Medication Safety Committee

April 6, 2016

California Hospital Association

1215 K Street, Suite 800

Sacramento, CA 95814

Conference Call Option:

(800) 882-3610 Access Code: 4206832#

Medication Safety Committee

AGENDA

10:00	**I. CALL TO ORDER/INTRODUCTIONS**		Hanni/Fong
	A. Membership		
	1. Roster		
	CHA MSC Roster - Page 6		
	2. Member Updates		
	Rita Shane (Karen Youmbi)		
	Kethen So		
	Nancy Blake		
	Christy Sinclair		
	3. Member Map		
	Member Representative - Page 10		
	4. CHA Member Breakdown		
	CHA MSC Member Breakdown - Page 11		
	5. CHA MSC Guidelines for Committee		
	MSC Guidelines - Page 12		
	6. CHA MSC Goals and Objectives 2016		
	MSC Objectives - Page 16		
10:15	**II. REVIEW OF PREVIOUS MEETING MINUTES**	*Recommend: Approval*	Hanni/Fong
	A. Draft Minutes - January 6, 2016		
	1. Draft Minutes - October 6, 2016 - Page 17		
	III. NEW BUSINESS		
10:20	A. Part B Prescription Drug Model		Keefe
	1. Medication Safety Committee Memo Part B Drug Model - Page 24		
	2. 03-08-2016 FINAL Medicare Part B Demo Technical Fact Sheet - Page 25		
10:50	B. California Poison Control System		Lewis
	1. CPCS Overview - Page 29		

11:00	C. Drug Pricing Issues	Bartleson
	1. Key Facts About the Misleading State Government Drug Purchasing Initiative - Page 54	
	2. CA Drug Price Relief - Page 57	
	3. No Misleading RX Measures - Page 62	
11:10	D. Revision of Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Toolkit	Munoz
	1. Guideline of Care Tool Kit - Page 64	

IV. OLD BUSINESS

11:15	A. CURES 2.0 Browser	Bartleson
11:20	B. Drug Quality and Security Act	Hanni
	1. Drug Supply Chain Security Act FAQs - Page 68	
11:35	C. Sterile Compounding	Fong
	1. Webinar	
	BOP Webinar Draft - Page 72	
	2. Title 16 - Second Modified Text - Page 73	
	3. Matrix	
	Board of Pharmacy Regulations CCR 1735 - Page 123	
11:50	D. CalOSHA Antineoplastic Regulations	Bartleson
	1. Antineoplastic Comment Letter 012016 - Page 128	
12:05	E. Drug Take Back Program	Bartleson
	1. BOP Drug Take Back Program Comment Letter 032816 - Page 130	
12:15	F. Drug Reconciliation and Inventory Regulations	Fong
	1. CHA Board of Pharmacy Inventory Letter - Page 134	
	2. Controlled Substances Best Practices (Draft) - Page 149	
	3. Title 16 - Proposed Text - Page 150	
12:25	G. CHA Medication Safety Tools	Bartleson
	1. Medication Safety Toolkit Manual Tracking - Page 152	

12:30	H. Small Bore Connectors	Jaffe
12:35	I. Hazardous Waste Pharmaceuticals	Bartleson
	1. Practice Greenhealth - Page 154	
	2. DTSC's Comment Letter - Page 195	
12:35	**V. LUNCH**	
12:50	**VI. STANDING REPORTS**	
	A. Board of Pharmacy	Herald
	B. CDPH	Lee/Woo
	C. CSHP	Hacker
	D. CALNOC	Foley
	E. ACNL	
	F. CHPSO	Jaffe
	G. CAHF	Montgomery
1:15	**VII. WORK GROUP RPEORTS**	
	A. Medication Technology	Jaffe
	B. Sterile Compounding	
	1. Andre Rossi, Candace Fong, Doug O'Brien, Eddie Averdikian, Christine Low, Lynn Paulson, Jeanette Hanni, Sarah Stevens, Steve HInz, Tom Jacobson	
	C. CURES 2.0 Browser	Bartleson
	1. Alecia Sanchez, Angelica Gonzalez, Candace Fong, Clara Evans, Dave Garrett, Doug O'Brien, Eddie Avedikian, Edward Lee, Garen Winetemute, Heather Davis, Michael Tou, Mike Small, Robert Sumner, Roneet Lev, Samantha Pellon, Scott Fishman, , Scott McDonald,	
	2. Shad Lappe, Stephen Henry, Weip Chen, William Elliott, Yvonne Choong	
	D. CHA Medication Safety Toolkit Plan	Bartleson
	E. CHA Antineoplastic Drug Handling	
	1. Albert Rizos, Angela Anson, Angeli, Mancuso, BJ Bartleson, Cheri Hummel, Chi Fong, Christine Low, Corbin Bennett, Diana Schultz, Dietmar Grellmann, Donna Goebel, Edward Ochi, Gail Blanchard-Saiger, Greg Light, Lynn Paulsen, Michael Brown	

2. Patricia Bollendorf-Perez, Shelley Rae Carry, Zan Sorooshian

1:30 **VIII. PHARMACY LEGISLATIVE UPDATES** Bartleson

A. Legislative Bills - Pharmacy - Page 208

B. Remarks for AB 2144 - Page 221

C. Pharmacy Bill Discussion Guide - Page 222

1:55 **IX. INFORMATIONAL ONLY** All

A. CHA Board of Trustees

1. CHA Board of Trustees Report

CHA BD Medication Safety Committee 2-4-16.pdf - Page 224

2. Opioid Articles

Opioid Crisis Puts Pharmacists on the Front Line, Pressed to Serve as Drug Cops - Page 226

FDA Takes Further Steps to Curb Opioid Abuse - Page 229

3. Articles

High Costs for Drugs Used by a Few are Starting to Add Up - Page 231

Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians - Page 233

Burwell: Office-Use Compounding Can Occur In Absence Of Guidance - Page 255

The Obscurity of Drug Spending in Medi-Cal - Page 256

Pharmacists to the fore article - Page 259

Fentanyl Alert - Page 262

X. 2016 MEETING DATES

A. July 6, October 5, 2016

2:00 **XI. ADJOURNMENT** Hanni

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2016

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Medication Safety Committee Representation

Rev. January 2015

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

Medication Safety Committee
Member Geographics - July 2015

HOSPITAL COMMITTEE MEMBERS

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

NON-HOSPITAL COMMITTEE MEMBER:

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

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 the following organizations:

California Department of Public Health
California Society of Health System Pharmacists
California Board of Pharmacy
Centers for Medi-Care and Medi-Caid Services
Association of California Nurse Leaders
California Medical Association
California HQI
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 Rehabilitation Services

Hospital Services for Continuing Care Committee
Governance
Quality Directors
Health Informatics and Technology Committee

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. Non hospital member representatives can only be appointed to the Committee at the discretion of the CHA President.

2. In addition to the Committee/Centers named above, 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.

3. Hospital members are appointed by CHA Staff.

4. Term:

(a) The initial term of office shall be three years, except that one-half of the initial members shall be appointed to two-year terms to ensure continuity of committee members in the future.

(b) As the terms of the members appointed in 2009 expire, or members otherwise leave, vacancies shall be filled to achieve the requirements of Article IV. Members are limited to two, three-year consecutive terms. An exception shall be granted in cases where a member is elected as a chair officer. Following two consecutive terms there must be a one-year interval before a member is eligible for another term.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee.

2. Identify issues and develop possible solutions and best practices to improve the safety of medication storage and distribution administration.

3. Work cooperatively with key stakeholders to develop creative solutions.

4. Provide communication to member hospitals regarding medication safety issues.

5. Maintain/increase 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 is not acceptable.

3. Three consecutive unexcused absences by a Committee member will initiate a review by the Chair and CHA staff for determination of the Committee member's continued service on the Committee.

4. Special meetings may be scheduled by the Chair, majority vote or CHA staff.

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, Vice Chair, Immediate Past Chair and CHA staff.

The Chair shall be elected by the Committee for a two-year term, except for the initial Chair, who shall be appointed by CHA staff for one year. Should a Chair vacate his/her position prior to the end of the term, CHA staff will appoint a replacement to complete the remainder of the term.

Past-chairs will remain as a member of the Committee.

A. SUB-COMMITTEES

1. Task forces of the Committee may be formed at the discretion of the Committee

Chair and members and CHA staff for the purpose of conducting activities specific to a special topic or goal.

VI. GENERAL PROVISIONS

The strategic plan defining the goals, objectives, and work plans shall be developed annually by the Committee with approval by CHA staff. 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 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 statutes or regulations shall be declared null and void as of the date of such determination.

Any portion of these Guidelines which are in conflict with the Bylaws and policies of CHA shall be considered null and void as of the date of the 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.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Medication Safety Committee, Mission, Purpose and 2016 Objectives

Mission:

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

Purpose:

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

2016 Goals and Objectives

1) Develop guidance, tools, information and strategies for hospitals and pharmacists involved in medication safety to enhance quality care and patient safety.

    a) Implement workgroups where members can apply their expertise to explore, plan and suggest strategies

        i) 2016 Workgroups: Sterile Compounding , Medication Technology, CURES 2.0 Browser Workgroup, Inventory and Reconciliation, Drug Quality and Security , Antineoplastic Regulations

        ii) Finalize the Sterile Compounding Matrix Tools, disseminate and implement an informational webinar to assist members with compliance

2) Advise the CHA Board of Trustees on issues relevant to medication safety, particularly under health care reform and projected care model changes.

    a) Develop an issue brief that describes the challenges of the present environment and make strategic recommendations for the pharmacy of the future
    b) Work with CHA Finance staff to assist with regulatory advocacy on pricing issues such as the 340B Drug Pricing Program Omnibus Guidance.

3) Develop new strategies for CHA Medication Safety Tools to be disseminated and distributed among California hospitals and stakeholders.

    a) Publish the CHA Medication Safety Tool Compendium that includes the numerous tools developed by the committee and disseminate to members.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
January 6, 2016 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: **Candace Fong, Eddie Avedikian, Jacalynn Blankenship, John Christensen, Kevin Dorsey-Tyler, Mary Foley, Amy Gutierrez, Lisa Hall, Rory Jaffe, Cari Lee, Christine Low, Robert Menet, Lori Nolan, Doug O'Brien, Lynn Paulsen, Dan Ross, Diane Schultz, Theresa Vidals, Jenna Fischer, Alicia Munoz,**

Members Absent: **Jeannette Hanni, Nancy Blake, Carolyn Brown, Katie Choy, Edna DeLeon, Virginia Herold, Randy Kajioka, Nasim Karmali, Patricia McFarland, Richard Rabens, Susan Reed, Christy Sinclair, Sarah Stephens, Art Woo,**

Invited Guests: **Gail Blanchard-Saiger, Pat Blaisdell, Cheri Hummel,**

CHA Staff: **BJ Bartleson, Ronda Fricke**

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Candace Fong at 10:00 AM.

A. Member Updates

Ms. Fong reviewed membership items included in the meeting book.

B. Committee Guidelines

Ms. Bartleson discussed the importance of the committee and thanked the members for their continued participation. Ms. Bartleson took the opportunity to remind the members that it would be a good time to recruit members from the Central Valley area and asked if anyone had a recommendation please forward to her. She also suggested a rural area pharmacist member.

