PARTIAL CREDIT DEVICES

For outpatient services that include certain medical devices, CMS reduces the APC payment if the hospital received a credit from the manufacturer. The offset can be 100 percent of the device amount when a hospital attains the device at no cost or receives a full credit from the manufacturer, or 50 percent when a hospital receives partial credit of 50 percent or more.

For CY 2018, CMS continues to reduce OPPS payment for device-intensive procedures by the full or partial credit that a provider receives for a replaced device. CMS also continues to determine the procedures to which this policy would apply using three criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (even if temporarily).

- The procedure must be device-intensive, defined as devices exceeding 40 percent of the procedure's average cost.

PAYMENT POLICY FOR LOW-VOLUME DEVICE-INTENSIVE PROCEDURES

In the CY 2017 final rule, CMS adopted a policy that the payment rate for any device-intensive procedure assigned to a clinical APC with fewer than 100 total claims for all procedures in the APC will be calculated using the median cost. For CY 2018, the only procedure to which this policy would apply continues to be CPT code 0308T (insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), which is currently assigned to APC 5495.

PAYMENT FOR DRUGS, BIOLOGICALS AND RADIOPHARMACEUTICALS

CMS pays for drugs and biologicals that do not have pass-through status in one of two ways: either packaged into the APC for the associated service or assigned to their own APC and paid separately. The determination is based on the packaging threshold.

For CY 2018, CMS finalized a packaging threshold of $120. Drugs, biologicals and radiopharmaceuticals that are above the $120 threshold will be paid separately using individual APCs; the baseline payment rate for CY 2018 is the ASP plus 6 percent.

As finalized in the CY 2017 final rule, CMS allows for a quarterly expiration of pass-through payment status of drugs and biologicals newly approved in CY 2017 and subsequent years in order to grant a pass-through period as close to a full three years as possible, and to eliminate the variability of the pass-through payment eligibility period without exceeding the statutory three-year limit.

Finally, CMS will allow the pass-through status for 19 drugs and biologicals listed in Table 69 of the final rule to expire on December 31, 2017. The agency also finalized pass-through status in CY 2018 for 50 other drugs and biologicals, shown in Table 70 of the final rule.

HIGH-COST/LOW-COST THRESHOLD FOR PACKAGED SKIN SUBSTITUTES

Previously, CMS finalized a policy in which skin substitutes are divided into low- and high-cost groups in terms of packaging. CMS assigns skin substitutes with a geometric mean unit cost (MUC) or a product per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high-cost group for CY 2018, as in CY 2017. For CY 2018, CMS will continue to assign those that did not exceed the thresholds but were assigned to the high-cost group for CY 2017 to the high-cost group. Lastly, CMS will also assign skin substitutes with pass-through payment status to the high-cost category; however, no skin substitutes have pass-through payment for CY 2018. A list of packaged skin substitutes and their group assignments is available in Table 72 of the final rule.

UPDATES TO THE INPATIENT-ONLY LIST

CMS continues to use the same methodology to review the IPO list. The criteria for a procedure to be removed from the IPO list include:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the IPO list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed for addition to the ASC list.

The proposed rule indicated that not all of the established criteria need to be met for a procedure to be removed from the IPO list.

CMS is finalizing its proposal to remove the procedures described by the following codes from the IPO list for 2018: CPT code 27447 (Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)) and CPT code 55866 (Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed).

CPT Code	Code Descriptor	2018 OPPS APC assignment	2018 OPPS status indicator
27447	Arthroplasty, knee, condyle and plateau; medical and lateral compartments with or without patella resurfacing (total knee arthroplasty)	5115	J1
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	5362	J1

Total Knee Replacement

For a number of years, TKA has been a topic of discussion for removal from the IPO list with both stakeholder support and opposition. CMS used the 2017 OPPS/ASC proposed rule to solicit public comments on the removal of the TKA procedure from the IPO list, without actually proposing to remove it. After considering comments received on the 2017 OPPS/ASC rule, CMS decided to propose removing TKA from the IPO list for 2018. CMS determined that TKA meets criteria 1, 2 and 4 above for being removed from the IPO list. The 2018 OPPS/ASC proposed rule requested comments on whether the public believes that these criteria are met and whether TKA meets any other of the five criteria listed above. CMS indicates that it expects providers to carefully develop evidence-based patient selection criteria to identify appropriate candidates for an outpatient TKA procedure, as well as exclusionary criteria that would disqualify a patient from safely undergoing an outpatient TKA procedure.

CMS proposed that CPT code 27447 would be assigned to C–APC 5115 (Level 5 Musculoskeletal Procedures) with status indicator ‘‘J1.’’ The proposed rule further noted that the decision of the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary’s individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. Therefore, CMS proposed to prohibit recovery audit contractor (RAC) review for patient status for TKA procedures performed in the inpatient setting for a period of two years to allow time for experience to accumulate with these procedures in this setting. CMS would not want hospitals to err on the side of inappropriately performing the procedure on an outpatient basis due to concerns about the possibility of an inpatient TKA claim being denied for patient status. Contractor reviews for issues other than patient status would continue to be permitted, including those for underlying medical necessity.

General Comments

There were comments both supporting and opposing removing TKA from the IPO list. Supporters of the proposal made the following points:

- TKA meets CMS’ established criteria for removing a procedure from the IPO list.

- Appropriately selected patients who are in excellent health and with no or limited medical comorbidities and sufficient caregiver support could be successful candidates for outpatient TKA.

Supporters of the proposed policy also requested that CMS:
- Develop, with input from stakeholders, patient selection criteria and risk stratification protocols for TKA to be performed in an outpatient setting. Two orthopedic specialty societies stated that their organizations were in the process of developing these patient selection and protocol tools.
- State explicitly that the surgeon is the final arbiter of the appropriate site for performance of the surgical procedure
- Provide an incentive for outpatient and ambulatory settings performing TKA, PHA and THA to be a part of a registry such as the American Joint Replacement Registry

Concerns raised by opponents of the proposed policy and others included:
- Removal of TKA from the IPO list may lead commercial payers to implement coverage policies that would drive these procedures from the inpatient setting to lower cost outpatient settings that may not be sufficiently prepared to handle the complexities or risks associated with some outpatient TKA procedures.
- Removing TKA from the IPO list could drive TKA to specific facilities based on cost alone, which could result in significant further stresses in isolated rural care settings.
- TKA is not clinically appropriate for the outpatient setting because it is invasive and Medicare beneficiaries are more likely to have comorbidities that could make pain more difficult to control. Because of these comorbidities, Medicare beneficiaries will face greater complications, recovery times and rehabilitation needs than non-Medicare populations to recover from TKA procedures.

CMS finalizes its proposal to remove TKA from the IPO list. CMS responded that the decision of the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary. It does not address the concerns about private insurers, which the agency says is outside of its authority.

Removal of any procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. The "two-midnight" rule will apply to TKA. This guidance provides that if the physician expects the beneficiary to require hospital care that spans at least two midnights and admits the beneficiary based upon that expectation, the case is appropriate for payment under the IPPS (80 FR 70539). For stays for which the physician expects the patient to need less than two midnights of hospital care, an inpatient admission is payable under Medicare Part A on a case-by-case basis if the documentation in the medical record supports the admitting physician's determination that the patient requires inpatient hospital care. This documentation and the physician's admission decision are subject to medical review.

CMS will not create or endorse specific patient selection guidelines because it believes that surgeons, clinical staff and medical specialty societies who perform outpatient TKA and possess specialized clinical knowledge and experience are most suited to create such guidelines.

Access to Post-Acute Care

Several commenters asked CMS to waive the three-day prior inpatient stay for coverage of skilled-nursing facility (SNF) care, stating that discharging outpatient TKA patients without a three-day stay and subsequent access to adequate rehabilitation would increase the likelihood of further medical concerns including in readmissions. Readmissions and other complications will result in higher expenses for the

beneficiary, the Medicare program and the hospital. Other commenters noted that the vast majority of beneficiaries who fit the criteria for an outpatient TKA procedure would not need institutional post-acute care services. Commenters also stated that a large percentage of TKA inpatients do not require a three-day length of stay, and that removing TKA from the IPO list would not preclude these patients from meeting the three-day qualifying stay requirement when warranted.

CMS reiterated its earlier response that removal of the TKA procedure from the IPO list does not require the procedure to be performed only on an outpatient basis. It further noted that Medicare Advantage plans may elect to provide SNF coverage without imposing the SNF three-day qualifying stay requirement and that CMS has issued conditional waivers of the three-day qualifying stay requirement as necessary to carry out the Medicare Shared Savings Program and to test certain Innovation Center payment models, including the Next Generation ACO Model and the Comprehensive Care for Joint Replacement Model. CMS agreed with commenters that suggested properly selected candidates for outpatient TKA would not be expected to require SNF care following surgery.

Bundled Payment Models

Numerous commenters were concerned that the proposal to remove TKA from the IPO list could result in younger and healthier patients preferentially undergoing outpatient TKA, so that a higher proportion of patients undergoing inpatient TKA would be high risk and/or more likely to require additional post-acute care support. The change in patient mix could increase the average episode payment of the remaining inpatients in TKA, Bundled Payments for Care Improvement (BPCI) Initiative and Comprehensive Care for Joint Replacement (CJR), hindering the hospital's ability to generate savings under the BPCI or CJR models. The commenters proposed refinements to the BPCI and CJR models to mitigate these effects, including adjusting the target price for BPCI and CJR episodes involving TKA to exclude procedures that could have been performed in the HOPD or allowing BPCI Model 2 and CJR episodes to be initiated by TKA performed in the hospital outpatient department.

CMS responded that it does not expect a significant volume of TKA cases currently being performed in the hospital inpatient setting to shift to the hospital outpatient setting as a result of removing TKA from the IPO list. Accordingly, CMS does not expect a substantial impact on the patient-mix for the BPCI and CJR models although it intends to monitor the overall volume and complexity of TKA cases performed in the hospital outpatient department to determine whether any future refinements to these models are warranted.

Payment

Commenters requested that CMS only use claims for CPT 27447 that include a joint implant and to assign the procedure to APC 5116 (Level 6 Musculoskeletal Procedures). One commenter also stated that CMS failed to provide the general public with an explanation of the source of the geometric mean cost of the TKA procedure, which was CMS' basis for assigning the TKA procedure to a C-APC.

CMS responded that it assigned TKA to C-APC 5115 based on clinical similarity with other musculoskeletal procedures. The 50th percentile IPPS payment for TKA without major complications or comorbidities (MS-DRG 470) is approximately $11,760 for FY 2018. The geometric mean cost for C-APC 5116 is over $15,000. As previously stated, CMS expects that beneficiaries selected for outpatient TKA would generally be less complex and not have major complications or comorbidities. Considering that there would be no room and board costs for outpatient TKA, CMS believes that its assignment to C-APC 5115 (mean costs=$10,122) is correct. With respect to the billing concern, CMS indicated that it relies on hospital charges to include all items and services that are furnished with a procedure.

RAC Review of TKA Procedures

Commenters generally supported CMS' proposed two-year moratorium on RAC review of patient status for TKA procedures performed in the inpatient setting. Some commenters requested a longer or even a permanent moratorium. Others requested clarification that RAC review of a TKA inpatient case could only occur upon referral from a Quality Improvement Organization (QIO) consistent with the two-midnight policy.

CMS finalized the two-year moratorium on RAC review of inpatient TKA cases as proposed. It further stated that the initial medical reviews of claims for short-stay inpatient admissions are conducted by QIOs, which may refer providers to the RACs due to exhibiting persistent noncompliance with Medicare payment policies, including having high denial rates and consistently failing to adhere to the two-midnight rule, or failing to improve their performance after QIO educational intervention.

CHANGES TO PAYMENT FOR FILM X-RAY

As required by the Consolidated Appropriations Act of 2016 and effective for services furnished in CY 2017 and subsequent years, payment under the OPPS for imaging services that are X-rays taken using film will be reduced by 20 percent with modifier "FX." CMS will phase-in a payment reduction for imaging services that are taken using computed radiography technology. Payments for such services furnished during CYs 2018 through 2022 would be reduced by 7 percent and by 10 percent in CY 2023 and subsequent years. CMS is establishing a new modifier "FY" that would be reported on claims to identify those HCPCS codes that describe X-rays taken using computed radiography technology beginning January 1, 2018.

APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING SERVICES

The Protecting Access to Medicare Act of 2014 requires professionals furnishing advanced diagnostic imaging services to report on the Medicare claim information about appropriate use criteria (AUC) reviewed by the ordering professional. This requirement applies to all applicable advanced diagnostic imaging services paid under the PFS, OPPS and ASC payment system.

Although statute required the program to begin January 1, 2017, CMS has taken a measured approach by establishing different components of the AUC program framework through rulemaking over the past couple of years. In the CY 2018 PFS final rule, CMS finalized that AUC reporting requirements will begin January 1, 2020. The first year of the program — 2020 — will be considered an "educational and operations testing year," during which CMS will pay claims regardless of whether they contain information on the required AUC consultation. The agency also plans to implement an 18-month voluntary reporting period beginning in July 2018. CHA urged CMS to allow providers adequate time to implement AUC requirements before they impact payment, and appreciates the delay in implementation.

REVISIONS TO THE LABORATORY DATE OF SERVICE POLICY

Date of service (DOS) is a required field on all Medicare claims for laboratory services. The requirements for DOS are used to determine whether a hospital bills Medicare for a clinical diagnostic laboratory test or whether the laboratory performing the test bills Medicare directly.

Under the current rules, if a test was ordered more than 14 days after a patient's discharge date, the DOS is the date the test was performed. The laboratory would bill Medicare directly for the test, and the laboratory would be paid directly by Medicare. If the test is ordered less than 14 days after a patient's

discharge date, the DOS is the date the specimen was collected from the patient and the hospital, not the laboratory, would bill Medicare for the test and then the hospital would pay the laboratory.

CMS sought public comment on potential modifications to the DOS policy that would allow laboratories to bill Medicare directly for certain laboratory tests excluded from the OPPS packaging policy, and ordered less than two weeks following the date of the patient's discharge. CMS' responses to the comments received may be found on pages 52,534 – 52,540. Additionally, CMS is implementing an exception to the current DOS regulations so that the DOS of molecular pathology tests and tests designated by CMS as Criterion (A) advanced diagnostic laboratory tests is the date that the test was performed only if all of the following criteria are met:

- The test was performed following the date of a hospital outpatient's discharge from the hospital outpatient department.
- The specimen was collected from a hospital outpatient during an encounter.
- It was medically appropriate to have collected the sample from the hospital outpatient during the hospital outpatient encounter.
- The results of the test do not guide treatment provided during the hospital outpatient encounter.
- The test was reasonable and medically necessary for the treatment of an illness.

CHANGES TO PARTIAL HOSPITALIZATION PROGRAM RATES

PHPs are intensive outpatient psychiatric programs providing outpatient services in place of inpatient psychiatric care, and may be provided in either a hospital outpatient setting or a freestanding CMHC. PHP providers are paid on a per diem basis with payment rates calculated using CMHC- or hospital-specific data.

In the CY 2017 OPPS rule, CMS finalized its proposal to combine the existing two-tiered PHP APCs into a single APC for each setting. Payments for the new APCs were calculated by combining the geometric mean per diem costs for existing Level 1 and Level 2 PHP APCs into a single value for the new, aggregated APCs. CMS believes that these newly combined APCs avoid further cost inversion issues (Level 1 geometric mean per diem cost greater than that of Level 2), and thus generate more appropriate payments for the services provided.

For 2018, CMS continues these policies and calculates the PHP APC per diem payment rates for hospital-based and CMHC PHP providers based on geometric mean per diem costs using the most recent claims and cost data for each provider type. CMS uses CMHC APC 5853 (Partial Hospitalization — Three or more Services per Day) and hospital-based PHP APC 5863 (Partial Hospitalization — Three or more Services per Day), as well as actual claims data from 2016 and the most recent cost data, for each provider type for PHP service days providing three or more services.

The table below compares the final CY 2017 and final CY 2018 PHP payment rates:

	Final Payment Rate 2017	**Final Payment Rate 2018**	**% Change**
APC 5853: Partial Hospitalization (3+ services) for CMHCs	$121.48	$143.30	+18.0%
APC 5863: Partial Hospitalization (3+ services) for Hospital-based PHPs	$207.27	$208.21	+0.5%

CMS will continue to make outlier payments to CMHCs at 50 percent of the amount by which the cost for the PHP service exceeds 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year.

PHP Service Utilization and 20-hour per Week Minimum
CMS previously expressed concern over the low frequency of individual therapy in PHP services, noting that its single-tier payment policy may result in PHP providers furnishing only three services per day while payment is heavily weighted to providing four or more services. As it did in the 2017 OPPS rulemaking cycle, CMS notes that the eligibility requirements under §410.43(a)(3) and (c)(1) state that PHP beneficiaries require a minimum of 20 hours per week in services as evidenced in the plan of care. CMS stated in several earlier regulations that a typical PHP includes five to six hours per day. CMS analyzed 2015 PHP claims data and determined that a majority of PHP patients did not receive at least 20 hours per week in partial hospitalization services, and just over half of PHP beneficiaries received 20 or more hours of services in 50 percent or more of non-transitional weeks.

In the proposed rule, CMS sought comment on the advisability of conditioning payment on the beneficiary's receipt of a minimum 20 hours of therapeutic services per week and on exceptions to that policy (i.e., circumstances that would cause a PHP patient to receive less than 20 hours of PHP services per week). CHA urged CMS to engage in a targeted probe and educate process for outlier providers rather than imposing a weekly billing or similar claim-processing requirement that would be administratively burdensome. CMS states it will consider all comments in future rulemaking or sub-regulatory guidance.

BENEFICIARY COINSURANCE
Medicare law provides that the minimum and maximum coinsurance rates for any service are 20 and 40 percent, respectively, of total OPPS payment to the hospital. The statute also limits a beneficiary's actual cost-sharing amount for a service to the inpatient hospital deductible for the applicable year, which is $1,316 in 2017. The inpatient hospital deductible limit is applied to the actual co-payment amount after adjusting for the wage index. For this reason, the co-insurance levels shown in the OPPS payment rate Addenda A and B to the proposed rule do not reflect application of the hospital deductible limit.

Although the last statutory reduction in the maximum coinsurance rate occurred in 2006, the methodology for calculating coinsurance rates ensures that beneficiary coinsurance amounts will continue to decrease gradually relative to the payment rates until all services have a coinsurance rate of 20 percent of the payment amount for the service.

For 2018, CMS determines the copayment amounts for new and revised APCs using the methodology first implemented in 2004. CMS refers readers to the November 7, 2003, OPPS final rule with comment period (68 FR 63458) for a full description of this methodology, which is summarized in the 2018 proposed rule. Also, for 2018, as in prior years, CMS reduces the beneficiary co-payment proportionately to the two percentage point conversion factor reduction when services are rendered in a hospital that does not report the required quality measures or that reported them unsatisfactorily.

The final rule estimates that, in aggregate, the percentage of beneficiary liability for OPPS payments in 2018 will be 18.5 percent, the same percentage estimated for 2017. As indicated above and demonstrated by Addendum A of the final rule, the transition to paying all services at a coinsurance rate of 20 percent appears to be at or near completion; coinsurance percentages are at, or round to, 20 percent for all but a small number of APCs.

HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM

CMS adopted changes to the Hospital OQR Program, including the removal of six measures and the indefinite delay of implementation of OAS CAHPS measures. In addition, CMS finalized changes to public display of one measure and to data submission and data validation requirements. A table at the end of this summary shows all adopted OQR Program measures for the 2016-21 payment determinations.

CMS makes no changes to existing policies on the retention and removal of OQR Program measures. As established under the CY 2013 OPPS final rule, once a measure is adopted for the Hospital OQR Program for a payment determination year, it is automatically adopted for subsequent years until CMS removes, suspends or replaces it. Previously, CMS adopted 25 mandatory measures, plus one voluntary measure, for the 2018 and 2019 payment determinations and 32 measures, plus one voluntary measure, for the 2020 payment determination.

Removal of Measures for 2020 and Subsequent Payment Determinations

CMS finalized the removal of six measures from the OQR Program, with a modification of the proposed rule's timing. All six measures will be removed beginning with payment year 2020; in the proposed rule CMS would have removed two measures in 2020 and four in 2021. CHA and other commenters encouraged CMS to remove the measures as soon as possible. CMS notes that, although while preparing the proposed rule it had believed it could not operationally remove all the measures at once, it has now concluded that this is feasible. CMS finalized removal, beginning with the 2020 payment determination, of:

- OP-21: Median Time to Pain Management for Long Bone Fracture
- OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures
- OP-1: Median Time to Fibrinolysis
- OP-4: Aspirin at Arrival
- OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional
- OP-25: Safe Surgery Checklist

CMS removes OP-21 due to what it describes as an abundance of caution over concerns with opioid prescribing practices. Specifically, CMS is concerned that the measure may unduly pressure hospital staff to prescribe more opioids. CMS removes OP-26 because it is not related to patient outcomes and believes the reporting burden outweighs the measure's value. CMS removes OP-1 because the measure OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival is more strongly associated with desired patient outcomes for the particular topic and the inclusion of OP-1 is redundant. CMS removes OP-4 and OP-25 because it has determined both measures meet the criteria as "topped out" for performance. OP-20 is removed in response to a technical expert panel review that found the measure is not linked to improved patient outcomes. CMS estimates that the removal of these six measures for the 2020 payment determination will reduce the aggregate reporting burden on hospitals by $16.7 million.

Delay of OAS CAHPS Measure

In the CY 2017 OPPS final rule, CMS adopted five OAS CAHPS-based measures for inclusion in the OQR Program beginning with the 2020 payment determination. However, CMS has since determined it lacks important operational and implementation data, and in this rule finalized its proposal to indefinitely delay implementation of the OAS CAHPS measures. CMS believes that the voluntary national implementation of the OAC CAHPS survey from January 2016 to December 2017 will provide CMS with valuable information to analyze and inform any necessary changes to the survey tool or CMS systems. In particular, CMS hopes to ensure that the survey measures appropriately account for patient response rates, both aggregate and by survey administration method; reaffirm the reliability of national OAS CAHPS survey data; and appropriately account for the burden associated with

administering the survey in the outpatient setting of care.

Possible Hospital OQR Program Measure Topics for Future Consideration
CMS is considering adding, in future rulemaking, an electronic version of OP-2: Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival as an electronic clinical quality measure (eCQM) in the Hospital OQR Program. CMS notes that because OP-2 is not yet developed as an eCQM, electronic measure specifications are not yet available; however, it believes this is the most feasible eCQM of all the existing Hospital OQR Program measures. Responding to comments opposing the use of eCQMs in the OQR Program until problems with eCQM reporting in the Inpatient Quality Reporting Program are resolved, CMS says that it will take lessons learned from that program into consideration.

Public Display of OP-18 Measure
CMS modified its proposal to publicly display measure OP-18: Median Time from Emergency Department Arrival to Emergency Department Departure for Discharged Emergency Department Patients. The measure data are stratified into four separate calculations: OP-18a is the overall rate; OP-18b is the reporting measure, which excludes psychiatric/mental health patients and transfer patients; OP-18c assesses psychiatric/mental health patients; and OP-18d assesses transfer patients.

CMS had proposed to publicly report OP-18c on *Hospital Compare* to address a behavioral health gap in the OQR Program measure set. However, in response to commenters who urged CMS to be cautious in reporting these data, CMS has modified its proposal. Rather than reporting the data on *Hospital Compare*, CMS will publish the data in downloadable forms on data.medicare.gov along with other OQR Program measure data. Affected parties will be notified of files' availability via CMS list serves, email, national provider calls and QualityNet announcements. Hospitals will be able to preview the data as part of the regular 30-day data preview process for OQR Program data.

In not going forward with public reporting of OP-18c on *Hospital Compare*, CMS is responding to comments expressing concern that public display of data on OP-18c could result in unintended consequences. In particular, CMS acknowledges concerns that the time to discharge for mental health patients may be influenced by the availability of community resources and that the measure could be perceived as pressuring providers to inappropriately limit care to quickly discharge these patients. CMS cites literature showing that the number of inpatient psychiatric beds declined from 400,000 in 1970 to 50,000 in 2006. CMS states that it will continue to work to find the best means to make the information from OP-18c more easily understandable to the public, and will consider other measures to help fill the behavioral health gap in the future.