Ms. Bartleson discussed the 2016, goals that have ongoing 2015 activity.

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the October 7, 2015, Medication Safety Committee meeting were reviewed as submitted.

IT WAS MOVED, SECONDED AND CARRIED:

- To approve the minutes of the October 7, 2015, Medication Safety Committee meeting with the correction that Mr. Jaffe did not attend the meeting.

Ms. Gutierrez abstained from voting due inability to access to BoardEffect.

III. OLD BUSINESS

A. CHA 340b Advisory Committee Update

Ms. Paulson discussed the 340b federal regulations, indicating it may be a long time before they are finalized. There were approximately 809 responses to the proposed regulations and the pharmaceutical community continues to press for limitations on the program.

B. CURES 2.0 Browser

Ms. Bartleson provided background on why CURES was developed and discussed member concerns with the CURES program, along with updated functionality and changes occurring to support member registration, she reminded the committee members to please bring member concerns/issues to her attention.

Ms. Gutierrez stated she reached out to Mr. Small who informed her that as of January 8, 2016, the CURES 2.0 system will be up and running and you can apply online for a password. Mr. O'Brien added CURES 2.0 is much more superior then the original version. He also agreed that having the ability to apply online is a huge benefit. Currently the need for an upgraded browser is the biggest challenge.

Dr. Jaffe noted he submitted his application in December 2015 but it was unclear as to what documentation was needed.

Ms. Bartleson informed the group that FAQ's and educational information on CURES usage is available on the CURES website. Ms. Gutierrez added the importance of marketing the availability to register online as well as the mandatory registration date of July 2016.

Action: Ms. Bartleson will continue to work with Mike Small from the DOJ and the CURES 2.0 Browser workgroup to monitor system problems affecting provider registration

C. Impact Act & CMS Drug Regime

Ms. Blaisdell updated the group on the CMS revised conditions for hospitals and post-acute care, including some pharmacy issues. Comments were due January 4 and CHA submitted an extensive comment letter that is available on the CHA website.

Ms. Blaisdell discussed several areas that may affect this committee as well as CHA's comments. She also noted that CMS has up to 3 years to finalize the conditions of participation but she feels they will finalize within a year. CHA has requested a year's leeway time to implement.

D. Drug Quality and Security Act

It was asked if the Kaiser FAQs could generically be used to submit to other hospitals. Ms. Bartleson mentioned that Mr. O'Brien agreed with the request and he added that the FAQs were pared down to must haves and he would share with others who needed the information.

Action: The CHA subgroup working on this will review and revise the FAQ's if necessary and post to members.

E. Sterile Compounding

Ms. Paulson noted the Board of Pharmacy (BOP) is finalizing the sterile compounding regulations but was unclear if there would be any additions.

Ms. Bartleson noted the matrixes provided to the group are an older version and the new ones will be added to the compendium. She reiterated that once the regulations are finalized a webinar would be scheduled.

Ms. Bartleson posed the question about a crosswalk and if whether it would be beneficial. Ms. Paulson stated it would be beneficial since 797 and 800 are to go live the same day.

Action: The Sterile Compounding Subcommittee will work finalize the matrixes and plan for a member webinar, and consider developing a crosswalk for 797, 800, and Cal OSHA antineoplasty, and finalize the sterile compounding FAQs. .

F. Cal OSHA Antineoplastic Regulations

Ms. Bartleson introduced Gail Blanchard-Saiger. Ms. Saiger provided background on the regulations and noted that Cal OSHA is moving slowly because there isn't a formal deadline to complete the regulations. Ms. Saiger shared that she has created a workgroup to assist with this complicated process and they met in December 2015. The workgroup will be ongoing and consist of sporadic calls. She noted she doesn't have a representative from Dignity Health at this time. Ms. Saiger shared that she is going to propose to a face to face meeting with Cal OSHA in the Oakland office and invited anyone interested in participating. Ms. Munoz added there should also be a UC System representative.

Action: Ms. Gutierrez will provide contact information to Ms. Bartleson for an oncology pharmacist that may be of assistance.

Ms. Saiger will reach out to Ms. Paulsen to see if she is available. Ms. Fong stated she would send information for a contact from Dignity Health.

G. **Drug Take Back Programs**

Ms. Gutierrez noted this is a politically charged topic and environmental groups are looking for options to keep drugs out of the landfill.

She added that the DEA regulations on controlled substance take back says a participant must have an active controlled substance license and nursing homes can only participate if they are linked to a pharmacy. Currently the DEA and the Board of Pharmacy are advocating a voluntary position for drug take back program participation by hospital pharmacies.

Ms. Bartleson thanked Ms. Gutierrez for making the members aware of this because she has been receiving questions about the issue. Ms. Gutierrez added it is her understanding that the issue is going back to the Board on January 19, 2016.

Mr. O'Brien suggested making the police department the take back location and Dr. Jaffe added police departments are difficult because they only have a limited number of one time "takeback" event days.

Mr. O' Brien talked about the complexity of the take back program and that most people won't know if their prescription is a controlled substance. He added that the DEA take back days have been quite successful. Ms. Gutierrez mentioned that when there is a large quantity of controlled substances, it is probably best for the police to handle that take back rather than a pharmacy.

Action: CHA will submit comments to the Board of Pharmacy's proposed drug takeback regulations.

H. Drug Reconciliation and Inventory Regulations

Ms. Fong provided background on the proposed regulation and reviewed the comment letter sent to the Board of Pharmacy adding that every record keeping infraction could result in a fine up to $10,000. She discussed the million dollar plus settlement between the DEA and Dignity Health adding that the organization has put numerous strategies in place as a result of the penalty. The premise of the regulation is to reconcile what you order and what you dispense. The proposed regulations would make it quite costly for an organization to adhere to them, especially as it applies to automated dispensing cabinets.

I. CHA Medication Safety Tools

Ms. Bartleson advised the committee that she is working with education to create a compendium to be distributed that includes all the past and present tools being developed. She asked for one CHA Med Safety Pharmacist content expert for each tool so that updates and changes can be accomplished efficiently.

J. Medication Reconciliation / Discharge Planning

Ms. Bartleson introduced Pat Blaisdell who gave a quick overview of what she presented at the last meeting. She reviewed the Discharge Planning Proposed Rule and the MAPS comments/recommendations as well as other concerns.

Ms. Bartleson asked if there was a site where the committee could review the information provided.

Action: Ms. Blaisdell suggested Ms. Bartleson contact Ms. Alyssa Keefe for the information.

IV. LUNCH

V. NEW BUSINESS

A. **Hazardous Waste Pharmaceuticals**

Ms. Bartleson introduced Cheri Hummel who provided a high level overview of the rule including the inability to flush controlled substances in the sewer. CHA submitted comments that asked for additional time to implement the regulations once they were released and for the Federal Government to provide assistance to the states. Ms. Hummel feels more education will be needed and CHA will assist with education.

Ms. Hummel noted the main concern is how the new rule will be interpreted in California.

Mr. O'Brien suggested the committee make comments once they review the PowerPoint. Ms. Bartleson asked each member to send her one or two questions and she would forward them on to Ms. Hummel.

Action: Ms. Fricke will send out PowerPoint presentation to the committee. And questions can be submitted back to Ms. Bartleson

Ms. Hummel asked for someone from the MSC committee to serve on her committee and then report back to this group.

B. USP 797, USP 800 Update
Discussed in sterile compounding.

C. CMS Regulations
Discussed in sterile compounding.

D. Small Bore Connectors

Dr. Jaffe discussed ISO standards for small bore connectors. It's impossible to design a connector that won't fit into everything else, so the design was based on risk assessment and lack of interconnectivity with other small bore connectors. The enteral feeding connector rule goes into effect in July 2016 and small volume syringe dosing is the only issue, which is being solved with a specially designed tip. One manufacturer won't make the new syringes yet so there may not be an adequate supply in the US. He added that Advamed and CHA's position is to not ask for an extension to comply because it is solely a manufacturer issue.

The neural connector requirement begins at the end of the year and will affect epidurals. Dr. Jaffe has asked for devices to be introduced 6 months before the deadline but he doesn't think that much time will be given. Ms. Bartleson asked how the information is being disseminated to the hospitals. Dr. Jaffe responded that he there will be webinars and monthly calls, but mainly through the GPOs (Group Purchasing Organizations). He added there will be a free webinar in April and more information will be provided later. Dr. Jaffe invited anyone with a question to call him directly. He also added that a lot of preparation will need to be done at the hospitals.

E. Proposed 2016 Guidelines for Prescribing Opioids for Chronic Pain

Dr. Jaffe reviewed the guidelines mentioning the comment period remains open through next week. He added that CHA would not be commenting but individual doctors / hospitals may want to.

VI. WORKGROUP REPORTS

A. Medication Technology
Dr. Jaffe is participating in several national groups adding AAMI is putting out some various guidances and useful information.

B. Sterile Compounding
Covered previously.

C. CURES 2.0 Browser
Covered previously.

D. CHA Medication Safety Toolkit Plan
Covered previously.

VII. STANDING REPORTS

A. Board of Pharmacy - none at this time

B. CDPH - Ms. Lee provided an update on MERP surveys sharing that 10 have been completed and 1 remains. CDPH is aiming for full implementation in March 2016. Ms. Lee stated that most hospitals are aware of the CDPH website to complete the survey and shared the results from the pilot surveys.

C. CSHP - Ms. Sinclair was not on call.

D. CALNOC – Ms. Blankenship spoke about CALNOC celebrating their 20th year and that their annual conference would be in Monterey in October. Update on work with creating nurse sensitive measures for ambulatory care. Lots of hospitals participated in the development and plan to make a

decision on the new measures to launch by the end of first quarter of this year.

E. CAFH - Ms. Hall had to leave the call due to another commitment. .

VIII. PHARMACY LEGISLATE UPDATE

None at this time.

IX. OTHER BUSINESS

X. ARTICLES OF INTEREST

XI. NEXT MEETING

April 6, 2016
July 6, 2016
October 5, 2016

XII. ADJOURNMENT

Having no further business, the committee adjourned at 1.51 PM.

TO: Medication Safety Committee
FROM: Alyssa Keefe, Vice President Federal Regulatory Affairs
SUBJECT: Medicare Part B Prescription Drug Payment Model Proposed Rule

The Centers for Medicare & Medicaid Services (CMS) issued a proposed rule that would test new Medicare payment models for covered Part B prescription drugs provided in physician offices, hospital outpatient departments and certain drugs furnished through durable medical equipment. The model, which would run for five years, would be mandatory for all providers and suppliers furnishing and billing for Part B drugs.

For most drugs, Medicare currently pays the drug's average sales price (ASP) plus a 6 percent add-on payment. The proposed model would test whether lowering the add-on payment to 2.5 percent, plus a flat fee of $16.80 per drug per day, would push prescribing incentives toward lower-cost drugs. CMS proposes that the first phase of this model would be effective later this fall, or 60 days after the final rule's issue date. In addition, CMS proposes a second phase to test value-based purchasing (VBP) models for specific drugs, beginning no earlier than January 2017. CMS notes that phase II would likely take multiple years to fully implement and seeks comment on four potential designs of this model.