Changes to the Notice of Participation Deadline
CMS does not finalize its proposal that hospitals must submit the Notice of Participation any time *prior to* registering on the QualityNet website. Because participants would have to login to QualityNet in order to submit the notice, the proposal was not logistically possible. CMS says it received no public comments on this issue. It will revisit the issue in future rulemaking with a goal of making it easier for hospitals to meet the OQR Program participation requirements.

Data Submission Requirements for Newly Participating Hospitals
CMS finalized its proposal that hospitals that did not participate in the previous year's OQR Program would be required to submit data beginning with encounters occurring during the first calendar quarter of the year prior to the affected payment year. This proposal would replace the previously adopted policy under which the deadline depends upon whether the hospital's Medicare acceptance date is before or after January 1 of the year prior to the payment year.

Data Validation Requirements
Under the previously adopted validation selection process, CMS will choose a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on two criteria: whether the hospital failed validation in the previous year, or whether the hospital has an outlier value for a measure, defined as greater than five standard deviations for the mean value for the measure. In this final rule, CMS clarified that the outlier value criterion refers specifically to hospitals with a poor score on a measure.

Specifically, beginning with validation of 2018 data for the 2020 payment determination, CMS formalized its current educational review process under which a hospital can request informal educational reviews for each quarter it receives validation results. The hospital has 30 days after posting of the validation results on the QualityNet secure portal to request review.

CMS finalized that during the educational review process, it will determine whether a quarterly validation score was correct using the same process adopted for reconsideration requests. Evaluation of the score will consist of reviewing data elements that were labeled as mismatched in the original validation results. CMS will consider written justifications provided by hospitals in the educational review request.

Beginning with the 2020 payment determination, if an educational review requested for any of the first three quarters of validation yields incorrect validation results for chart-abstracted measures, any quarterly score that is recalculated and corrected during the educational review process will be used to compute the hospital's final validation confidence interval at the end of the year. Notably, CMS will only use the educational review process to recalculate the validation confidence interval if the result would favor the hospital.

Extraordinary Circumstances Extensions or Exemptions
CMS finalized its proposal to align the OQR Program extraordinary circumstances extensions or exemptions processes with similar processes for its other quality reporting and value-based purchasing programs. Beginning January 1, 2018, the nomenclature will be changed to "extraordinary circumstances exceptions." CMS further notes that it strives to complete its review of each request within 90 days.

ADDITIONAL INFORMATION
As previously mentioned, CHA will host a member forum to review the payment and quality provisions of the OPPS and PFS final rules on December 8 at noon (PT). To participate in the call, register at www.surveymonkey.com/r/NPW35HP by noon on December 7.

CHA will also issue DataSuite reports detailing the estimated impact of the provisions outlined in the CY 2018 final rule. For additional information about the final rule summary, please contact Alyssa Keefe, CHA vice president, federal regulatory affairs, at (202) 488-4688 or akeefe@calhospital.org. For additional information on CHA DataSuite reports, please contact Ron Yaw, CHA vice president, finance & economic analysis, at (916) 552-7695 or ryaw@calhospital.org.

[i] The rule clearly states that CAHs and hospitals paid under the Maryland waiver DO NOT report modifier "JG" that triggers payment for separately payable drugs at ASP minus 22.5 percent. With respect to informational modifier "TB," the rule makes no statement as to whether it is required from CAHs and Maryland hospitals. It says "rural SCHs, children's hospitals and PPS-exempt cancer hospitals…will be required to report information modifier "TB" for 340B-acquired drugs, and will continue to be paid ASP + 6 percent."
[ii] Community Oncology Alliance. Report: "How Abuse of the 340B Program is Hurting Patients"

(September 2017). Available at: https://www.communityoncology.org/wpcontent/uploads/2017/09/COA_340B-PatientStories_FINAL.pdf.

[iii] Of note, CMS will pay for separately payable drugs at ASP plus 6 percent in physician offices and when hospitals do not acquire drugs under the 340B program. It will pay at ASP minus 22.5 percent at a hospital when separately payable drugs are acquired under the 340B program. As a result, beneficiary coinsurance will be less for separately payable drugs acquired under the 340B program in a hospital than in a hospital that does not acquire the drugs under the 340B program or a physician's office.

[iv] Dobson Davanzo & Associates, Update to a 2012 Analysis of 340B Disproportionate Share Hospital Services Delivered to Vulnerable Patient Populations Eligibility Criteria for 340B DSH Hospitals Continue to Appropriately Target Safety Net Hospitals (Nov. 15, 2016). Available at: http://www.340bhealth.org/files/Update_Report_FINAL_11.15.16.pdf.

[v] Dobson Davanzo & Associates, Analysis of the Proportion of 340B DSH Hospital Services Delivered to Low-Income Oncology Drug Recipients Compared to Non-340B Provider (2017). Available at: http://www.340bhealth.org/files/LowIncomeOncology.pdf.

[vi] Section 1871 of the Social Security Act (42 U.S.C. 1395hh). "No rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits under this subchapter shall take effect unless it is promulgated by the Secretary by regulation..."

Summary of Hospital Outpatient Quality Reporting Program Measures CY 2016-2021

OQR Measures for 2016-2021							
NQF	**CMS ID and Name**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**
0287+	OP-1: Median Time to Fibrinolysis (NQF 0287)	X	X	X	X	Removed	
0288	OP-2: Fibrinolytic Therapy Received Within 30 Minutes of ED arrival	X	X	X	X	X	X
0290	OP-3: Median Time to Transfer to Another Facility for Acute Coronary Intervention	X	X	X	X	X	X
0286+	OP-4: Aspirin at Arrival	X	X	X	X	Removed	
0289+	OP-5: Median Time to ECG	X	X	X	X	X	X
	OP-6: Timing of Antibiotic Prophylaxis	X	Removed				
	OP-7: Prophylactic Antibiotic Selection for Surgical Patients	X	Removed				
0514	OP-8: MRI Lumbar Spine for Low Back Pain	X	X	X	X	X	X
	OP-9: Mammography Follow-up Rates	X	X	X	X	X	X
	OP-10: Abdomen CT – Use of Contrast Material	X	X	X	X	X	X
0513	OP-11: Thorax CT – Use of Contrast Material	X	X	X	X	X	X
	OP-12: The Ability for Providers with HIT to Receive Laboratory Data Electronically Directly into their ONC Certified EHR System as Discrete Searchable Data	X	X	X	X	X	X
0669	OP-13: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low-Risk Surgery	X	X	X	X	X	X
	OP-14: Simultaneous Use of Brain Computed Tomography (CT) and Sinus Computed Tomography (CT)	X	X	X	X	X	X
0491+	OP-17: Tracking Clinical Results between Visits	X	X	X	X	X	X
0496	OP-18: Median Time from ED Arrival to ED Departure for Discharged ED Patients	X	X	X	X	X	X
	OP-20: Door to Diagnostic Evaluation by a Qualified Medical Professional	X	X	X	X	Removed	

0662	OP-21: ED- Median Time to Pain Management for Long Bone Fracture	X	X	X	X	Removed	
0499+	OP-22: ED- Left Without Being Seen	X	X	X	X	X	X
0661	OP-23: ED- Head CT Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT Scan Interpretation Within 45 minutes of Arrival	X	X	X	X	X	X
	OP-25: Safe Surgery Checklist Use	X	X	X	X	Removed	
	OP-26: Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures (see note below)	X	X	X	X	Removed	
0431	OP-27: Influenza Vaccination Coverage among Healthcare Personnel	X	X	X	X	X	X
0658	OP-29: Appropriate Follow- up Interval for Normal Colonoscopy in Average Risk Patients	X	X	X	X	X	X
0659	OP-30: Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use	X	X	X	X	X	X
1536	OP-31: Cataracts – Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Adopted, then excluded	Voluntary				
2539	Op-32: Facility Seven Day Risk Standardized Hospital Visit Rate After Outpatient Colonoscopy			X	X	X	X
1822	OP-33: External Beam Radiotherapy for Bone Metastases			X	X	X	X
	OP-35 Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy					X	X
2687	OP-36 Hospital Visits After Hospital Outpatient Surgery					X	X
	OP 37a OAS CAHPS – About Facilities and Staff					Delayed	
	OP-37b: OAS CAHPS – Communication About Procedure					Delayed	
	OP-37c: OAS CAHPS – Preparation for Discharge and Recovery					Delayed	
	OP-37d: OAS CAHPS – Overall Rating of Facility					Delayed	
	OP-37e: OAS CAHPS – Recommendation of Facility					Delayed	
+ NQF Endorsement Removed							

Medicare Outpatient Prospective Payment System
Final Rule Impact Analysis – Calendar Year 2018

-Version 1, November 2017-

Analysis Description

The calendar year (CY) 2018 Medicare Outpatient Prospective Payment System (OPPS) Final Rule Analysis is intended to show providers how Medicare outpatient fee-for-service (FFS) payments will change from CY 2017 to CY 2018 based on the policies implemented in the CY 2018 OPPS final rule. The analysis incorporates changes to outpatient payments mandated by Congress and implemented by the Centers for Medicare and Medicaid Services (CMS).

Final Rule Impact Analysis

The following changes are modeled in this analysis:

- Marketbasket Update: 2.7% marketbasket increase to the outpatient rate.
- ACA-Mandated Marketbasket Reductions: Combined 0.6 percentage point productivity reduction and 0.75 percentage point pre-determined reduction to the marketbasket authorized by the Affordable Care Act (ACA) of 2010.
- 340B Drug Payment Reduction BN Adjustment: 3.19% increase to the OPPS rate to maintain program budget neutrality (BN) with the implementation of CMS' payment adjustment for drugs purchased under the 340B program.
- Other BN Adjustments: Reflects the impact of adjustments to the rate based on changes to the wage index (-0.03%), cancer hospital payments (+0.08%), as well as pass-through spending and outlier payments (+0.20%) in order to maintain program budget neutrality.
- Wage Index: Updated wage index values based on the final FFY 2018 hospital wage indexes, including the impact of new wage data, reclassifications, rural and legislated floors, and other adjustments to the wage indexes.
- APC Factor/Updates: This impact represents the changes to the APC assignments and weights adopted for CY 2018. It is inclusive of CMS' policies regarding the creation of comprehensive APCs; the expansion of the categories of items/services that are packaged into APCs for payment as opposed to separately paid; the anticipated change in outlier payments; as well as the payment reduction for hospitals participating in the 340B Drug Pricing Program. This impact is derived by attributing all remaining payment changes to this category (after impact for wage index, marketbasket, etc.).

The impacts provided do not include the 2.0% sequestration reduction to all lines of Medicare payment authorized by Congress and currently in effect through FFY 2025 unless Congress intervenes. The impact of sequester applicable to OPPS-specific payment has been calculated separately and is provided at the bottom of the impact table.

In addition, this analysis models the estimated impact of two other CMS changes that are calculated separately from the values provided above:

- Estimated Impact of CMS' "340B Reduction" to Drugs and Biologicals Purchased Through HRSA's 340B Drug Pricing Program: Reflects the estimated impact on CY 2018 OPPS revenue of CMS' decision to reduce payment for nonpass-through separately payable drugs and biosimilar biological products purchased under the 340B Drug Pricing Program from Average Sales Price (ASP)+6% to ASP-22.5%.

  Impacts provided here are based on Medicare claims data from the CY 2016 Medicare 100% Standard Analytic File (SAF). Revenues exclude those received through sources outside the OPPS, and are used to determine a percentage impact of 340B, assuming that it impacts all drugs marked with Status Indicator K for those on the list of 340B covered entities. This percentage is then applied to the 2018 revenue estimate prior to the application of updated case mix values in order to determine the approximate impact of the 340B adjustment.

  Hospitals flagged as 340B covered entities are based on the list maintained by the Health Resources & Services Administration (HRSA) as of November 15, 2017.

- Potential Impact of Performing Total Knee Arthroplasty (TKA) Procedures in an Outpatient Setting Using CPT Code 27447: Represents the potential impact for 2018 of CMS' decision to remove CPT code 27447 (Total knee arthroplasty (TKA)) from the inpatient-only list. Estimates assume that all knee procedures described by CPT code 27447 will be performed in the outpatient setting, actual shifts will be based on clinical judgement.

  Estimated Diagnosis-Related Group (DRG) procedure volumes are from the CY 2016 SAF for Inpatient Services, cases without a reported length of stay are removed. Estimated base OPPS payments are calculated using hospital payment data provided by CMS in the CY 2018 OPPS final rule. Inpatient Prospective Payment System (IPPS) base DRG payments were estimated using hospital payment data from the FFY 2018 IPPS final rule correction notice.