For phase I, CMS proposes to randomly place providers and suppliers in either a control group or a study group based on primary care service areas — of which there are more than 7,000 in the country and nearly 400 in California — but does not yet specify which areas will be in each testing group. CMS will continue to provide the ASP plus 6 percent to the control group and proposes to apply the ASP plus 2.5 percent, with a flat fee of $16.80 per drug per day, to the study group.

For phase II, CMS will divide the original participants into four groups and add a VBP design component. CMS proposes phase I will be budget neutral, but phase II — which includes VBP — would seek to achieve savings for the Medicare program. CMS estimates that for phase I, those hospitals paid ASP plus 2.5 percent would see an estimated decrease in payments of 0.3 percent, or about $7 million, but would see an overall decrease in drug spending of negative 2.3 percent.

CHA has issued a detailed summary of the proposed rule, prepared by Health Policy Alternatives, Inc., which is available at http://www.calhospital.org/part-b-drug-model-proposed-summary. A CMS fact sheet is attached to this memo.

CHA will host a member forum on the proposed rule on April 29 at 11 a.m. (PT) to provide an overview of the proposed rule and solicit member input for comments, which are due May 9. To register for the member forum, visit https://www.surveymonkey.com/r/partbdrugmodel.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 352-G
200 Independence Avenue, SW
Washington, DC 20201

CENTERS FOR MEDICARE & MEDICAID SERVICES
OFFICE OF COMMUNICATIONS

FACT SHEET

FOR IMMEDIATE RELEASE
March 8, 2016

Contact: CMS Media Relations
(202) 690-6145 | CMS Media Inquiries

CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries

Today, the Centers for Medicare & Medicaid Services (CMS) announced a proposed rule to test new models to improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care.

Today's proposal is part of the Administration's broader strategy to encourage better care, smarter spending, and healthier people by paying providers for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality.

CMS values public input and looks forward to continuing to work with stakeholders through the rulemaking process to maximize the value and learning from the proposed tests.

CMS is accepting comment on the proposed rule through May 9, 2016.

The proposed rule is available at https://www.federalregister.gov/public-inspection.

Prescription Drugs under Medicare Part B

Medicare Part B covers prescription drugs that are administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Drugs paid under Medicare Part B generally fall into three categories:

- Drugs furnished incident to a physician's service in the office or hospital outpatient settings,
- Drugs administered via a covered item of durable medical equipment, and
- Other categories of drugs explicitly identified in the law.

The proposed Medicare Part B Model would test new ways to support physicians and other clinicians as they choose the drug that is right for their patients. It is designed to test different physician and patient incentives to do two things: drive the prescribing of the most effective drugs, and test new payment approaches to reward positive patient outcomes.

Improving Incentives for the Best Clinical Care

Today, Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. CMS would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period. This test would begin in late 2016 (no earlier than 60 days after the rule is finalized).

The independent Medicare Payment Advisory Commission (MedPAC) described a similar approach in its June 2015 report to Congress.

CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate. CMS intends for the test to result in savings through changes in prescribers' behavior.

Physicians often can choose among several drugs to treat a patient, and the current Medicare Part B drug payment methodology can penalize doctors for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence. To illustrate the effect of this change, consider two drugs each prescribed for a similar condition, with similar patient outcomes, but with widely varying prices. The average sales price for Drug A is $5, and for Drug B it's $100. Today, Drug A is paid at $0.30 above the price of the drug and Drug B at $6.00. But under this proposal, Medicare would pay Drug A at $16.93 above the average sales price and Drug B at $19.30.

Illustrative Example: Drug Payment under Current Policy and Proposed Medicare Part B Drug Payment Model				
Average Sales Price (ASP) per Drug	**Current Add On Payment Rate (6% ASP)**	**Proposed Add On Payment Rate (2.5% ASP + $16.80)**	**Current Add On Payment Rate as a Percentage of ASP**	**Proposed Add On Payment Rate as a Percentage of ASP**
$5.00	$0.30	$16.93	6%	339%
$10.00	$0.60	$17.05	6%	171%
$100.00	$6.00	$19.30	6%	19%
$1,000.00	$60.00	$41.80	6%	4%

Value-based Purchasing Tools

Commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization successfully employ an array of tools including value-based

pricing and feedback on prescribing patterns to improve the value of drug payments. To produce a menu of value-based purchasing options, CMS reviewed the numerous tools used by entities that manage drug and health benefits and identified those that may be applicable to payment for Part B drugs with the same positive results. These tests would begin no sooner than January 1, 2017.

The proposed value-based pricing strategies include:

- **Discounting or eliminating patient cost-sharing.** Patients are often required to pay for a portion of their care through cost-sharing. This proposed test would decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.
- **Feedback on prescribing patterns and online decision support tools.** This proposed test would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications. Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.
- **Indications-based pricing.** This proposed test would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time. The goal is to pay for what works for patients.
- **Reference pricing.** This proposed model would test the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products.
- **Risk-sharing agreements based on outcomes.** This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Testing the Model to See What Works

CMS would conduct a complete evaluation of the proposed model, which would run for five years, with the goal of having the incentive and value-based purchasing tests fully operational during the last three years to evaluate changes and collect sufficient data.

As with other evaluations, the criteria for a successful model will be whether it reduces net Medicare spending, without limiting coverage or benefits, while maintaining or improving patient care. CMS plans to implement a concurrent real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures.

All providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model, although not all would be part of each test, as described below. This would help ensure that observed outcomes do not suffer from selection bias inherent in a voluntary participation model and would help test whether the model can ultimately be generalized to providers and suppliers billing for Part B drugs with various characteristics, such as different geographies, patient populations, and specialty mix. With limited exceptions, CMS is proposing to include all Part B drugs and biologicals in this model.

Providers and suppliers would be placed in a control or study groups based on Primary Care Service Areas, which are clusters of zip codes based upon patterns of Medicare Part B primary care services (excluding the state of Maryland where hospital outpatient departments operate under an all-payer model) as follows –

- No earlier than 60 days after the final rule is released to the public. CMS would begin to test the changes to Medicare Part B average sales price payments for drugs by creating a control group and a study group. One group would remain under the 6 percent add-on arrangement and the second would receive 2.5 percent of the average sales prices of a drug plus a flat $16.80 per drug per day payment.
- No earlier than January 2017. CMS would begin to test value-based purchasing arrangements by further dividing the average sales price test and control groups. The same set of value-based purchasing tools will be used in each of the two new study groups.

No earlier than 60 days after the final rule	No earlier than January 2017
106% Average Sales Price (ASP) (control)	106% ASP
	106% ASP with value-based purchasing tools
102.5% ASP + $16.80 flat per day per drug payment	102.5% ASP + $16.80
	102.5% ASP + $16.80 with value-based purchasing tools

This proposed model would not affect drug coverage or any other benefits, and beneficiaries will still have complete freedom of choice of doctors, hospitals, and other providers and suppliers.

CMS looks forward to public feedback on the proposed Medicare Part B Drug Payment Model.

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THE CALIFORNIA POISON CONTROL SYSTEM (CPCS)

Justin C. Lewis, PharmD, DABAT

California Poison Control System

Interim Director, Sacramento Division

Assistant Clinical Professor of Pharmacy, UCSF

California Poison Control System

- Four Statewide Answering Divisions
  - *University of California, Davis, Medical Center in Sacramento*
  - *San Francisco General Hospital in San Francisco*
  - *Children's Hospital Central California in Madera/Fresno*
  - *University of California, San Diego, Medical Center in San Diego*

- Managed by the University of California, San Francisco, School of Pharmacy

University of California
San Francisco
UCSF
School of Pharmacy
Department of Clinical Pharmacy

CALIFORNIA
POISON CONTROL
SYSTEM

California Poison Control System

- Toll-free Emergency Hotline
  - *Serves entire state of California 24/7*
  - *Single number for the entire state/nation*
    - 1-800-222-1222
  - *Automatic call distribution system*
  - *Interpreting services in over 100 languages.*