  Case counts less than 11 are redacted due to CMS privacy rules.

Data Sources

Except where mentioned above, hospital characteristics, outpatient procedure volumes, and estimated 2017 and 2018 outpatient revenues are from the CMS CY 2018 OPPS final rule Impact File (CY 2016 outpatient claims data). OPPS conversion factors are from the CY 2017 final rule and the CY 2018 final rule. Wage indexes are based on the wage index tables from the federal fiscal year (FFY) 2017 Inpatient Prospective Payment Systems (IPPS) final rule correction notice (released October 2016) and the FFY 2018 IPPS final rule correction notice (released October 2017).

This analysis was developed to measure the impact of OPPS policy changes only. Hospitals' rural status, volume, and patient mix are held constant at the value published in the final OPPS CY 2018 Impact File.

Methods

The dollar impact of each component change has been calculated starting with estimated 2017 outpatient payments as provided by CMS in its CY 2018 OPPS final rule Impact File. Estimated 2017 outpatient payments include outliers and the rural Sole Community Hospital (SCH) add-on, where appropriate.

The CY 2017 to CY 2018 percent change, for each outpatient payment change component analyzed, is calculated and applied to estimated CY 2017 payments. Generally, the percentage impacts are applied sequentially in order to capture the compounded dollar impacts. For example, the percent change due to the marketbasket update is

applied to total CY 2017 payments. Then, the percent change in the ACA-mandated marketbasket reductions is applied to the dollar result of the first change. This method continues for the remaining changes, creating a compounded effect. The difference between the results after each layered component is the impact of that component.

For changes to the OPPS rate and wage index, CY 2017 payments and volumes provided by CMS are divided into two parts based on the revenue and volumes from the 2016 SAF in order to avoid applying marketbasket and wage index updates to payments not based on the OPPS conversion factor. The first part is made up of those services to which payment is based on the OPPS rate, and is then adjusted by the changes to that rate and the wage index. The second part is made up of portion of those services for which payment is made outside of the rate (e.g. drugs paid at ASP+6%), which is held constant until changes to case mix and outliers are calculated.

Based on the limitations of CMS' Impact File, an "APC Factor/Updates" adjustment factor is calculated and used to estimate the value of payment changes that cannot be broken out by individual component. This hospital-specific factor/impact is derived by dividing total payments by the wage index and SCH add-on-adjusted conversion factor. The result of the first calculation is divided by the Medicare service count provided in the OPPS CY 2018 final rule Impact File. This factor impact represents the impact of changes to the APC assignments and weights and the outlier threshold.

Note: Individual percentages and dollars shown in this analysis may not add to total due to compounding and rounding. Dollar amounts less than $50 and percentages less than 0.05% will appear as zeros due to rounding.

This analysis does not include payment estimates for services provided to Medicare Advantage patients or modifications in FFS payments as a result of provider participation in new payment models being tested under Medicare demonstration/pilot programs. Dollar impacts in this analysis may differ from those provided by other organizations/associations due to differences in source data and analytic methods.

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

CHA Joins Litigation Effort to Overturn Cuts to 340B Program

DECEMBER 13, 2017 | JACKIE GARMAN | ALYSSA KEEFE

CHA has joined 31 other state and regional hospital associations in filing the attached *amicus* (friend of the court) brief in a lawsuit challenging the Centers for Medicare & Medicaid Services' proposed cuts to the Medicare 340B Drug Pricing Program.

In *American Hospital Association v. Hargan*, filed on Nov. 13, the American Hospital Association and various other hospital associations, hospitals and health systems seek to invalidate the finalized regulation that would cut payments to many hospitals in the 340B program by nearly 30 percent. According to the amicus brief filed by CHA and the other hospital associations last Friday, "If the new rule is allowed to stand, safety-net providers will be forced to eliminate or dramatically curtail crucial programs that treat a wide range of medical conditions – from cancer to mental health disorders to diabetes to opioid addiction to HIV/AIDS … Given their unique position, *amici* respectfully submit this brief to inform the Court about what will happen if CMS is permitted to take a scalpel — or really, an old-fashioned amputation saw — to the 340B Program."

Plaintiffs seek a preliminary injunction to prevent the regulation from going into effect on Jan. 1, as scheduled; the defendant has responded with a motion to dismiss the lawsuit. Both motions are scheduled to be heard by the court on Dec. 21.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Legislation

SUMMARY

There have been numerous pharmacy bills this year and CHA has been working closely with all stakeholders to align bill positions with member needs. Of particular interest are SB 1254 and SB 1447. SB 1254 is the bill that would require a pharmacist (pharm tech or intern) to obtain an accurate medication profile or list for each high-risk patient (as defined by the organization) upon admission of the patient upon specified circumstances. SB 1447 is a bill that licenses and implements specific requirements for automated drug delivery systems.

ACTION REQESTED

- Discussion related to specific issues regarding these and other bills.

Attachments: SB 1254
SB 1447
Pharmacy bill list

BJB:br

AMENDED IN ASSEMBLY JUNE 28, 2018

AMENDED IN ASSEMBLY JUNE 21, 2018

AMENDED IN ASSEMBLY JUNE 12, 2018

AMENDED IN SENATE MAY 1, 2018

AMENDED IN SENATE APRIL 18, 2018

AMENDED IN SENATE APRIL 2, 2018

SENATE BILL No. 1254

Introduced by Senator Stone

February 15, 2018

An act to add Section 4118.5 to the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1254, as amended, Stone. Hospital pharmacies: medication profiles or lists for high-risk patients.

Existing law, the Pharmacy Law, a willful violation of which is a misdemeanor, provides for the licensure and regulation of pharmacists, intern pharmacists, pharmacy technicians, and pharmacies by the California State Board of Pharmacy. Existing regulatory law requires a pharmacy to maintain medication profiles on all patients who have prescriptions filled at that pharmacy, except under specified circumstances.

This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission of the patient under specified circumstances. The bill would authorize an intern pharmacist or a pharmacy technician to perform the

task of obtaining an accurate medication profile or list for a high-risk patient if certain conditions are satisfied. The bill would require the hospital to establish criteria regarding who is a high-risk patient for purposes of the bill's provisions, and determine a timeframe for completion of the medication profile or list, based on the populations served by the hospital. The bill would exclude the State Department of State Hospitals from the bill's provisions.

By placing new requirements on a pharmacist, this bill would expand the scope of an existing crime and would, therefore, 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 4118.5 is added to the Business and Professions Code, to read:

4118.5. (a) A pharmacist at a hospital pharmacy shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patient under the following conditions:

(1) The hospital has more than 100 beds.

(2) The accurate medication profile or list may be acquired by the pharmacist during the hospital pharmacy's hours of operation.

(b) Notwithstanding any other law, a pharmacy technician or an intern pharmacist may perform the task of obtaining an accurate medication profile or list for a high-risk patient if both of the following conditions are satisfied:

(1) The hospital pharmacy has a quality assurance program to monitor competency.

(2) The hospital has established policies and procedures for training and proctoring pharmacy technicians or intern pharmacists by the hospital pharmacy department and the pharmacy technician or intern pharmacist has completed that training and proctoring.

(c) The hospital shall establish criteria regarding who is a high-risk patient for purposes of this section, and shall determine the timeframe for completion of the medication profile or list, based on the patient populations served by the hospital.

(d) The board may adopt rules and regulations to carry out the purposes and objectives of this section.

(e) This section shall not apply to the State Department of State Hospitals.

(f) Nothing in this section shall be construed to prohibit a healing arts licensee licensed pursuant to this division from obtaining an accurate medication profile or list.

SEC. 2. 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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AMENDED IN ASSEMBLY JULY 3, 2018

AMENDED IN ASSEMBLY JUNE 20, 2018

AMENDED IN SENATE APRIL 17, 2018

SENATE BILL No. 1447

Introduced by Senator Hernandez

February 16, 2018

An act to amend Section 4400 of, to amend and repeal Sections 4105.5 and 4119.1 of, to amend, repeal, and add Sections 4008 and 4186 of, to add Section 4017.3 to, and to add Article 25 (commencing with Section 4427) to Chapter 9 of Division 2 of, the Business and Professions Code, and to amend, repeal, and add Section 1261.6 of the Health and Safety Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 1447, as amended, Hernandez. Pharmacy: automated drug delivery systems.

Existing law, the Pharmacy Law, establishes the California State Board of Pharmacy, within the Department of Consumer Affairs, to license and regulate the practice of pharmacy. Existing law makes any violation of the Pharmacy Law punishable as a crime.

Existing law generally requires a pharmacy that owns or provides dangerous drugs or devices dispensed through an automated drug delivery system (ADDS) to register the system, as provided, and authorizes the pharmacy to use the ADDS only if certain conditions are satisfied. Existing law authorizes the board to prohibit a pharmacy from using an ADDS if the board determines that those conditions are not satisfied. Existing law exempts from these requirements an ADDS operated by a licensed hospital pharmacy for doses administered in a

facility operated under a consolidated license. Existing law specifies additional conditions for an ADDS located in a licensed clinic or a health facility, as defined. Existing law authorizes a pharmacy or licensed wholesaler that is also an emergency medical services provider agency to restock dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system that is licensed by the board, as provided. Existing law authorizes an inspector employed by the board to enter specified locations to inspect those locations for compliance with the Pharmacy Law.

This bill, beginning on ~~July 1, 2019,~~ *January 1, 2020,* would repeal the general ADDS provisions and the additional conditions for an ADDS located in a health facility. The bill instead would require an ADDS, as defined, to meet specified requirements in order to be installed, leased, owned, or operated in the state, including a license for the ADDS issued by the board to the holder of a current, valid, and active pharmacy license. The bill would limit the placement and operation of an ADDS to specified locations, including the licensed pharmacy holding that ADDS license, a licensed health facility, a licensed clinic, or a specified medical office if the ADDS is an automated patient dispensing ~~system,~~ *system (APDS),* as defined. The bill would require the pharmacy holding the ADDS license to own *or lease* the ADDS and the drugs and devices located within it, *as provided,* and would require that pharmacy to supervise the operation of the ADDS. The bill would prescribe specified stocking and transfer requirements for those drugs and devices. The bill would require the pharmacy holding the ADDS license to provide training on the operation and use of that ADDS to specified individuals and would require the pharmacy to complete periodic self-assessments. The bill would require additional conditions for ~~automated patient dispensing systems, as defined.~~ *APDS.* The bill would also authorize a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS to inspect the ADDS or the location pursuant to these provisions. ~~The bill would repeal these provisions on January 1, 2021.~~ *This bill would require on or before January 1, 2024, the board to report to the appropriate policy committees of the Legislature on the regulation of ADDS units, as provided.* Because a violation of the Pharmacy Law is punishable as a crime, the bill would expand the scope of an existing crime, thereby imposing 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.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 4008 of the Business and Professions Code is amended to read:

4008. (a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate,

the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119 or 4119.1.

(g) This section shall remain in effect only until ~~July 1, 2019,~~ *January 1, 2020,* and as of that date is repealed.

SEC. 2. Section 4008 is added to the Business and Professions Code, to read:

4008. (a) Except as provided by Section 159.5, the board may employ legal counsel and inspectors of pharmacy. The inspectors, whether the inspectors are employed by the board or the department's Division of Investigation, may inspect during business hours all pharmacies, wholesalers, dispensaries, stores, or places where drugs or devices are compounded, prepared, furnished, dispensed, or stored.

(b) Notwithstanding subdivision (a), a pharmacy inspector may inspect or examine a physician's office or clinic that does not have a permit under Section 4180 or 4190 only to the extent necessary to determine compliance with and to enforce either Section 4080 or 4081.

(c) (1) (A) A pharmacy inspector employed by the board or in the department's Division of Investigation shall have the authority, as a public officer, to arrest, without warrant, any person whenever

the officer has reasonable cause to believe that the person to be arrested has, in his or her presence, violated a provision of this chapter or of Division 10 (commencing with Section 11000) of the Health and Safety Code.

(B) If the violation is a felony, or if the arresting officer has reasonable cause to believe that the person to be arrested has violated any provision that is declared to be a felony, although no felony has in fact been committed, he or she may make an arrest although the violation or suspected violation did not occur in his or her presence.