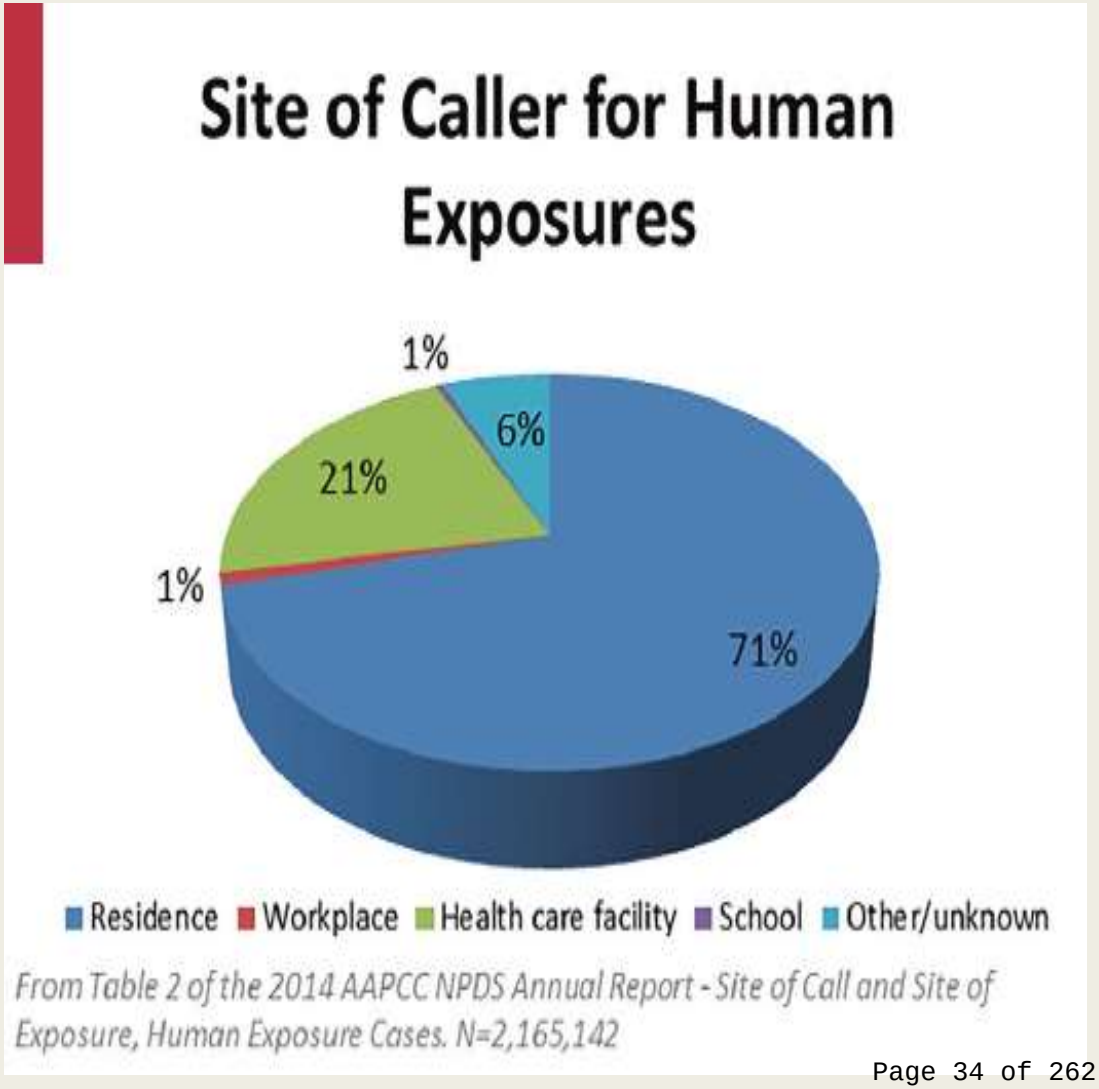

Oregon
Del Norte
Siskiyou
Modoc
Humboldt
Trinity
Shasta
Lassen
530
Tehama
Plumas
Mendocino
707
Glenn
Butte
Sierra
Nevada
Colusa
Yuba
Placer
Lake
Sutter
Yolo
El Dorado
Sonoma
Napa
Sacramento
916
Alpine
Amador
Solano
Calaveras
Marin
415
San Joaquin
Tuolumne
Contra Costa
510
San Francisco
925
Alameda
Stanislaus
Mariposa
San Mateo
650
Santa Clara
209
Merced
Santa Cruz
408
Madera
Fresno
831
San Benito
559
Tulare
Monterey
Kings
Pacific Ocean
661
Kern
760
San Luis Obispo
805
Santa Barbara
818
626
909
Los Angeles
213
323
Ventura
562
951
310/424
714
Riverside
Orange
949
442
San Diego
858
619
935
Imperial
Mexico
Nevada
Arizona
Inyo
Mono
CALIFORNIA POISON CONTROL SYSTEM
Sacramento Division
Fresno/Madera Division
San Francisco Division
San Diego Division
Hospital Coverage by Region
Preferred ACD Call Routing with Area Code Overlay
May 4, 2000 Update
Jeff Paterson, CPCS Central Office
CPCS Counties.psd

CPCS Staffing

- Certified Specialists in Poison Information (CSPIs)
  - *Clinical Pharmacists and Registered Nurses*
  - *Clinical Toxicologists (DABAT)*
- Poison Information Providers (PIPs)
  - *Pharmacy Technicians and Paramedics*
- Medical Toxicologist Backup
  - *Board Certified Physicians*

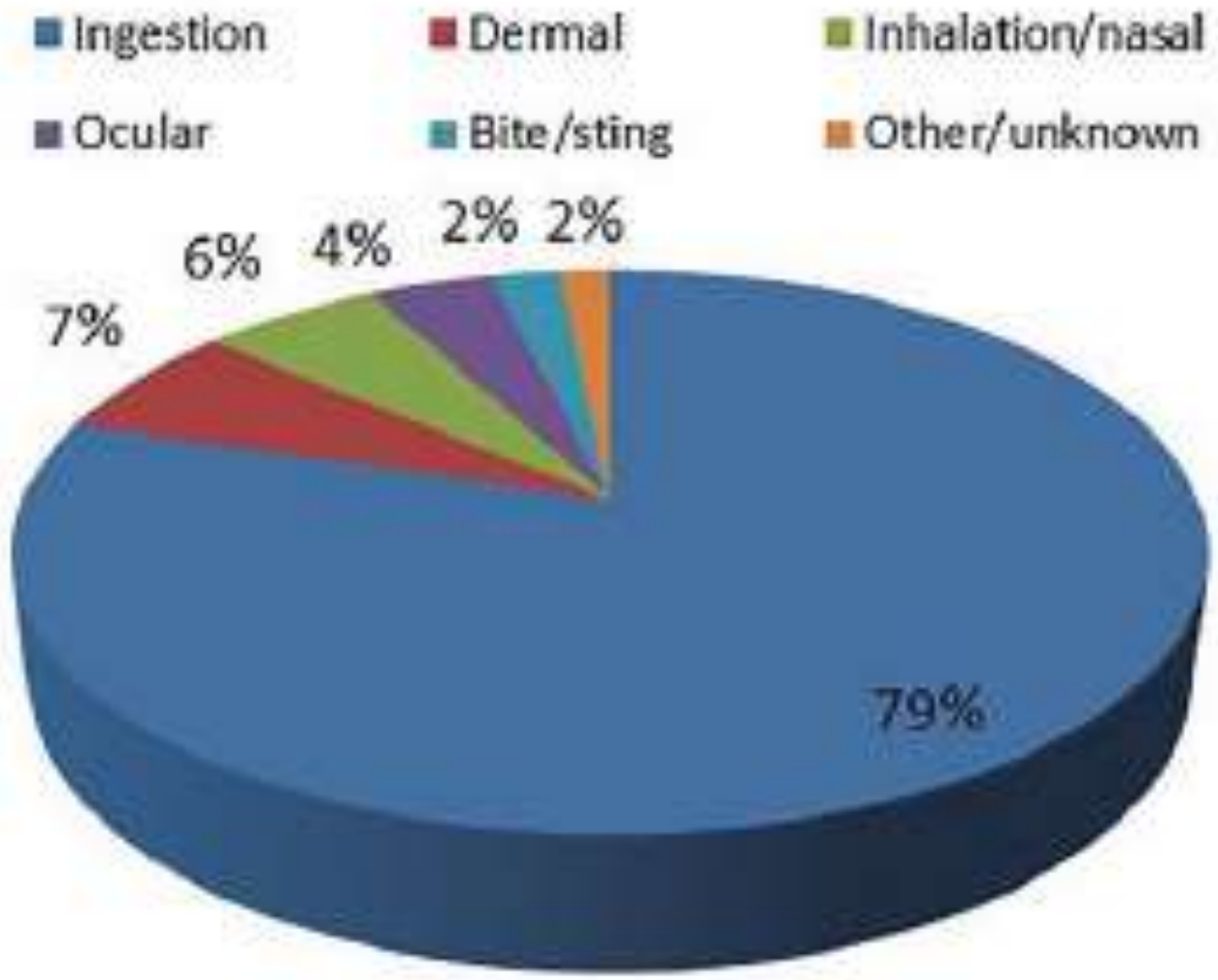
Types of Calls Managed

- **Exposure Calls**
  - *Calls from Home*
  - *Calls from Health Care Facilities*
  - *Calls from:*
    - Advice Nurses
    - Medical Assistants
    - Clinic / Urgent Care
    - School Nurses



From Table 2 of the 2014 AAPCC NPDS Annual Report - Site of Call and Site of Exposure, Human Exposure Cases. N=2,165,142

Route of Exposure



From Table 9 of the 2014 AAPCC NPDS Annual Report - Route of Exposure for Human Exposure Cases. N=2,277,006

Types of Calls Managed

- Information Calls
  - *Poison prevention information*
    - www.calpoison.org
  - *Drug information*
  - *Drug identification*
    - From the public
    - Pharmacies
    - Law enforcement

www.calpoison.org/order/Catalog1.htm

Apps | UCDHS Messaging W | impact 360 | Imported From IE | vpn | Reference ranges for | Box - UCSF

ABOUT | HEALTH PROFESSIONALS | EDUCATORS | YOU & YOUR FAMILY | PRESS | ORDER MATERIALS

1

2

CALIFORNIA RESIDENTS:

To order from our full range of FREE health education materials, please click here to visit our new online ordering page! This online ordering system allows you to view descriptions of our FREE health education materials, and order directly from us online. Shipping & Handling is still FREE, but remember if expedited shipping is requested, please provide a FedEx or UPS account number in the notes section during the check-out process. California Poison Control System appreciates your help in going green with this new ordering process.

www.calpoison.org

California Poison Control System

10-14-2014

ANTIDOTE CHART

(Suggested Stocking Level is based on dose to treat a single 100 kg patient for 8 hours and for 24 hours.* Large medical centers who may receive large numbers of patients in a single incident must stock larger amounts of antidotes or have an effective and efficient drug sharing/transfer procedure in place to rapidly obtain additional antidotal supplies.)

Generic/ Name Brand	Indications	Notes	Suggested Stocking Level	Access Priority
Atropine	Organophosphate/ carbamate insecticide poisoning and other cholinesterase inhibitors (eg, warfare agents); bradycardia induced by a variety of toxins	May require large amounts in severe cholinesterase inhibitor poisoning. Also stocked in the Strategic National Stockpile but will need supplies for first 48 hours. For mass casualties, local cache may provide supplies for first 48 hours coordinated by state department of health and emergency response system.	**8 Hours**: 100 mg **or** 13 vials (0.4 mg/mL, 20 mL each) **24 hours**: 200 mg **or** 26 vials (0.4 mg/mL, 20 mL each) *Use preservative free product*	**Immediate emergency department**
Antivenom, Crotalidae Polyvalent Immune-FAB(ovine)/ Cro-Fab®	Rattlesnake envenomation		**8 hours**: 18 vials **24 hours**: 36 vials	**Within 1 hour**
Antivenom, Black Widow Spider/ Antivenom (Latrodectus Mactans)®	Black Widow Spider envenomation	Equine base risk of allergic hypersensitivity.	**8 hours**: 1 vial **24 hours**: 1 vial	**Special Access- contact manufacturer- Merck (800)-672-6372**
BAL(Dimercaprol)/ BAL in oil 10%●	Heavy metal poisoning	IM administration only.	**8 hours**: 600 mg **or** 2 amps (100 mg/mL, 3 mL each) **24 hours**: 1800 mg **or** 6	**Within 1 hour**

Breakdown of Poison Calls in The Sacramento Division

- *Exposures 75% (150-187 calls per day)*
  - Humans 64%
  - Animals 11%

- *Information Calls 25% (50-62 calls per day)*
  - Drug identification calls 75%
  - All other information calls 25%

Facts About Poisonings

- Poisoning is the leading cause of unintentional injury hospitalization in the 1 - 4 year age group in children
- Children age 5 years and younger are involved in 51% of poisonings
- Most poison exposures occur at home
- With poison center assistance, *80%* of cases are managed at home

Value of Poison Centers

Poison Centers Save Money!

Dollars Spent

$1

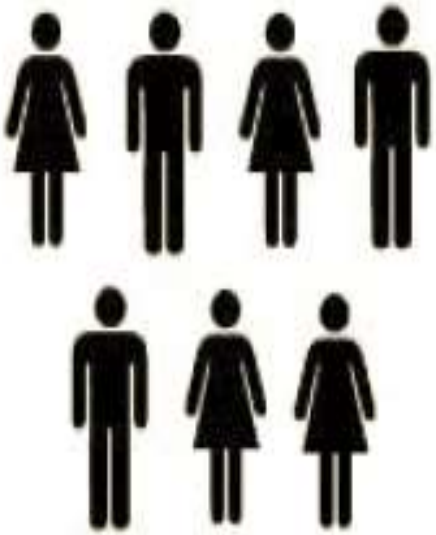
Dollars Saved

$13.39

Every dollar invested in the poison center system saves $13.39 in health care costs and lost productivity.

Is Poisoning an Issue?

More than 40,000 people die every year from unintentional poisonings.



Poison centers receive about 4 million calls every year. About 2.4 million are calls about poison exposures

Poisonings account for:

438,244 hospitalizations

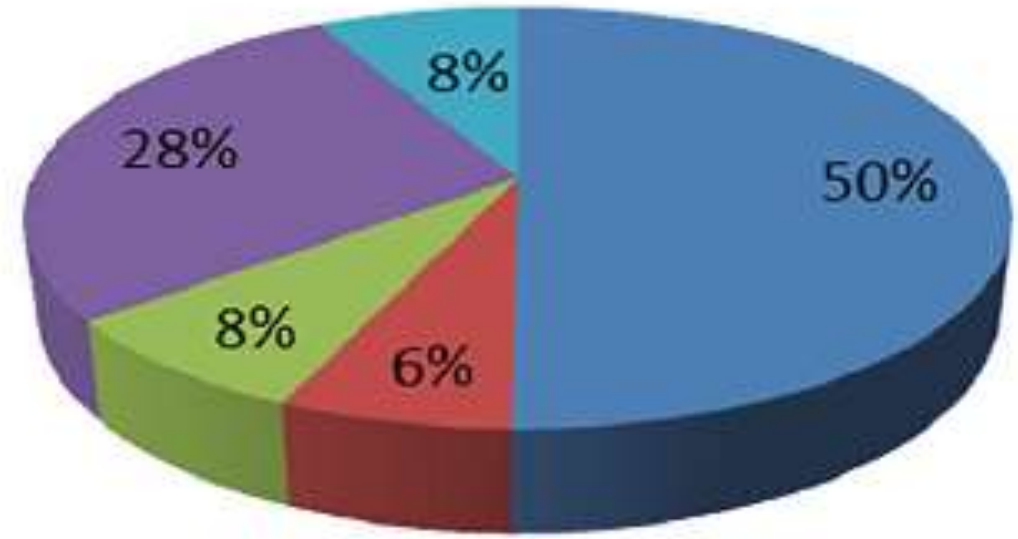
749,061 emergency room visits

1.4 million physician visits

What Happens During a Poison Center Call?

- Get a thorough and reliable history of the exposure
- Determine severity of poisoning exposure
- Triage: home management vs. hospital
- Recommend specific treatment advice
  - *For public and health providers*
- Follow-up on patient outcome

Age Distribution of Human Exposures



From Table 3A of the 2014 AAPCC NPDS Annual Report - Age and Gender Distribution of Human Exposures. Excludes unknown age categories. N=2,056,697

How Old are the Poison Victims?

< 1 year	5.3%
1 years	16.2%
2 years	16.6%
3 years	7.2%
4 years	3.4%
5 years	2.0%
Unknown child age	0.2%
Total children under 6 yrs	50.9%

Children will eat anything…

CALIFORNIA POISON CONTROL SYSTEM

It only takes a second…

Child Resistant ≠ Child Proof

Most Frequently Involved Substances

CALIFORNIA POISON CONTROL SYSTEM

Top 10 Exposure Substances by Age Category

All Human Exposures		Pediatric (≤ 5 years) Exposures		Adult (20 years +) Exposures	
Analgesics	13%	Cosmetics/Personal Care Products	15%	Analgesics	16%
Cosmetics/Personal Care Products	9%	Household Cleaning Substances	11%	Sedative/Hypnotics/Antipsychotics	14%
Household Cleaning Substances	9%	Analgesics	10%	Antidepressants	9%
Sedative/Hypnotics/Antipsychotics	7%	Foreign Bodies/Toys/Misc.	7%	Cardiovascular Drugs	8%
Antidepressants	5%	Topical Preparations	6%	Household Cleaning Substances	8%
Antihistamines	5%	Vitamins	5%	Alcohols	6%
Cardiovascular Drugs	5%	Antihistamines	4%	Anticonvulsants	5%
Foreign Bodies/Toys/Misc.	5%	Pesticides	3%	Pesticides	5%
Pesticides	4%	Gastrointestinal Preparations	3%	Bites and Envenomations	4%
Topical Preparations	4%	Plants	3%	Antihistamines	4%

Data from the 2014 AAPCC NPDS Annual Report

From Table 17A. N = 2,165,142 human exposures | *From Table 17C. N = 1,031,927 pediatric exposures* | *From Table 17D. N=825,009 adult exposures*

Substance categories causing the largest number of deaths

- Analgesics
- Sedative/hypnotics
- Antidepressants
- Stimulants/street drugs
- Cardiovascular drugs
- Alcohols
- Anticonvulsants
- Antihistamines
- Fumes/vapors
- Muscle relaxants
- Hormones
- Chemicals
- Unknown drugs
- Cleaning substances
- GI Preparations
- Pesticides
- Automotive products
- Antimicrobials

2014 AAPCC Annual Report

Poison Center Call Outcomes

- No symptoms develop in most home cases
- If symptoms do develop, they are usually minor
- Transport to a hospital is not needed
- Prevents unnecessary ambulance run
- Saves time of health care professionals so they can treat other more critical patients

Conclusions

- Most poisonings occur in children under the age of 6 years
- Most poisonings involve common household products
- Poison centers can manage most pediatric poisonings at home
- Most pediatric poisonings have good outcomes

Questions?

jlewis@calpoison.org

Talking Points

Key Facts About the Misleading State Government Drug Purchasing Initiative

Controversial activist Michael Weinstein is behind a misleading initiative proposed for California's November 2016 ballot. This initiative attempts to prohibit certain state agencies from entering into contracts for prescription drugs unless the contracted prices are the same or lower than the prices paid by the United States Department of Veterans Affairs (VA).

The proponent wants voters to believe the initiative would somehow significantly reduce prescription drug prices in California. In fact, if passed, it could increase costs and reduce the availability of prescription medicines for Californians, including veterans. Here are some key facts about what this initiative would and wouldn't do:

The measure only applies to a limited number of state programs, and would have negative impacts even on the programs it affects.

Even the proponent admits the measure would only apply to a limited number of state programs.

The ballot initiative does not apply to more than 34 million Californians, including 20 million Californians covered by private sector plans; 9.9 million patients covered by Medi-Cal Managed Care, representing approximately 80% of all Medi-Cal patients; and 1.5 million patients in Covered California, the state's new health insurance exchange under Obamacare.

Moreover, there's no guarantee that it would reduce costs. In fact, it could actually increase costs for these state programs.

Major implementation problems with the measure would cost taxpayers millions in bureaucracy, red tape and delays.

The measure contains absolutely no proposed language for how the stated requirements would be implemented.

It would require the state to make decisions based on confidential and proprietary information not presently available to the state. As recently noted by the state's independent Legislative Analyst's Office[1], many VA prescription drug prices are not publicly available, so it is unclear how California agencies could even obtain the basic information necessary to implement the measure.

Furthermore, the VA has consistently objected to efforts to expand its pricing model for veterans and military to other government programs, including state programs.

Additionally, some state agencies have no direct contractual relationship with drug manufacturers. Rather, prescription drug benefits are provided with other health care benefits negotiated through private HMOs or indirectly through purchasing agreements managed by Pharmacy Benefit Managers (PBMs). It is difficult to see how the state could implement this measure given the various private contractual relationships, and the number of private entities involved in state prescription drug purchasing and dispensing.

Given these significant implementation hurdles and the initiative's lack of any specificity for how it is to be implemented, this measure will clearly result in bureaucracy, red tape, litigation and delays.

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[1] http://www.scpr.org/news/2015/12/23/56415/will-calif-ballot-measure-lower-drug-prices/

The measure could increase health costs for veterans, active duty military, their families and retirees by undermining special price considerations provided to those who serve our country.

The VA and drug manufacturers negotiate special discounts for veterans, retirees, active duty military and their families, in recognition of their service to our country.

Under federal regulations, drug manufacturers extend discounts to the VA for innovative drugs and may also negotiate additional discounts for drugs to be included on the VA formulary. This is necessary for a company's drugs to be paid for under other federal health care programs, including Medicare and Medicaid. Manufacturers also provide additional discounts to support our military and veterans.

These discounted prices were never intended to be extended to larger populations and would not be sustainable if applied to additional programs in California or other states.

The US Department of Veterans Affairs and the US General Accounting Office[2] have warned that extending VA pricing to additional agencies could result in increased prices to the VA.

> ***"VA has been able to get substantial discounts from manufacturers... However, if manufacturers had to make these prices available to a larger market, they might be considerably less willing to continue to offer these prices"***[3]
>
> ***-US General Accounting Office testimony before Congress***

The measure could actually result in higher prescription drug spending by the state.

The measure could result in the state losing tens of millions of dollars in existing "state rebates" negotiated between drug manufacturers and the Department of Health Care Services Medi-Cal Fee for Service program.

That's because the measure does not actually prohibit the state from paying more than the VA price for prescription drugs.

Rather, it prohibits the state from entering into any "*agreements*" (contracts) with a drug manufacturer for greater than the VA price.

The only contract available to the state's Medi-Cal Fee for Service program to implement this measure is the current supplemental rebate program. Under the supplemental rebate program, drug manufacturers agree to provide additional discounts to Medi-Cal in exchange for inclusion on the state's preferred drug list.

To meet the measure's requirements, the state may ask manufacturers to provide a supplemental rebate in an amount that brings the total cost of the drug below the VA price. It is reasonable to expect that many manufacturers may be unwilling to enter into contracts under these terms. This would result in canceling the existing state rebates – at tremendous cost to the state.

The Medi-Cal Fee for Service program currently receives $233 million in supplemental rebates from drug manufacturers[4], $97.7 million of which benefits the state's General Fund.

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[2] Now named US Government Accountability Office

[3] Pharmaceutical Prices, and Draft Legislation on Homeless Veterans Programs and Issues Related to Persian Gulf War Illness: Hearing Before House Comm. Veterans' Affairs. 105th Congress 66. 87 (1997) pg. 5; Bernice Steinhardt, Director, Health Services Quality and Public Health Issues, General Accounting Office Opening Statement

[4] Amounts based on the fiscal 2016-17 supplemental rebates from the Medi-Cal November 2015 Local Assistance Estimate, Regular Policy Change #60

However, Medi-Cal is required by federal law to cover medically necessary outpatient drugs, regardless of a manufacturer's willingness to provide the state supplemental rebate. As a result, the state could have to purchase these drugs without the benefit of the state rebate – **therefore paying higher prices for those drugs than the state pays today**.

The measure could result in more physician paperwork and more hassle for patients, reducing or delaying access to prescription drugs.

This measure could limit the ability of doctors and patients to choose the best drug for each patient.

Under existing law, state agencies are required to consider both price AND access to medicines when negotiating contracts. The proposed measure would impose a new statutory requirement that the state government base drug purchases on VA prices alone - even, potentially, if it restricts patients' access to vitally needed medications.

As discussed above, the Medi-Cal Fee for Service program negotiates supplemental state rebates. These supplemental rebate contracts guarantee that a manufacturer's drug will be placed on the Medi-Cal List of Contract Drugs (List). Drugs not on the List require a Treatment Authorization Request (TAR), or prior authorization, to be prescribed by doctors and dispensed for patients.

Under the initiative, drug manufacturers may not enter into contracts at unsustainable prices. This would result in fewer drugs on the List, which would create a new prior authorization hurdle for doctors and their patients. Ultimately, this measure could delay or even eliminate patient access to needed medicines.