(2) In any case in which an arrest authorized by this subdivision is made for an offense declared to be a misdemeanor, and the person arrested does not demand to be taken before a magistrate, the arresting inspector may, instead of taking the person before a magistrate, follow the procedure prescribed by Chapter 5C (commencing with Section 853.5) of Title 3 of Part 2 of the Penal Code. That chapter shall thereafter apply with reference to any proceeding based upon the issuance of a citation pursuant to this authority.

(d) There shall be no civil liability on the part of, and no cause of action shall arise against, a person, acting pursuant to subdivision (a) within the scope of his or her authority, for false arrest or false imprisonment arising out of an arrest that is lawful, or that the arresting officer, at the time of the arrest, had reasonable cause to believe was lawful. An inspector shall not be deemed an aggressor or lose his or her right to self-defense by the use of reasonable force to effect the arrest, to prevent escape, or to overcome resistance.

(e) Any inspector may serve all processes and notices throughout the state.

(f) A pharmacy inspector employed by the board may enter a facility licensed pursuant to subdivision (c) or (d) of Section 1250 of the Health and Safety Code to inspect an automated drug delivery system operated pursuant to Section 4119.

(g) A pharmacy inspector employed by the board may enter the location, or proposed location, of an automated drug delivery system to inspect that automated drug delivery system or proposed location pursuant to Article 25 (commencing with Section 4427).

(h) This section shall become operative on ~~July 1, 2019.~~ *January 1, 2020.*

SEC. 3. Section 4017.3 is added to the Business and Professions Code, to read:

4017.3. (a) "Automated Drug Delivery System" (ADDS) means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An ADDS shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(b) An "Automated Unit Dose System" (AUDS) is an ADDS for storage and retrieval of unit doses of drugs for administration to patients by persons authorized to perform these functions.

(c) An "Automated Patient Dispensing System" (APDS) is an ADDS for storage and dispensing of prescribed drugs directly to patients pursuant to prior authorization by a pharmacist.

(d) This section shall become operative on ~~July 1, 2019.~~ *January 1, 2020.*

SEC. 4. Section 4105.5 of the Business and Professions Code is amended to read:

4105.5. (a) For purposes of this section, an "automated drug delivery system" has the same meaning as that term is defined in paragraph (1) of subdivision (a) of Section 1261.6 of the Health and Safety Code.

(b) Except as provided by subdivision (e), a pharmacy that owns or provides dangerous drugs dispensed through an automated drug delivery system shall register the automated drug delivery system by providing the board in writing with the location of each device within 30 days of installation of the device, and on an annual basis as part of the license renewal pursuant to subdivision (a) of Section 4110. The pharmacy shall also advise the board in writing within 30 days if the pharmacy discontinues operating an automated drug delivery system.

(c) A pharmacy may only use an automated drug delivery system if all of the following conditions are satisfied:

(1) Use of the automated drug delivery system is consistent with legal requirements.

(2) The pharmacy's policies and procedures related to the automated drug delivery system to include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(3) The pharmacy reports drug losses from the automated drug delivery system to the board as required by law.

(4) The pharmacy license is unexpired and not subject to disciplinary conditions.

(d) The board may prohibit a pharmacy from using an automated drug delivery system if the board determines that the conditions provided in subdivision (c) are not satisfied. If such a determination is made, the board shall provide the pharmacy with written notice including the basis for the determination. The pharmacy may request an office conference to appeal the board's decision within 30 days of receipt of the written notice. The executive officer or designee may affirm or overturn the prohibition as a result of the office conference.

(e) An automated drug delivery system operated by a licensed hospital pharmacy as defined in Section 4029 for doses administered in a facility operated under a consolidated license under Section 1250.8 of the Health and Safety Code shall be exempt from the requirements of subdivision (b).

(f) This section shall remain in effect only until ~~July 1, 2019,~~ *January 1, 2020,* and as of that date is repealed.

SEC. 5. Section 4119.1 of the Business and Professions Code is amended to read:

4119.1. (a) A pharmacy may provide pharmacy services to a health facility licensed pursuant to subdivision (c), (d), or both, of Section 1250 of the Health and Safety Code, through the use of an automated drug delivery system that need not be located at the same location as the pharmacy.

(b) Drugs stored in an automated drug delivery system shall be part of the inventory of the pharmacy providing pharmacy services to that facility, and drugs dispensed from the pharmacy system shall be considered to have been dispensed by that pharmacy.

(c) (1) The pharmacy shall maintain records of the acquisition and disposition of dangerous drugs and dangerous devices stored in the automated drug delivery system separate from other pharmacy records.

(2) The pharmacy shall own and operate the automated drug delivery system.

(3) The pharmacy shall provide training regarding the operation and use of the automated drug delivery system to both pharmacy and health facility personnel using the system.

(4) The pharmacy shall operate the automated drug delivery system in compliance with Section 1261.6 of the Health and Safety Code.

(d) The operation of the automated drug delivery system shall be under the supervision of a licensed pharmacist. To qualify as a supervisor for an automated drug delivery system, the pharmacist need not be physically present at the site of the automated drug delivery system and may supervise the system electronically.

(e) This section shall not be construed to revise or limit the use of automated drug delivery systems as permitted by the board in any licensed health facility other than a facility defined in subdivision (c) or (d), or both, of Section 1250 of the Health and Safety Code.

(f) This section shall remain in effect only until ~~July 1, 2019,~~ *January 1, 2020,* and as of that date is repealed.

SEC. 6. Section 4186 of the Business and Professions Code is amended to read:

4186. (a) Automated drug delivery systems, as defined in subdivision (h), may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an

inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way audio and video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) For purposes of this section, an "automated drug delivery system" means a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(i) This section shall remain in effect only until ~~July 1, 2019,~~ *January 1, 2020,* and as of that date is repealed.

SEC. 7. Section 4186 is added to the Business and Professions Code, to read:

4186. (a) Automated drug delivery systems, as defined in Section 4017.3, may be located in any clinic licensed by the board pursuant to Section 4180. If an automated drug delivery system is located in a clinic, the clinic shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. All policies and procedures shall be maintained at the location where the automated drug system is being used.

(b) Drugs shall be removed from the automated drug delivery system only upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. Drugs removed from the automated drug delivery system shall be provided to the patient by a health professional licensed pursuant to this division.

(c) The stocking of an automated drug delivery system shall be performed by a pharmacist.

(d) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be the responsibility of the clinic. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(e) The automated drug delivery system used at the clinic shall provide for patient consultation pursuant to Section 1707.2 of Title 16 of the California Code of Regulations with a pharmacist via a telecommunications link that has two-way ~~audio and~~ *audio, and where possible* video.

(f) The pharmacist operating the automated drug delivery system shall be located in California.

(g) Drugs dispensed from the automated drug delivery system shall comply with the labeling requirements in Section 4076.

(h) This section shall become operative on ~~July 1, 2019.~~ *January 1, 2020.*

SEC. 8. Section 4400 of the Business and Professions Code is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115).

If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be

two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270)

and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the

amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) Beginning on and after ~~July 1, 2019,~~ *January 1, 2020,* the fee for an automated drug delivery system license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250). The annual renewal of the license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

SEC. 9. Article 25 (commencing with Section 4427) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 25. Automated Drug Delivery System

4427. An ADDS shall not be installed or operated in the State of California unless it meets the requirements of this article.

4427.1. (a) An ADDS installed, leased, owned, or operated in the State of California shall be licensed by the board.

(b) An ADDS license shall only be issued to the holder of a current, valid, and active pharmacy license.

(c) A separate application and license shall be required for each ADDS.

(d) An ADDS license shall only be issued when the following conditions are met:

(1) Use of the ADDS is consistent with legal requirements.

(2) The proposed location for installation of the ADDS meets the requirements of Section 4427.2 and the ADDS is secure from access and removal by unauthorized individuals.

(3) The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

(4) The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

(e) Prior to issuance of the license, the board shall conduct a prelicensure ~~inspection~~ *inspection, within 30 days of a completed application for an ADDS license,* at the proposed location of the ADDS. Relocation or replacement of the ADDS shall require a new application for licensure.

(f) The ADDS license shall be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license may be submitted to the board.

(g) The holder of an ADDS license shall advise the board in writing within 30 days if use of the ADDS is discontinued.

(h) The ADDS license shall be renewed annually, and the renewal date shall be the same as the underlying pharmacy license.

(i) An AUDS operated by a licensed hospital pharmacy, as defined in Section 4029, and used solely to provide doses administered to patients while in a facility operated under a license pursuant to Section 1250.8 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license pursuant to this section. The licensed hospital pharmacy shall maintain a list of the location of each ADDS it operates and shall make the list available to the board upon request.

(j) An ADDS license is not required for technology, installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and devices.

4427.2. (a) An ADDS shall be placed and operated inside an enclosed building, with a premises address, at a location approved by the board.

(b) An ADDS shall be placed and operated in one of the following locations:

(1) Adjacent to the secured pharmacy area of the pharmacy holding the ADDS license.

(2) A health facility licensed pursuant to Section 1250 of the Health and Safety Code that complies with Section 1261.6 of the Health and Safety Code.

(3) A clinic licensed pursuant to Section 1204 or 1204.1 of the Health and Safety Code, or Section 4180 or 4190 of this code.

(4) If the ADDS is an APDS, in a location as provided in subdivision (j) of Section 4427.5.

(c) Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) shall jointly develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. These policies and procedures shall be maintained at the location of the ADDS and at the pharmacy holding the ADDS license.

4427.3. (a) The ~~ADDS, and drugs and devices located within the ADDS,~~ *ADDS* shall be owned *or leased* by the pharmacy holding the license for the ADDS.

(b) Each ADDS shall only be operated under the supervision of the pharmacy holding the ADDS license.

(c) An ADDS shall be considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and shall be subject to inspection pursuant to Section 4008.

(d) Drugs and devices stored in an ADDS shall be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and drugs and devices dispensed from the ADDS shall be considered to have been dispensed by that pharmacy.

(e) The stocking and restocking of an ADDS shall be performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility licensed pursuant to Section 1250 of the Health and Safety Code, where the stocking and restocking of the ADDS may be performed in compliance with Section 1261.6 of the Health and Safety Code.

(f) If drugs or devices are not immediately transferred into an ADDS upon arrival at the ADDS location, the drugs and devices shall be stored for no longer than 48 hours in a secured room. Upon retrieval of these drugs and devices from secured storage, an inventory shall be taken to detect any losses or overages.

4427.4. Prior to installation, and annually thereafter, the pharmacy holding the ADDS license shall provide training on the operation and use of the ADDS to pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to subdivision (b) of Section 4427.2.

4427.5. In addition to any other requirements imposed by this article, an APDS shall additionally meet the following requirements:

(a) The pharmacy shall develop and implement, and review annually, written policies and procedures pertaining to the APDS, including all of the following:

(1) Maintaining the security of the APDS and the dangerous drugs and devices within that APDS.

(2) Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS.

(4) Describing assignment of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of Section 4427.2, regarding maintenance and filing procedures for the APDS.

(5) Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring that patient use of the APDS does not interfere with delivery of drugs and devices.

(6) Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

(b) The APDS shall only be used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established pursuant to subdivision (a).

(c) The APDS shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent.

(d) A pharmacist licensed by the board shall perform all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation.

(e) Drugs shall be dispensed from the APDS only upon authorization by a licensed pharmacist after the pharmacist has

reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions.

(f) All prescribed drugs and devices dispensed from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via a telecommunications link that has two-way ~~audio and~~ *audio, and where possible* video.

(g) The APDS shall include a notice, prominently posted on the APDS, providing the name, address, and phone number of the pharmacy that holds the ADDS license for that APDS.

(h) The labels on all medications dispensed by the APDS shall comply with Section 4076 and with Section 1707.5 of Title 16 of the California Code of Regulations.

(i) Any incident involving the APDS where a complaint, error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program pursuant to Section 4125.

(j) An APDS may be located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, and where drugs and devices are routinely dispensed in compliance with Section 4170, except that paragraph (5) of subdivision (a) of Section 4170, requiring prescriber ownership of any dispensing device and its contents, shall not apply to that office or location if the APDS is operated by the pharmacy holding the APDS license.

(k) The board shall not issue a pharmacy more than ~~eight~~ *10* ADDS licenses for APDS units. Consistent with Section 4001.1, the board, by regulation, may reduce the number of ADDS licenses a pharmacy may be issued for APDS units.

(*l*) The pharmacy holding the ADDS license for an APDS shall maintain the policies and procedures developed pursuant to subdivision (a) for three years after the last date of use of that APDS.