The measure could have a chilling effect on cutting edge medical research and cures.

If California and other states pass laws that set arbitrary price limits on innovative drugs, it would limit investments in the research and development of new drugs and cures.

Limiting investment could cause medical research facilities in California to lose funds for cutting edge research, resulting in lost California jobs and fewer cures.

According to the Tufts Center for the Study of Drug Development[5], on average, it costs pharmaceutical companies $2.6 billion to do the years of research and tests necessary to develop a single new drug.

> **"Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs."[6]**
>
> *- Darius Lakdawalla,*
> *Professor of Pharmaceutical Development and Regulatory Innovation,*
> *USC School of Pharmacy*

[5] PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing; November 18, 2014. Boston Mass.: CSDD. Accessed November 2015.

[6] http://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health

Michael Weinstein
[Residence Address Included on Elections Code Section 9001(b) Certificate of Residency Transmitted with January 30, 2015 Letter and Incorporated Herein by This Reference]

April 3, 2015

Ms. Ashley Johansson
Initiative Coordinator
Office of the Attorney General
1300 "I" Street, Suite 125
Sacramento, CA 95814-2919

Re: Request for Title and Summary for Proposed Initiative 15-0009 *as Amended*

Dear Ms. Johansson:

Pursuant to California Elections Code section 9002(b) (and particularly section 9002(b)(4) and section 15 with regard to timing), by this letter I respectfully submit amendments to the proposed statewide initiative measure entitled "The California Drug Price Relief Act" (the "measure") (Initiative 15-0009). These amendments are reasonably germane to the theme, purpose, and/or subject of the measure as originally proposed and therefore are encouraged and permitted by the recent Ballot Initiative Transparency Act (Senate Bill 1253).

Further, I request that the Attorney General prepare a circulating title and summary using the amended language submitted herewith and incorporated herein by this reference. For ease of reference, I include both a "clean" copy and a "red-lined" copy of the amended language.

Please direct all inquiries and correspondence regarding the measure to:

Bradley W. Hertz, Esq.
The Sutton Law Firm
22815 Ventura Boulevard, #405
Los Angeles, CA 91364
Tel: 818/593-2949
Fax: 818/593-2948
Email: bhertz@campaignlawyers.com

Thank you for your time and attention to this matter.

Sincerely,

Michael Weinstein
Proponent

15-0009 Amdt. # 1

The California Drug Price Relief Act

The People of the State of California do hereby ordain as follows:

Section 1. Title.

This Act shall be known and may be cited as "The California Drug Price Relief Act" (the "Act").

Section 2. Findings and Declarations.

The People of the State of California hereby find and declare all of the following:

(a) Prescription drug costs have been, and continue to be, one of the greatest drivers of rising health care costs in California.

(b) Nationally, prescription drug spending increased more than 800 percent between 1990 and 2013, making it one of the fastest growing segments of health care.

(c) Spending on specialty medications, such as those used to treat HIV/AIDS, Hepatitis C, and cancers, are rising faster than other types of medications. In 2014 alone, total spending on specialty medications increased by more than 23 percent.

(d) The pharmaceutical industry's practice of charging inflated drug prices has resulted in pharmaceutical company profits exceeding those of even the oil and investment banking industries.

(e) Inflated drug pricing has led to drug companies lavishing excessive pay on their executives.

(f) Excessively priced drugs continue to be an unnecessary burden on California taxpayers that ultimately results in cuts to health care services and providers for people in need.

(g) Although California has engaged in efforts to reduce prescription drug costs through rebates, drug manufacturers are still able to charge the State more than other government payers for the same medications, resulting in a dramatic imbalance that must be rectified.

(h) If California is able to pay the same prices for prescription drugs as the amounts paid by the United States Department of Veterans Affairs, it would result in significant savings to California and its taxpayers. This Act is necessary and appropriate to address these public concerns.

Section 3. Purposes and Intent.

The People of the State of California hereby declare the following purposes and intent in enacting this Act:

(a) To enable the State of California to pay the same prices for prescription drugs as the prices paid by the United States Department of Veterans Affairs, thus rectifying the imbalance among government payers.

(b) To enable significant cost savings to California and its taxpayers for prescription drugs, thus helping to stem the tide of rising health care costs in California.

(c) To provide for the Act's proper legal defense should it be adopted and thereafter challenged in court.

Section 4. The California Drug Price Relief Act shall be codified by adding the following Section to the California Welfare and Institutions Code:

Section 14105.32. Drug Pricing

(a) Notwithstanding any other provision of law and insofar as may be permissible under federal law, neither the State of California, nor any state administrative agency or other state entity, including, but not limited to, the California Department of Health Care Services, shall enter into any agreement with the manufacturer of any drug for the purchase of a prescribed drug unless the net cost of the drug, inclusive of cash discounts, free goods, volume discounts, rebates, or any other discounts or credits, as determined by the California Department of Health Care Services, is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs.

(b) The price ceiling described in subsection (a) above also shall apply to all programs where the State of California or any state administrative agency or other state entity is the ultimate payer for the drug, even if it did not purchase the drug directly. This includes, but is not limited to, California's Medi-Cal fee-for-service outpatient drug program, and California's AIDS Drug Assistance Program. In addition to agreements for any cash discounts, free goods, volume discounts, rebates, or any other discounts or credits already in place for these programs, the responsible state agency shall enter into additional agreements with drug manufacturers for further price reductions so that the net cost of the drug, as determined by the California Department of Health Care Services, is the same as or less than the lowest price paid for the same drug by the United States Department of Veterans Affairs. The requirements of this Section shall not be applicable to drugs purchased or procured, or rates developed, pursuant to or under any Medi-Cal managed care program.

(c) It is the intent of the People of the State of California that the State of California, and all state agencies and other state entities that enter into one or more agreements with the manufacturer of any drug for the purchase of prescribed drugs, shall implement this section in a timely manner, and to that end the State of California and all such state agencies and other state entities are required to implement and comply with this law no later than July 1, 2017.

(d) The State of California, and each and every state administrative agency or other state entity, may adopt rules and/or regulations to implement the provisions of this Section, and may seek any waivers of federal law, rule, and/or regulation necessary to implement the provisions of this Section.

Section 5. Liberal Construction.

This Act is an exercise of the public power of the People of the State of California for the protection of their health, safety, and welfare, and shall be liberally construed to effectuate its purposes.

Section 6. Conflicting Measures.

This Act is intended to be comprehensive. It is the intent of the People of the State of California that in the event this Act and one or more measures relating to the same subject shall appear on the same statewide ballot, the provisions of the other measure or measures shall be deemed to be in conflict with this Act. In the event that this Act receives a greater number of affirmative votes, the provisions of this Act shall prevail in their entirety, and all provisions of the other measure or measures shall be null and void.

Section 7. Proponent Accountability.

The People of the State of California hereby declare that the proponent of this Act should be held civilly liable in the event this Act is struck down, after passage, in whole or in part, by a court of law for being constitutionally or statutorily impermissible. Such a constitutionally or statutorily impermissible initiative is a misuse of taxpayer funds and electoral resources and the Act's proponent, as drafter of the Act, must be held accountable for such an occurrence.

In the event this Act, after passage, is struck down in a court of law, in whole or in part, as unconstitutional or statutorily invalid, and all avenues for appeal have been exhausted, the proponent shall pay a civil penalty of $10,000 to the General Fund of the State of California for failure to draft and sponsor a wholly constitutionally or statutorily permissible initiative law but shall have no other liability to any person or entity with respect to, related to, or arising from the Act. No party or entity may waive this civil penalty.

Section 8. Amendment and Repeal.

This Act may be amended to further its purposes by statute passed by a two-thirds (2/3) vote of the Legislature and signed by the Governor.

Section 9. Severability.

If any provision of this Act, or part thereof, or the applicability of any provision or part to any person or circumstances, is for any reason held to be invalid or unconstitutional, the remaining provisions and parts shall not be affected, but shall remain in full force and effect, and to this end the provisions and parts of this Act are severable. The voters hereby declare that this Act, and each portion and part, would have been adopted irrespective of whether any one or more provisions or parts are found to be invalid or unconstitutional.

Section 10. Legal Defense.

The People of the State of California desire that the Act, if approved by the voters, and thereafter challenged in court, be defended by the State of California. The People of the State of California, by enacting this Act, hereby declare that the proponent of this Act have a direct and personal stake in defending this Act from constitutional or statutory challenges to the Act's validity. In the event the Attorney General fails to defend this Act, or the Attorney General fails to appeal an adverse judgment against the constitutionality or statutory permissibly of this Act, in whole or in part, in any court of law, the Act's proponent shall be entitled to assert its direct and personal stake by defending the Act's validity in any court of law and shall be empowered by the citizens through this Act to act as agents of the citizens of the State of California subject to the following conditions: (1) The proponent shall not be considered an "at-will" employee of the State of California, but the Legislature shall have the authority to remove the proponent from their agency role by a majority vote of each house of the Legislature when "good cause" exists to do so, as that term is defined by California case law; (2) The proponent shall take the Oath of Office under California Constitution, Article XX, §3 as an employee of the State of California; (3) The proponent shall be subject to all fiduciary, ethical, and legal duties prescribed by law; and (4) The proponent shall be indemnified by the State of California for only reasonable expenses and other losses incurred by the proponent, as agent, in defending the validity of the challenged Act. The rate of indemnification shall be no more than the amount it would cost the State to perform the defense itself.

Section 11. Effective Date.

Except as otherwise provided herein, this Act shall become effective the day after its approval by the voters.

NO / MISLEADING Rx MEASURE

Why the Misleading Rx Measure Hurts Patients and Health Care Providers

Controversial activist Michael Weinstein is behind a misleading initiative proposed for California's November 2016 ballot. The measure's supposed "price ceiling" for state-purchased drugs is unworkable and unenforceable. This flawed initiative could actually increase prescription drug costs and reduce access to drugs for patients. Here's why:

The measure only applies to a limited number of state programs, and it would negatively impact those programs.

The ballot initiative **does not apply to more than 34 million** Californians, including 20 million Californians covered by private sector plans; 10.2 million patients covered by Medi-Cal Managed Care, representing nearly 80% of all Medi-Cal patients; and 1.5 million patients in Covered California, the state's new health insurance exchange under Obamacare.

Moreover, because of the flaws in the measure, it could actually increase costs for the state programs it does attempt to cover.

34 million Californians would be excluded from the measure

The measure could result in more physician paperwork and more hassle for patients, reducing or delaying access to prescription drugs.

California's Medi-Cal Fee for Service program has currently negotiated many agreements with drug manufacturers, where manufacturers provide "state rebates" in order to be included on the state's preferred drug list.

The Medi-Cal Fee for Service supplemental rebate contracts guarantee that a manufacturer's drug will be placed on the Medi-Cal List of Contract Drugs (List). Drugs not on the List require a Treatment Authorization Request (TAR), or prior authorization, to be prescribed by doctors and dispensed for patients.

One potential consequence of this measure could be that the state is forced to invalidate many existing supplemental rebate agreements it has with drug manufacturers if the net price of those agreements is higher than the VA price.