4427.6. (a) A pharmacy holding an ADDS license shall complete an annual self-assessment, performed pursuant to Section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in the self-assessment.

(b) The pharmacy shall comply with all recordkeeping and quality assurance requirements established in pharmacy law and

regulation, and shall maintain those records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records.

4427.7. (a) This article shall become operative on ~~July 1, 2019.~~ *January 1, 2020.*

~~(b) This article shall remain in effect only until January 1, 2021, and as of that date is repealed.~~

(b) On or before January 1, 2024, as part of the board's sunset evaluation process, and notwithstanding Sections 9795 and 10231.5 of the Government Code, the board shall report to the appropriate committees of the Legislature on the regulation of ADDS units as provided in this article. At a minimum, this report shall require all of the following:

(1) The use and dispersion of ADDS throughout the health care system.

(2) The number of ADDS inspections conducted by the board each year and the findings from the inspections.

(3) Public safety concerns relating to the use of ADDS as identified by the board.

SEC. 10. Section 1261.6 of the Health and Safety Code is amended to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Section 4119.1 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for

administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section,

the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall remain in effect only until ~~July 1, 2019,~~ *January 1, 2020,* and as of that date is repealed.

SEC. 11. Section 1261.6 is added to the Health and Safety Code, to read:

1261.6. (a) (1) For purposes of this section and Section 1261.5, an "automated drug delivery system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of drugs. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability.

(2) For purposes of this section, "facility" means a health facility licensed pursuant to subdivision (c), (d), or (k), of Section 1250 that has an automated drug delivery system provided by a pharmacy.

(3) For purposes of this section, "pharmacy services" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician.

(b) Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law. These records shall be maintained in the facility for a minimum of three years.

(c) Individualized and specific access to automated drug delivery systems shall be limited to facility and contract personnel authorized by law to administer drugs.

(d) (1) The facility and the pharmacy shall develop and implement written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. Policies and procedures shall define access to the automated drug delivery system and limits to access to equipment and drugs.

(2) All policies and procedures shall be maintained at the pharmacy operating the automated drug delivery system and the location where the automated drug delivery system is being used.

(e) When used as an emergency pharmaceutical supplies container, drugs removed from the automated drug delivery system shall be limited to the following:

(1) A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from

the pharmacy, or 72 hours, whichever is less. The drugs shall be retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(2) Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist.

(3) Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from an automated drug delivery system pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility. Within 48 hours after retrieval under this paragraph, the case shall be reviewed by a pharmacist.

(f) When used to provide pharmacy services pursuant to Sections 4017.3 and 4427 of the Business and Professions Code, the automated drug delivery system shall be subject to all of the following requirements:

(1) Drugs removed from the automated drug delivery system for administration to a patient shall be in properly labeled units of administration containers or packages.

(2) A pharmacist shall review and approve all orders prior to a drug being removed from the automated drug delivery system for administration to a patient. The pharmacist shall review the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions.

(3) The pharmacy providing services to the facility pursuant to Section 4119.1 of the Business and Professions Code shall control access to the drugs stored in the automated drug delivery system.

(4) Access to the automated drug delivery system shall be controlled and tracked using an identification or password system or biosensor.

(5) The automated drug delivery system shall make a complete and accurate record of all transactions that will include all users accessing the system and all drugs added to, or removed from, the system.

(6) After the pharmacist reviews the prescriber's order, access by licensed personnel to the automated drug delivery system shall be limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the

prescriber's order requires a dosage variation of the same drug, licensed personnel shall have access to the drug ordered for that scheduled time of administration.

(7) (A) Systems that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed under this subdivision if those systems have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient. Each facility using such an automated drug system shall notify the department in writing prior to the utilization of the system. The notification submitted to the department pursuant to this paragraph shall include, but is not limited to, information regarding system design, personnel with system access, and policies and procedures covering staff training, storage, and security, and the facility's administration of these types of systems.

(B) As part of its routine oversight of these facilities, the department shall review a facility's medication training, storage, and security, and its administration procedures related to its use of an automated drug delivery system to ensure that adequate staff training and safeguards are in place to make sure that the drugs delivered are appropriate for the patient. If the department determines that a facility is not in compliance with this section, the department may revoke its authorization to use automated drug delivery systems granted under subparagraph (A).

(g) The stocking of an automated drug delivery system shall be performed by a pharmacist. If the automated drug delivery system utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility if all of the following conditions are met:

(1) The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.

(2) The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.

(3) The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable

pockets, cards, drawers, or unit of use or single dose containers are properly placed into the automated drug delivery system.

(h) Review of the drugs contained within, and the operation and maintenance of, the automated drug delivery system shall be done in accordance with law and shall be the responsibility of the pharmacy. The review shall be conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system.

(i) Drugs dispensed from an automated drug delivery system that meets the requirements of this section shall not be subject to the labeling requirements of Section 4076 of the Business and Professions Code or Section 111480 of this code if the drugs to be placed into the automated drug delivery system are in unit dose packaging or unit of use and if the information required by Section 4076 of the Business and Professions Code and Section 111480 of this code is readily available at the time of drug administration. For purposes of this section, unit dose packaging includes blister pack cards.

(j) This section shall become operative on ~~July 1, 2019.~~ *January 1, 2020.*

SEC. 12. 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.

O

CA AB 315

AUTHOR: Wood [D]
TITLE: Pharmacy Benefit Management
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/06/2017
LAST AMEND: 07/11/2017
DISPOSITION: Pending
FILE: A-35
LOCATION: Senate Inactive File
SUMMARY:

Requires pharmacy benefit managers to be registered with the Department of Managed Health Care. Requires the department to develop applications for the registration, and specifies certain information to be provided in those applications. Requires a pharmacy benefit manager to exercise a duty of good faith and fair dealing in the performance of its contractual duties to a purchaser. Requires a pharmacy benefit manager to notify a pharmacy network provider of certain contract changes.

STATUS:

09/07/2017 In SENATE. From third reading. To Inactive File.
INDEX: 39, 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 587

AUTHOR: Chiu [D]
TITLE: State Government: Pharmaceuticals: Procurement
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/14/2017
LAST AMEND: 07/12/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

Requires the Department of General Services to convene the state Pharmaceutical Collaborative to address the rising cost of pharmaceuticals, coordinate best value clinical treatment protocols, leverage governmental efficiencies to achieve best value procurement, and negotiate with manufacturers for discounts on pharmaceuticals. Requires the participation of various agencies in the collaborative.

STATUS:

08/21/2017 In SENATE Committee on APPROPRIATIONS: Not heard.
INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 1751

AUTHOR: Low [D]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 01/03/2018
LAST AMEND: 07/05/2018
DISPOSITION: Pending
FILE: 13
LOCATION: Senate Second Reading File
SUMMARY:

Authorizes the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for the purposes of participating in

interjurisdictional information sharing between prescription drug monitoring programs across state lines. Requires any agreement entered into by the department for those purposes to ensure that all access to data within the Controlled Substance Utilization Review and Evaluation System (CURES) complies with California law.

STATUS:

07/05/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA AB 1752

AUTHOR:	Low [D]
TITLE:	Controlled Substances: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/03/2018
LAST AMEND:	06/20/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/06/2018 10:00 am

SUMMARY:

Adds Schedule V controlled substances to the Controlled Substances Utilization Review and Evaluation System, or CURES database. Requires a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than a working day after a controlled substance is dispensed.

STATUS:

06/26/2018	From SENATE Committee on PUBLIC SAFETY: Do pass to Committee on APPROPRIATIONS. (6-1)
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1753

AUTHOR:	Low [D]
TITLE:	Controlled Substances: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/03/2018
LAST AMEND:	04/18/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/06/2018 10:00 am

SUMMARY:

Authorizes the Department of Justice to reduce or limit the number of security printers approved by the department to 3. Requires the prescription forms for controlled substance prescriptions to have a uniquely serialized number, in a manner prescribed by the department, and requires a printer to submit specified information to the department for all prescription forms delivered.

STATUS:

06/26/2018	From SENATE Committee on PUBLIC SAFETY: Do pass to Committee on APPROPRIATIONS. (7-0)
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1998

AUTHOR: Rodriguez [D]
TITLE: Opioids: Safe Prescribing Policy
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/01/2018
LAST AMEND: 07/02/2018
DISPOSITION: Pending
COMMITTEE: Senate Appropriations Committee
HEARING: 08/06/2018 10:00 am
SUMMARY:

Requires every health care practitioner, with the exception of veterinarians, who prescribes, administers, or furnishes opioids classified as Schedule II and Schedule III to adopt, review, and periodically update a safe opioid prescribing policy. Prohibits the safe opioid prescribing policy from placing a limitation on the prescription, ordering, administration, or furnishing of opioids to patients with prescribed conditions.

STATUS:

07/02/2018 In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.

INDEX: 73, 89
ISSUES: BJ, DP*
LOBBYIST: AH
POSITION: PR, X

CA AB 2037

AUTHOR: Bonta [D]
TITLE: Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/06/2018
LAST AMEND: 05/25/2018
DISPOSITION: Pending
COMMITTEE: Senate Appropriations Committee
HEARING: 08/06/2018 10:00 am
SUMMARY:

Amends the Pharmacy Law relating to automated drug delivery systems. Provides that a pharmacy is responsible for obtaining a license from the Board to operate an automated drug delivery system at a covered entity, to pay an application and renewal fee, and develop and implement written policies and procedures to ensure certain criteria for stored drugs.

STATUS:

06/25/2018 From SENATE Committee on BUSINESS, PROFESSIONS AND ECON. DEVELOPMENT: Do pass to Committee on APPROPRIATIONS. (9-0)

INDEX: 89
ISSUES: AO, BJ*, DP
LOBBYIST: AH*, BG
POSITION: F, X

CA AB 2086

AUTHOR: Gallagher [R]
TITLE: Controlled Substances: CURES Database
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/07/2018
LAST AMEND: 04/03/2018
DISPOSITION: Pending
FILE: 284
LOCATION: Senate Consent Calendar - First Legislative Day
SUMMARY:

Allows prescribers to access the Controlled Substance Utilization Review and

Evaluation System, or CURES, for a list of patients for whom that prescriber is listed in the database.

STATUS:

07/03/2018	In SENATE. Read second time. To Consent Calendar.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	S, X

CA AB 2384

AUTHOR:	Arambula [D]
TITLE:	Medication Assisted Treatment
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/14/2018
LAST AMEND:	07/03/2018
DISPOSITION:	Pending
LOCATION:	Senate Appropriations Committee

SUMMARY:

Requires a health insurer or a health care service plan, including a Medical managed care plan, to cover, at a minimum, one version of each medication-assisted treatment and overdose reversal approved prescription drug for opioid use disorder. Provides that one version of each medication-assisted treatment, as identified by a health care service plan or health insurer, is not subject to specified requirements of a health care service plan or policy of health insurance, including prior authorization.

STATUS:

07/03/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	65, 89
ISSUES:	AM, BJ, DG*, SL
LOBBYIST:	AH*, BG
POSITION:	F

CA AB 2576

AUTHOR:	Aguiar-Curry [D]
TITLE:	Emergencies: Health Care
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
LAST AMEND:	06/27/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/06/2018 10:00 am

SUMMARY:

Authorizes the Governor, during a state of emergency, to direct all state agencies to utilize, employ, and direct state personnel, equipment, and facilities for the performance of any and all activities that are designed to allow community clinics and health centers to provide and receive reimbursement for services provided during or immediately following the emergency. Authorizes any agency directed by the Governor to perform those activities to expend any of the moneys that have been appropriated to it.

STATUS:

06/27/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	31, 89
ISSUES:	AK, BJ, CLH*, DG, RY, SL
LOBBYIST:	AH, KAS*
POSITION:	F

CA AB 2624

AUTHOR:	Brough [R]

TITLE: Prescriptions
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
DISPOSITION: Pending
LOCATION: ASSEMBLY
SUMMARY:

Makes a nonsubstantive change to the Pharmacy Law, which authorizes a pharmacist filling a prescription order for a drug product prescribed by its brand or trade name to select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form.

STATUS:

02/15/2018 INTRODUCED.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA AB 2741

AUTHOR: Burke [D]
TITLE: Prescription Drugs: Opioid Medications: Minors
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 06/13/2018
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Prohibits a prescriber, as defined, from prescribing more than a certain supply of opioid medication to a minor unless the prescription is for specified uses, with certain exceptions. Requires a prescriber to take certain steps before prescribing a minor a course of treatment with opioid medication, including discussing risks and obtaining verbal consent, except in specified instances. Makes unprofessional conduct a violation and subjects the prescriber to disciplinary action by their licensing board.

STATUS:

06/18/2018 In SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT: Not heard.
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 2760

AUTHOR: Wood [D]
TITLE: Prescription Drugs: Prescribers: Naloxone Hydrochloride
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 06/20/2018
DISPOSITION: Pending
COMMITTEE: Senate Appropriations Committee
HEARING: 08/06/2018 10:00 am
SUMMARY:

Requires a prescriber to offer a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression to a patient when certain conditions are present and to provide education on overdose prevention and the use of naloxone hydrochloride or another drug to the patient and specified others.

STATUS:

06/20/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA AB 2789

AUTHOR:	Wood [D]
TITLE:	Health Practitioners: Prescriptions: Electronic Data
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
LAST AMEND:	07/03/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/06/2018 10:00 am

SUMMARY:

Requires health care practitioners authorized to issue prescriptions to have the capability to transmit electronic data transmission prescriptions. Requires pharmacies to have the capabilities to receive those transmissions. Requires a pharmacy to transfer or forward the prescription to another pharmacy at the request of the patient. Requires that a health care practitioner, pharmacist, or pharmacy who fails to meet applicable requirements be referred for administrative sanctions.

STATUS:

07/03/2018	From SENATE Committee on APPROPRIATIONS with author's amendments.
07/03/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA AB 2863

AUTHOR:	Nazarian [D]
TITLE:	Health Care Coverage: Prescriptions
FISCAL COMMITTEE:	no
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2018
LAST AMEND:	07/03/2018
DISPOSITION:	Pending
COMMITTEE:	Senate Appropriations Committee
HEARING:	08/06/2018 10:00 am

SUMMARY:

Limits the amount a health care service plan or health insurer may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost-sharing amount or the retail price. Prohibits a health care service plan or health insurer from requiring a pharmacy to charge or collect a cost sharing amount from an enrollee or insured that exceeds the total retail price for the prescription drug. Requires a pharmacy to inform a customer about the cost sharing amount.

STATUS:

07/03/2018	From SENATE Committee on APPROPRIATIONS with author's amendments.
07/03/2018	In SENATE. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.
INDEX:	89
ISSUES:	AK, DP, RY*

LOBBYIST: AH
POSITION: F

CA SB 212

AUTHOR: Jackson [D]
TITLE: Solid Waste: Pharmaceutical and Sharps Waste
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/01/2017
LAST AMEND: 06/18/2018
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Establishes a pharmaceutical and sharps waste stewardship program, under which each manufacturer of covered drugs or sharps, as defined, in the state would be required to establish and implement, either on its own or as part of a group of covered manufacturers through membership in a pharmaceutical and sharps waste stewardship organization, a pharmaceutical and sharps waste stewardship program.

STATUS:

06/27/2018 In ASSEMBLY. Coauthors revised.
INDEX: 75, 89
ISSUES: BJ*, LR
LOBBYIST: AH
POSITION: O/A, X

CA SB 528

AUTHOR: Stone [R]
TITLE: Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/16/2017
LAST AMEND: 06/12/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Provides an alternative program to authorize a pharmacy to provide pharmacy services to covered entities that are eligible for discount drug programs under federal law, as specified, through the use of an automated drug delivery system.

STATUS:

09/01/2017 In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA SB 716

AUTHOR: Hernandez [D]
TITLE: California State Board of Pharmacy: Pharmacy Technician
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/17/2017
LAST AMEND: 04/26/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Increases the number of members of the Board of Pharmacy by adding one pharmacy technician appointed by the Governor.

STATUS:

07/19/2017 In ASSEMBLY Committee on APPROPRIATIONS: Not heard.

	INDEX:	89
	ISSUES:	BJ*, DP
	LOBBYIST:	AH
	POSITION:	N, X

CA SB 1021

AUTHOR:	Wiener [D]
TITLE:	Prescription Drugs
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/07/2018
LAST AMEND:	06/14/2018
DISPOSITION:	Pending
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Amends existing law relating to drug formularies. Requires a prescription drug benefit to provide that an enrollee or an insured is not required to pay more than the retail price for a prescription drug if a pharmacy's retail price is less than the applicable copayment or coinsurance amount, and the payment rendered by an enrollee or insured would constitute the applicable cost sharing, as specified.

STATUS:

06/19/2018	From ASSEMBLY Committee on HEALTH: Do pass to Committee on APPROPRIATIONS. (15-0)
INDEX:	89
ISSUES:	BJ, DG*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1229

AUTHOR:	Stone [R]
TITLE:	Pharmacists: Opioid Medications: Consultation
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
LAST AMEND:	04/09/2018
DISPOSITION:	Pending
LOCATION:	Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires a pharmacist, on dispensing any opioid medication to a patient for the first time, to provide oral consultation before dispensing the medication. Prohibits the pharmacist from dispensing the medication if the patient declines the consultation.

STATUS:

04/09/2018	From SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT with author's amendments.
04/09/2018	In SENATE. Read second time and amended. Re-referred to Committee on BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	F, X

CA SB 1240

AUTHOR:	Stone [R]
TITLE:	Prescription Drugs: CURES Database
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/15/2018
LAST AMEND:	04/09/2018

DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires a prescription, if in writing or transmitted electronically, to include an ICD 10 Code or a legible clear notice of the condition or purpose for which the drug is being prescribed, unless the patient requests this information to be omitted and would require a prescription transmitted orally to include either the code or a description of the condition or purpose for which the drug is being prescribed. Requires a pharmacy to immediately convey prescription profile data to the requesting pharmacy.

STATUS:

04/16/2018 In SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT: Not heard.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA SB 1254

AUTHOR: Stone [R]
TITLE: Hospital Pharmacies: Medication Profiles
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 06/28/2018
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee

SUMMARY:

Requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile for each high risk patient upon admission of the patient under specified circumstances. Authorizes an intern pharmacist or pharmacy technician to perform the task of obtaining an accurate medication profile or list for a high risk patient, if certain conditions are satisfied.

STATUS:

06/28/2018 In ASSEMBLY. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: S, X

CA SB 1264

AUTHOR: Stone [R]
TITLE: MediCal: Hypertension Medication Management
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/15/2018
LAST AMEND: 05/01/2018
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee

SUMMARY:

Includes providing specified hypertension medication management services as a covered pharmacist service under the Medi-Cal program.

STATUS:

06/19/2018 From ASSEMBLY Committee on HEALTH: Do pass to Committee on APPROPRIATIONS. (12-1)

INDEX: 65, 89
ISSUES: AK*, BJ
LOBBYIST: AH, BG*
POSITION: F

CA SB 1285

AUTHOR: Stone [R]
TITLE: Health Care Coverage: Advanced Practice Pharmacist
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Health Committee
SUMMARY:

Requires coverage for services provided by an advanced practice pharmacist, as defined, performed within the scope of his or her practice, including but not limited to, comprehensive medication management (CMM) services, as defined, in a health care service plan contract and health insurance policy, and, to the extent that federal financial participation is available, in a Medi-Cal managed care plan.

STATUS:

04/25/2018	In SENATE Committee on HEALTH: Failed passage.
04/25/2018	In SENATE Committee on HEALTH: Reconsideration granted.

INDEX: 39, 89
ISSUES: BJ, DG*, DP
LOBBYIST: AH
POSITION: F

CA SB 1286

AUTHOR: Pan [D]
TITLE: Pharmacy Technicians
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Allows a pharmacy with only one pharmacist to have no more than 4 pharmacy technicians performing packaging, manipulative, repetitive, or other nondiscretionary tasks.

STATUS:

03/01/2018	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.

INDEX: 57, 89
ISSUES: BJ, GBS*
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1404

AUTHOR: Stone [R]
TITLE: Pharmacists: Exemption From Overtime Regulations
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
DISPOSITION: Pending
LOCATION: Senate Labor and Industrial Relations Committee
SUMMARY:

Provides that a person employed in the practice of pharmacy, who is participating in a postgraduate training program, as specified, who is in a field relating to the practice of pharmacy or pharmacy research, or who is performing certain procedures or functions, is not subject to coverage under any provisions of the orders of the Industrial Welfare Commission.

STATUS:

04/25/2018	In SENATE Committee on LABOR AND INDUSTRIAL

RELATIONS: Not heard.

INDEX: 57, 89
ISSUES: BJ, CM
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1426

AUTHOR: Stone [R]
TITLE: Pharmacists: Authority To Prescribe and Dispense
FISCAL COMMITTEE: no
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 03/22/2018
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee

SUMMARY:

Requires the State Board of Pharmacy to convene a Public Health and Pharmacy Formulary Advisory Committee to advise the board in promulgating regulations to establish a formulary of drugs and devices that an advanced practice pharmacist may furnish to a patient. Requires the Board to establish a formulary of dangerous drugs and devices that an advanced practice pharmacist may furnish to a patient. Authorizes an advanced practice pharmacist to furnish a dangerous drug or device included on the formulary.

STATUS:

04/04/2018 Re-referred to SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F, X

CA SB 1442

AUTHOR: Wiener [D]
TITLE: Community Pharmacies: Staffing
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 06/21/2018
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee

SUMMARY:

Prohibits a community pharmacy from requiring a pharmacist to engage in the practice of pharmacy at any time the pharmacy is open to the public, unless either another employee of the pharmacy or, if the pharmacy is located within another establishment, an employee of the establishment within which the pharmacy is located is made available to assist the pharmacist at all times.

STATUS:

06/21/2018 In ASSEMBLY. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.

INDEX: 57, 89
ISSUES: BJ, GBS*
LOBBYIST: AH*, KAS
POSITION: F, X

CA SB 1447

AUTHOR: Hernandez [D]
TITLE: Pharmacy: Automated Drug Delivery Systems
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/16/2018
LAST AMEND: 07/03/2018

DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Amends the Pharmacy Law. Repeals the general automated provisions and the additional conditions for an Automated Drug Delivery Systems located in a health facility beginning on a specified date. Requires the Board of Pharmacy to report on the regulation of ADDS units, as provided.

STATUS:

07/03/2018 In ASSEMBLY. Read second time and amended. Re-referred to Committee on APPROPRIATIONS.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: O/A, X

CA SB 1495

AUTHOR: Health Cmt
TITLE: Health
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/28/2018
LAST AMEND: 06/14/2018
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Excludes from the definition of stem cell therapy those therapies involving HCT/Ps that meet specified criteria pursuant to, or that qualify for an exception under, federal law. Requires only health care practitioners who perform a stem cell therapy that is subject to FDA regulation, and that is not FDA-approved, to provide the notice and writing to their patients. Exempts from these requirements a health care practitioner who has obtained clearance for an investigational new drug.

STATUS:

06/26/2018 From ASSEMBLY Committee on HEALTH: Do pass to Committee on APPROPRIATIONS. (15-0)

INDEX: 89
ISSUES: BJ, DP, LR*
LOBBYIST: AH
POSITION: F

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Prescriptions of Buprenorphine or Methadone to Manage Opioid Withdrawal for Patients Admitted for Medical Conditions

SUMMARY

Recently, member questions arose as to the nature of opioid withdrawal management for patients admitted to a hospital with a medical or psychiatric condition. We asked our legal counsel to comment on two issues:

1) Are all California hospitals permitted to prescribe buprenorphine or methadone to manage opioid withdrawal when patients are admitted for medical conditions?; and
2) If a patient is admitted to a hospital for a primary psychiatric indication, is buprenorphine or methadone administration legal for treatment of their opioid withdrawal?

The DEA regulations do not specifically answer this question. Her response is detailed in the attached letter.

ACTION REQESTED

- Have hospitals/physicians raised this issue with you

Attachments: CHA Letter

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

May 18, 2018

TO: David Perrott

FROM: Jackie Garman

SUBJECT: **Prescription of Buprenorphine or Methadone to Manage Opioid Withdrawal for Patients Admitted for Medical Conditions**

ISSUES

1. Are all California hospitals permitted to prescribe buprenorphine or methadone to manage opioid withdrawal when patients are admitted for medical condition?

2. If a patient is admitted to a hospital for a primary psychiatric indication, is buprenorphine or methadone administration legal for treatment of their opioid withdrawal? The DEA regulations I linked to above do not specifically answer this question.