If the state was not able to maintain these current contracts with manufacturers, it would result in fewer drugs on the List, which would create a new prior authorization hurdle for doctors and their patients.

As a result, this measure could delay or even eliminate patient access to needed medicines and cost the state tens of millions of dollars in supplemental rebate agreements.

The measure could actually result in higher prescription drug costs for the state.

As discussed above, one potential consequence of this measure could be the invalidation of some or many existing state supplemental rebate agreements between the state and manufacturers if the net price isn't at or below the VA price. These rebates totaled $233 million last year, $97.7 million of which benefits the state's General Fund.[1]

3.18.16

Medi-Cal is required by federal law to cover medically necessary outpatient drugs, regardless of whether the state receives a supplemental rebate.

As a result, the state could be required to purchase these drugs without the benefit of the state rebate – **paying higher prices for those drugs than the state pays today.**

There is tremendous uncertainty around how it would be implemented.

The measure's language is legally flawed and at odds with how the sale and purchase of prescription drugs work.

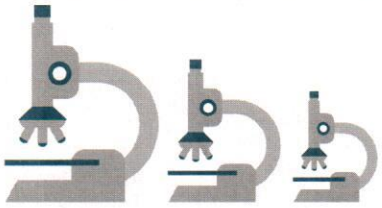
The measure, as written, does not compel drug manufacturers to sell their products to state agencies at certain prices. Rather, it seeks to prohibit the state from entering into "agreements" (contracts) with drug manufacturers above the Veterans Affairs price.

The measure contains absolutely no language for how it is to be implemented, and as recently noted by the state's independent Legislative Analyst's Office,[2] many VA prescription drug prices are not publicly available. So the state may not even be able to obtain the basic information it would need to begin to implement this measure.

The measure could have a chilling effect on cutting edge medical research and cures.

If California and other states pass laws that seek to extend VA prices on innovative drugs, it would reduce revenues and thus limit future investments in the research and development of new drugs and cures.

Limiting investment could cause medical research facilities in California to lose funds for cutting edge research, resulting in lost California jobs and fewer cures.



According to the Tufts Center for the Study of Drug Development,[3] on average, it costs pharmaceutical companies $2.6 billion to do the years of research and tests necessary to develop a single new drug.

"Drug price controls would stifle the introduction of valuable new drugs, because innovators will spend less pursuing new drugs." [4]

– Darius Lakdawalla
Professor of Pharmaceutical Development and Regulatory Innovation
USC School of Pharmacy

1 Amounts based on the fiscal 2016-17 supplemental rebates from the Medi-Cal November 2015 Local Assistance Estimate, Regular Policy Change #60

2 http://www.scpr.org/news/2015/12/23/56415/will-calif-ballot-measure-lower-drug-prices/

3 PhRMA adaptation based on Dimasi JA. Cost of developing a new drug. Tufts Center for the Study of Drug Development (CSDD). R&D Cost Study Briefing; November 18, 2014. Boston Mass.: CSDD. Accessed November 2015.

4 http://www.nytimes.com/roomfordebate/2015/09/23/should-the-government-impose-drug-price-controls/drug-price-controls-end-up-costing-patients-their-health

Paid for by Californians Against the Misleading Rx Measure, sponsored by Pharmaceutical Research and Manufacturers of America, with major funding by Pfizer, Inc., Johnson & Johnson and other companies.

Respiratory Monitoring of Patients Outside the ICU

Guidelines of Care Tool Kit

June 2014

VA SAN DIEGO HEALTHCARE SYSTEM

St. Joseph Health

CareFusion

Scripps
A World of Healing

SHARP

PALOMAR HEALTH

UC San Diego
HEALTH SYSTEM

Tri-City Medical Center

About This Document

The purpose of this tool kit is to provide evidenced-based recommendations and best practices on safe and effective assessment, monitoring, and intervention of patients at risk for unrecognized respiratory depression outside the ICU.

Intended Audience

This document is intended for health care practitioners and leaders involved in caring for adult and pediatric patients in hospital procedural and non-procedural areas.

Organization of This Document

This document is organized into the following sections: Introduction, improvement project method, respiratory monitoring care process, recommendations (by care process step), and approach and tools for implementing these respiratory monitoring guidelines.

Acknowledgement

The San Diego Patient Safety Council wishes to acknowledge each of the institutions listed on the cover that contributed the valuable time of its expert clinicians in the creation of this tool kit:

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Disclosure

This document is a collection of experience and learning from San Diego Patient Safety Council members incorporating referenced evidence-based literature and is not intended to be a comprehensive source for all relevant information. The San Diego Patient Safety Council and its collaborating organizations are not responsible for any claims or losses arising from the use of, or from any errors or omissions in this tool kit. It is important for hospitals to incorporate current state of monitoring technology as the organization transitions to these recommended future state $EtCO_2$ monitoring practices.

A financial grant provided by Cardinal Health Foundation was administered by the Hospital Association of San Diego and Imperial Counties for facilitation and tool kit writing activities. No payment was made to any council member. Sharp HealthCare Foundation Patient Safety Fund received compensation for the facilitator's time. CareFusion did not supervise, oversee, or influence any of the proceedings and does not accept any responsibility for the information contained in this document. SDPSC collaborating organizations are not responsible for any claims or losses arising from the use of or from any errors or omissions in this tool kit.

Introduction

Need for Change

There is growing evidence supporting what clinicians, providers, anesthesiologists, and pharmacists know is a serious patient safety risk: Postoperative patients are subjected to significant harm or death while receiving sedating medications without appropriate monitoring and intervention.[4,5] In fact, the Anesthesia Patient Safety Foundation (APSF) stated in 2011 that preventable deaths and anoxic brain injury from unrecognized opioid-related sedation and respiratory depression remain a serious and growing patient safety concern.[6] In 2012, The Joint Commission's Sentinel Event Alert Issue #49, identified these sentinel events, described their common underlying causes, and encouraged hospitals to prevent occurrences in the future.[7]

A number of contributing factors makes the risk of respiratory depression more commonplace in hospital procedural and non-procedural areas. These include:

- An increase in patients with obesity, sleep-disordered breathing, and Obstructive Sleep Apnea (OSA);
- The increased use of general anesthesia to manage patient pain and improve satisfaction;
- A growing reliance on Patient Controlled Analgesia (PCA) delivery systems on medical-surgical units;
- Unrealistic expectations for frequency of assessments by nurses on medical-surgical units;
- Inconsistent screening of and non-standard orders for at-risk, sedated patients outside the Intensive Care Unit (ICU); and
- Variability of respiratory monitoring practices between units and caregivers.

Incidents of permanent damage and death from opioid-induced respiratory depression are avoidable. An increase in End-Tidal Carbon Dioxide ($EtCO_2$) might be the only early clue to hypoventilation and potential respiratory compromise.[8] Continuous evaluation of $EtCO_2$ allows clinicians to actively monitor patients for inadequate ventilation before oxygen desaturation and harm occur. This technique enhances patient safety by providing continuous data on airway patency, ventilatory rate and quality, and circulatory sufficiency.[9]

"Leah was a healthy 11-year-old girl," says her mother, Lenore Alexander. "In the surgery, the doctors used an epidural anesthetic, which was left in place for postoperative pain management. I stayed with Leah that night and finally fell asleep after being up for more than 36 hours. When I woke up two hours later, I found Leah dead. My screams were what alerted hospital staff that something had happened to Leah."

"Leah was not monitored, neither by a pulse oximeter nor capnograph," says Ms. Alexander. "Had she been monitored, perhaps she would still be alive today."[10]

Leah's mother visited SDPSC members and shared her poignant account of the events leading up to her daughter's death. Lenore works to make continuous postoperative monitoring the law (Leah's Law) and help prevent other children suffering the same fate as Leah. ***San Diego Patient Safety Council dedicates this tool kit to Leah Coufal and her mother, Lenore Alexander.***

San Diego Patient Safety Council (SDPSC) endorses the APSF statement[6] that urges health care professionals to consider the potential safety value of using available technology to continuously monitor both oxygenation and ventilation in patients at risk for respiratory depression. A shared need exists for hospitals to set respiratory monitoring guidelines of care for patients located outside the ICU.

Performance Improvement Project

SDPSC consists of countywide acute care facilities with representati from across multiple disciplines, including nurses, pharmacists, providers, and respiratory care practitioners. Members reviewed literature, consulted institutional thought leaders, applied process improvement and facilitation tools, and shared experience and best practices to obtain consensus in building a comprehensive set of recommendations for safe and effective respiratory monitoring of patients in procedural and non-procedural hospital units. This tool l contains these recommendations along with the tools to assist hospitals in implementing the guidelines.

Goal

The goal of this SDPSC improvement project is to provide evidenced-based recommendations and best practices for safe and effective assessment and monitoring of patients at risk for respiratory depression outside the ICU, resulting in:

- Reduced sentinel events for patients
- Decreased adverse drug events
- Reduced liability and monetary fines
- Increased compliance with policies/procedures
- Increased patient satisfaction scores
- Reduced length of stays and transfers to higher levels of care, an
- Reduced pharmacy (e.g., less Narcan) and laboratory (e.g., less arterial blood gas) costs.

Scope

The scope of this SDPSC improvement project includes adult and pediatric (older than 14 years or hospital-defined) patients receivir any kind of sedating medication in procedural and non-procedural areas (e.g., emergency department, endoscopy, post anesthesia care units, interventional radiology, catheterization laboratory).

Respiratory monitoring defined in this tool kit includes surveillance of a patient's ventilation and oxygenation via these methods:

- Pulse Oximetry
- Capnography – Capgnometry and Transcutaneous monitoring
- Acoustic respiratory monitoring
- Multi-parameter monitoring
- Physical assessment.

This improvement project excludes:

- Monitoring during cardiopulmonary resuscitation
- Neonatal and pediatric patients
- Patients in the ICU
- Actively laboring women not at high risk
- Medication and sedation protocols (*see* previous SDPSC tool kit:

Method

SDPSC met as a group and in workgroups over one year using meeting facilitation techniques to reach consensus, devise assessment and monitoring standards, and document best practices.

Step 1: Created a Shared Vision

SDPSC members determined the improvement project charter: current state, need for change, problem statement, project scope, key stakeholders, elevator speech, goal, potential benefits, and tool kit deliverables.

Step 2: Established Workgroups

SDPSC's facilitator identified four workgroups: Obstructive Sleep Apnea; Non-Procedural/Central Nervous System Depressed; Procedural/Postop; and Technology/Cost Benefit Analysis. Members volunteered to participate in at least one of the workgroups and met outside the regular council meeting times to investigate current practices and identify recommendations.

Step 3: Discussed Findings

Each workgroup reviewed literature; gathered current in-house practices, protocols, order sets, and tools; and assembled and reported issues/barriers, recommendations, and next steps. Collaboratively, SDPSC members vetted workgroup recommendations against the following criteria: target-audience-focused, actionable, meaningful, practical, evidenced-based (if possible), and at appropriate level of detail.

Step 4: Documented Recommendations

Members' collective experience, literature review, and shared practices contributed to SDPSC discussions and decision-making. The facilitator polled each member using the "Fist to Five" technique to achieve consensus on processes, algorithms, recommendations, protocols, and other tool kit deliverables.