SUMMARY

The relevant statutes, Health & Safety Code section 11217 and 11217.5[1], are not susceptible to a conclusive determination of whether (1) all California hospitals are permitted to prescribe buprenorphine or methadone to manage opioid withdrawal when patients are admitted for medical condition; or (2) buprenorphine or methadone may be administered to a patient admitted to a hospital for a primary psychiatric indication to treat their opioid withdrawal. Unfortunately, ambiguous drafting of key provisions of the relevant statutes leaves the answers to these questions uncertain, putting providers and facilities at risk if they prescribe methadone or buprenorphine under the circumstances identified. The reasons for this conclusion are summarized as follows:

1. The fact that federal law, in 21 CFR 1306.07, expressly does not limit the ability of a physician or hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of other conditions is not controlling. Where, as here, federal law does not preempt any state law in the field, states are free to impose additional and more restrictive requirements.

2. The use of the conjunction "and" in Health & Safety Code § 11217(h) rather than "or" can be construed as requiring that a facility qualify as either one of the first two facilities listed (a 1250(a) general acute care hospital or a 1250(b) acute psychiatric hospital) **plus** as a 1250.3 chemical dependency recovery hospital in order to qualify as a location in which an addict may be treated for addiction to a narcotic drug. By contrast, if the first two types of facilities listed were separated

[1] All subsequent statutory references are to the Health & Safety Code unless otherwise noted.

from the third by "or," instead, this provision would be most susceptible to the interpretation that a hospital falling within any one of these categories would be an authorized location for such treatment.

3. Section 11217 contains the following exception to that statute's mandate that treatment of an addict occur in one of the places specified: "This section does not apply during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age." However, the conditions specified in this provision are unlikely to be interpreted sufficiently broadly to encompass all medical or surgical conditions for which an addict might be admitted.

4. Section 11217.5, which allows a physician, notwithstanding section 11217, to "treat an addict for addiction in any . . . medical facility which . . . is medically proper" with "those medications and therapeutic agents which, in the judgment of such [physician] are medically necessary," specifies that "nothing in this section shall authorize the administration of any narcotic drug." Thus, this provision is unavailing with respect to authorizing the administration of methadone or buprenorphine.

ANALYSIS

I. THE USE OF "AND" IN SECTION 11217(h) IS AMBIGUOUS WITH RESPECT TO WHETHER AN ADDICT MAY BE TREATED FOR ADDICTION TO A NARCOTIC DRUG IN A FACILITY THAT IS SOLELY A GENERAL ACUTE CARE HOSPITAL.

As a matter of federal law, 21 CFR § 1306.07, which specifies conditions under which a practitioner may administer or dispense narcotic drugs, acknowledges a broad exception to these requirements in subparagraph (c) of the regulation. This exception provides: "This section is not intended to impose any limitations on a physician or authorized hospital staff to administer or dispense narcotic drugs in a hospital to maintain or detoxify a person as an incidental adjunct to medical or surgical treatment of conditions other than addiction, or to administer or dispense narcotic drugs to persons with intractable pain in which no relief or cure is possible or none has been found after reasonable efforts."

California law provides no such broad and clear exception to the use of narcotic drugs for patients requiring maintenance or detoxification as an incidental adjunct to medical or surgical treatment of conditions other than addiction. Rather, Health & Safety code section 11217 limits the places where an addict can be treated for addiction to, in pertinent part, as follows:

> Except as provided in Section 11223, no person shall treat an addict for addiction to a narcotic drug except in one of the following:
>
> (a) An institution approved by the State Department of Health Care Services, and where the patient is at all times kept under restraint and control.
>
> (b) A city or county jail.
>
> (c) A state prison.

> (d) A facility designated by a county and approved by the State Department of Health Care Services pursuant to Division 5 (commencing with Section 5000) of the Welfare and Institutions Code.
>
> (e) A state hospital.
>
> (f) A county hospital.
>
> (g) A facility licensed by the State Department of Health Care Services pursuant to Division 10.5 (commencing with Section 11750).
>
> (h) **A facility as defined in subdivision (a) or (b) of Section 1250 and Section 1250.3.**
>
> A narcotic controlled substance in the continuing treatment of addiction to a controlled substance shall be used only in those programs licensed by the State Department of Health Care Services pursuant to Article 1 (commencing with Section 11839) of Chapter 10 of Part 2 of Division 10.5 on either an inpatient or outpatient basis, or both.
>
> **This section does not apply during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age.**
>
> . . . . (Emphasis added.)

Under section 11217, the only location where addicts may be treated that may arguably encompass non-public hospitals or those not designated as LPS facilities (§11217(f)) are those that qualify under subparagraph (h) which, as noted, authorizes treatment of an addict in "[a] facility as defined in subdivision (a) or (b) of Section 1250 [of the Health & Safety Code] **and** Section 1250.3 [of the Health & Safety Code]" (emphasis added).

If this list of three types of facilities were entirely in the alternative ("a facility as defined in subdivision (a) or (b) of Section 1250 **or** Section 1250.3"), this provision would most persuasively be interpreted as allowing an addict to be treated in any one of the three listed facilities, since "or" is commonly interpreted, as a matter of statutory construction, to mean any one of the listed alternatives. Since the hospitals which prompted this inquiry are all general acute care hospitals, they are all hospitals defined in section 1250(a), and thus would be locations where addicts could be treated for addiction to narcotic drugs. But because the first two listed facilities are connected to the third (1250.3 chemical dependency recovery hospitals) by the conjunction "and," common principles of statutory construction would likely interpret this provision to mean that the facility must be **either** a 1250(a) or a 1250(b) **plus** a 1250.3—in other words, either a general acute care or an acute psychiatric hospital **and** a chemical dependency recovery hospital.

To be clear, this interpretation of the significance of the use of "and" in subparagraph (h) is not definitive. As has been noted:

> "*Every* use of 'and' or 'or' as a conjunction involves *some* risk of ambiguity." [Citation omitted.] Thus, in the main text of *Words and Phrases* (1953)---excluding pocket parts—the word "and takes up 61 pages of digested cases interpreting it in myriad ways, and

> the word "or" takes up another 84 pages of digested cases interpreting it in an equally broad array of senses. Virtually every book on drafting legal documents contains a section on the ambiguity of the two words.

Garner, *A Dictionary of Modern Legal Usage* (2nd Ed. 1995) p. 624, col. 1). But as I have been unable to find any case or other authority interpreting this provision, I have applied common principles of statutory construction which indicate this provision at best is ambiguous as to whether a hospital that is solely a general acute care hospital may serve as a location where an addict may be treated and at worst indicate that it must, in addition, be a chemical dependency recovery hospital. Given this ambiguity, providers would be at risk of violating section 11217 in using methadone or buprenorphine to manage opioid withdrawal when patients are admitted to a general acute care hospital for a medical or surgical condition.

II. SECTION 11217'S EXPRESS INAPPLICABILITY TO TREATMENT FOR SPECIFIED CONDITIONS LIKELY DOES NOT EXTEND THE EXEMPTION TO HOSPITALIZATION FOR ALL MEDICAL OR SURGICAL TREATMENT.

As noted above, section 11217 expressly provides: "This section does not apply during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age." While this is a fairly broad list of conditions that that are exempt from section 11217's limitations on the locations at which an addict may be treated for addiction, it is not sufficiently broad to encompass all medical or surgical conditions for which an addict may be hospitalized.

Again, there is no dispositive authority on how this language should be interpreted. But a basic principle of statutory construction is *expressio unius est exclusio alterius* ("the express mention of one thing excludes all others"). This means that when there is a list of certain items, other items that are not on the list are presumed not to be included in the absence of language (for example, "such as" or "includes") that indicates the list is merely illustrative, not exclusionary. Applying this doctrine here, the listing of emergency treatment, where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age as conditions exempted from section 11297's location limitations presumably excludes other medical or surgical conditions not included in the list.

III. SECTION 11217.5, WHICH PERMITS TREATMENT OF AN ADDICT IN ANY "MEDICALLY PROPER" FACILITY, DOES NOT AUTHORIZE THE ADMINISTRATION OF ANY NARCOTIC DRUG.

Section 11217.5 provides a broad exemption from the location limitations of section 11217:

> **Notwithstanding the provisions of Section 11217**, a licensed physician and surgeon may treat an addict for addiction in any office **or medical facility which, in the professional judgment of such physician and surgeon, is medically proper for the rehabilitation and treatment of such addict**. Such licensed physician and surgeon may administer to an addict, under his direct care, those medications and therapeutic agents which, in the judgment of such physician and surgeon, are medically necessary, **provided that nothing in this section shall authorize the administration of any narcotic drug**. (Emphasis added.)

While section 11217.5 allows treatment of an addict in **any** medical facility which, in the professional judgment of a licensed physician, "is medically proper for the rehabilitation and treatment of such addict," and thus would permit treatment in a general acute care hospital, presumably including when such treatment is ancillary to treatment for another medical or surgical condition, the statute's exclusion of administration of "any narcotic drug" precludes administration of methadone or buprenorphine.

IV. CONCLUSION

As there is no case law or regulations interpreting the provisions in issue, I have been forced to rely on very general provisions of statutory construction which, in all candor, are not applied consistently. It is therefore not impossible that a court or other legal authority might come to a contrary conclusion. But given the ambiguity of the statute, I think a hospital would be at risk in treating a patient with methadone or buprenorphine ancillary if the patient is admitted for a medical or surgical condition that does not qualify as "emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age."

There are two ways that I can see to attempt to cure this problem. The first is to seek an Attorney General's opinion presenting the questions and hope that the AG comes to a conclusion that will allow use of the medications in question to treat addicts hospitalized in general acute care hospitals for the full range of medical and surgical conditions. The second is to seek to amend the relevant provisions of section 11217 along the following lines:

- Amend section 11217(h) as follows:

  A facility as defined in subdivision (a) or (b) of Section 1250 ~~and~~or Section 1250.3.

- Amend the following provision as shown:

  This section does not apply ~~during emergency treatment, or where the patient's addiction is complicated by the presence of incurable disease, serious accident, or injury, or the infirmities of old age.~~when a patient is admitted to a licensed hospital for medical, surgical, or psychiatric treatment of conditions other than addiction and narcotic drugs are administered or dispensed to maintain or detoxify the patient as an incidental adjunct to such treatment.

JJG:me

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: Candace Fong, Pharm.D., Co-Chair CHA Medication Safety Committee

SUBJECT: Narcotic Inventory Reconiliation Regulations

SUMMARY
Questions and concerns have come from members relative to present narcotic inventory reconciliation regulations.

Quarterly CII reconciliation
Situation: Intent of regulation is to ensure accountability of CII inventory to prevent diversion by identifying discrepancies in a timely fashion

Background:
Pharmacies that have automated perpetual inventory systems under the supervision of a pharmacist and the following safeguards in place have **real-time processes** to prevent diversion

- Utilize central pharmacy ADDs (such as CII-safe®) for inventory of CII and other Controlled Substances
- Blind count performed whenever any medications are added or removed from the central pharmacy ADDs
- Realtime interface with ADDs units located in patient care areas
- Immediate discrepancy alerts for any actions for both central and decentral ADDs
- Reconciliation reports reviewed each shift to determine any medication dispositions that need follow up

Assessment/Recommendation:

- Maintain reconciliation of CII and controlled substances orders placed and medications received
- Allow institutions that have the automated perpetual inventory systems as described above to be exempt from quarterly manual reconciliation since reconciliation is performed real-time

ACTION REQESTED

- Discuss the process and opportunities to streamline activities.

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 11, 2018

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services
Janette Wackerly, MBA, RN, Board of Registered Nursing, Supervising Nursing Education Consultant Practice Liaison

SUBJECT: Nursing and Sterile Compounding

SUMMARY

The Board of Registered Nursing is willing to work with us to do Sterile Compounding FAQs to clarify and confirm what constitutes reconstitution, compounding and sterile compounding, and how it applies to all settings in which nurses work. For example, if a registered nurse has a vial of medication in powdered form, such as ceftriaxone, and reconstitutes it with NS, then draws the medication out of the vial and injects it into an IV bag, is this permissible for the RN, or would it be considered sterile compounding.

CHA and the Board of Registered Nursing would like to convene a small work group on related pharmacy and nursing questions to define and clarify these issues.

ACTION REQESTED

- Appoint members from CHA, Board of Pharmacy, and Board of Nursing to work on FAQs to describe how sterile compounding applies to nursing practice in al settings.

BJB:br