Care Process

SDPSC members developed a high-level flow diagram of a bedside caregiver's respiratory monitoring care process (Figure 1.0). This figure illustrates the problem-solving and decision-making process of assessing, planning, implementing, and evaluating respiratory status and care for the non-ICU patient:

1. **Assess for Risk Factors** – The bedside caregiver assesses the patient for the presence of identified risk factors using standardized and validated tools (*see* Step 1. Assess for Risk Factors section).

2. **Identify Risk Level** – The bedside caregiver categorizes and identifies the patient's risk level for respiratory depression as Very Low, Low to Moderate, Moderate to High, or Very High (*see* Step 2. Identify Risk Level section).

3. **Monitor?** – Knowing the patient's risk level, the bedside caregiver references the Respiratory Monitoring Risk Level table and determines if the patient should be monitored (*see* Step 3. Monitor? section).

4. **Determine Monitoring Method** – If the patient should be monitored and based on the patient's risk level, the bedside caregiver identifies how the patient should be monitored, including the monitoring type, frequency, location, etc. (*see* Step 4. Determine Monitoring section).

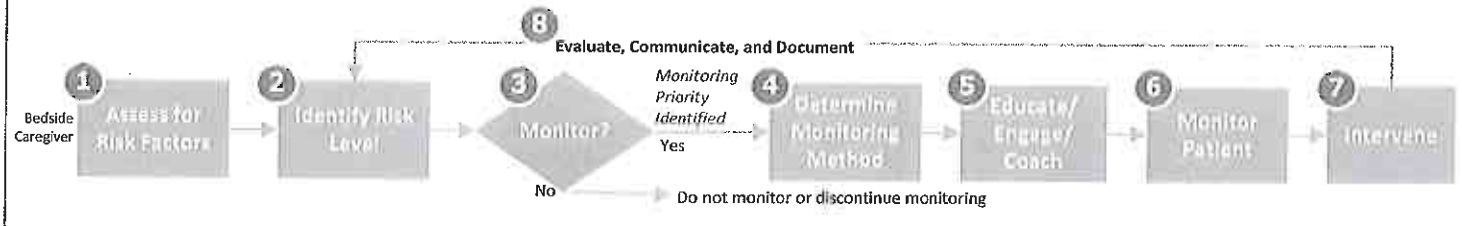
5. **Educate/Engage/Coach** – The bedside caregiver engages the patient and family/care partner by educating and coaching them on the monitoring device (e.g., proper use, alarms, warning signs), procedures, and expectations (*see* Step 5. Education/Engage/Coach section).

6. **Monitor Patient** – The bedside caregiver monitors the patient's oxygenation and ventilation for airway obstruction or respiratory depression (*see* Step. 6 Monitor Patient section).

7. **Intervene** – During the care process, in the event of an alarm or early indication of respiratory deterioration, the bedside caregiver evaluates monitored data and responds to the data as appropriate, (*see* Step 7. Intervene section).

8. **Document, Communicate, and Evaluate** – The bedside caregiver determines whether to continue monitoring of patient by periodically evaluating the patient's risk level with measurable criteria (by starting over at Step #1 of the Care Process (*see* Step 1. Assess for Risk Factors section).

Figure 1.0: Respiratory Monitoring Care Process Flow



CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Frequently Asked Questions about the
Drug Supply Chain Security Act of 2013

March 22, 2016

CHA's Medication Safety Committee has prepared a list of frequently asked questions on the U.S. Food and Drug Administration's (FDA) Drug Quality and Security Act (DSCSA), signed into law by President Obama on November 27, 2013. The FDA released its final guidance; as of July 1, 2015, all pharmacies are required to maintain and check for DSCSA information from wholesalers or direct vendors.

These FAQs are intended for hospital and health care providers' consideration as they evaluate current practices and develop specific programs, and are based on information obtained on the FDA website.

Brief History and Overview

What is the DSCSA?

The DSCSA is a ten-year comprehensive program to prevent suspect or illegitimate pharmaceutical products from entering the U.S. pharmaceutical supply chain. The law — which affects all pharmacies, manufacturers and wholesalers across the country — creates national requirements for tracing pharmaceuticals across the supply chain and includes provisions for product identification, tracing and verification, detection and response, notification, wholesaler licensing and third-party logistics provider licensing.

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

Yes. Originally known as ePedigree, the initiative is now commonly referred to as the DSCSA, Drug Quality Security Act or simply Track and Trace.

Which regulatory agency is most commonly associated with Track and Trace lawmaking and enforcement?

The U.S. Food and Drug Administration. Information can be found on the FDA website.

When does the DSCSA take effect?

The law went into effect for all dispensers — including pharmacies — on July 1, 2015, although the FDA has stated that enforcement officially began for dispensers on March 1, 2016. Full implementation of DSCSA will occur within the next 10 years, and will result in standardized, unit-level traceability from the manufacturer to the dispensing pharmacy or practitioner.

Why do we need to implement this program?

One of the biggest problems affecting today's health care industry is the increase of counterfeit drug sales. Global counterfeit drug sales currently range between $75 and $200 billion annually, meaning between 8 and 15 percent of all medicines sold around the world are counterfeit. The DSCSA will help prevent suspect or illegitimate products from entering the pharmaceutical supply chain by hospitals conducting business only with "authorized trading partners."

DSCSA Specifics

What is an "authorized trading partner"?

An authorized distribution center or pharmacy is one that is licensed under state law; a manufacturer is considered authorized if it holds an FDA establishment registration.

How do the new requirements change things?

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

What is meant by 3T information or data?

3T information includes transaction information, transaction history and transaction statement data, commonly referred to as TI/TH/TS.

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

Do all drugs require 3T information?

No — certain drug categories are out of scope, including over the counter drugs, compounded drugs and intravenous drugs.

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

No — internal transfers are not required to include 3T information at this time.

Is 3T data required when a pharmacy lends a product to an external hospital or pharmacy, or for return-in-kind transaction?

First, check to see if 3T data is required for the type of drug you are lending.
Assuming 3T information is required for the product, the lending of product to an outside organization is a change of ownership transaction requiring 3T data. Per the DSCSA, only products that are "fulfilling a specific patient need" are exempt from this requirement 3T data is required for all return-in-kind transactions, without exception.

Do non-sellable product returns require 3T information?

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

How do we handle suspected illegitimate products?

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

Are drug wholesalers exempt from providing Lot 3 information as part of the transaction information requirement?

Yes. Wholesale distributors, such as Amerisource Bergen, are exempt from providing Lot 3 information at this time. All other direct vendors, however, must produce Lot 3 information with their transaction information.

For how long must 3T data be stored?

The DSCSA states that all 3T information must be stored for six years.

In the event of an FDA audit, how much time will the pharmacy be given to produce 3T information?

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

Does FDA have standardized forms for transaction information, transaction history and transaction statements?

No — FDA has not established standardized forms for product tracing information, but has issued a draft guidance that establishes initial standards to help trading partners understand the methods available for exchanging product tracing information.

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

3T data is not required in the event of a public health emergency, but is required during drug shortages. The DSCSA states that "a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason."

Do drugs administered at skilled-nursing facilities require 3T information?

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

Do clinical trials or research drugs require 3T information?

Not at this time. Fully validating 3T data for clinical trial drugs is universally unfeasible due to high levels of variation, including: 1) lack of consistency in packing slips included with the drug; 2) missing key transaction information elements or unavailable transaction statements; 3) purposefully unlabeled drug names, particularly in cases of placebo or study drugs; and 4) new clinical trial drugs that are not fully FDA-approved and have not yet been assigned national drug code numbers.

Next Steps

What's next for the DSCSA requirements?

Additional regulations spanning 2017-2023 will require product lot-level traceability and eventually item-level serialization throughout the entire supply chain.

What additional items should hospitals and health systems consider?

Policies and procedures should be developed to ensure alignment with the new DSCSA; a system to assure policies and procedures are updated as the law matures over the next 10 years is highly recommended. Training requirements and additional resource needs should be considered with implementation of the DSCSA. The FDA represents the ultimate authority and providers are encouraged to visit its website for the most updated information.

What other resources are available on DSCSA?

The American Society of Health System Pharmacists has created a comprehensive DSCSA Resource Center.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

April 6, 2016

TO: CHA Medication Safety Committee

FROM: CHA Medication Safety Committee, Sterile Compounding Workgroup

RE: Proposed CHA Sterile Compounding Webinar

The CHA Sterile Compounding group has proposed the following draft for an upcoming member webinar to be held, tentatively, on Tuesday June 28, 2016.

Members: Jeannette Hanni, Candace Fong, Eddie Avedikian, Lynn Paulsen, Tom Jacobsen, Doug O'Brien, Steve Hinz, Christine Lowe, Andre Rossi, Sara Stevens, Glenn Gall, Grace Delizo, Ginny Herold/Amy Gutierrez

The proposed 2 hour webinar content and tentative speakers:

1. Introduction- Jeannette Hanni- cover issues such as New England Compounding Center and issues that have occurred both from the state and federal level -10 min
2. Federal USP Legislation – USP 797& USP 800- Doug O'Brien – 10 min
3. California BOP Sterile Compounding Regulations – Christine Acosta – 15 minutes
4. (Brief mention on Cal OSHA Antineoplastic Regulations)
5. California BOP Waiver Process and OSHPD approval process for structural change- Ginny Herold 15 minutes
6. Sterile Compounding Tools for Change – Lynn Paulsen, 30 minutes
7. Audience Participation- 20 min

Discussion Questions

1. Do we have all the topics covered we need?
2. Do we need to add an example hospital relative to "how to"?
3. Other comments??

Title 16. Board of Pharmacy

Second Modified Text

Changes made to the originally proposed language are shown by ~~double strike-through~~ for deleted language and double underline for added language. (The changes are also indicated in red font)

Changes made to the modified proposed language are shown by ~~double strike-through/bold underline~~ for deleted language and curved underline for added language. (The changes are also indicated in blue font)

To Amend § 1735 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735. Compounding in Licensed Pharmacies.

(a) "Compounding" means any of the following activities occurring in a licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug

(2) Altering the strength of a drug

(3) Combining components or active ingredients

(4) Preparing a compounded drug ~~product~~ preparation from chemicals or bulk drug substances

(b) "Compounding" does not include reconstitution of a drug pursuant to a manufacturer's direction(s) ~~for oral, rectal, topical, or injectable administration~~, nor does it include the sole act of tablet splitting or crushing, capsule opening, or the addition of flavoring agent(s) to enhance palatability.

~~(c) "Compounding" does not include, except in small quantities under limited circumstances as justified by a specific, documented, medical need, preparation of a compounded drug product that is commercially available in the marketplace or that is essentially a copy of a drug product that is commercially available in the marketplace~~

~~(d)~~(c) The parameters and requirements stated by ~~this~~ Article 4.5 (Section 1735 et seq.) apply

to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.1 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.1. Compounding Definitions.

(a) "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 ~~buffer area or~~ 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.

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

(c) "Biological Safety Cabinet (BSC)" means a ventilated cabinet for compounding~~ed~~ 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 ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI.

~~(d) "Buffer area" means an area which maintains segregation from the adjacent ante-area by means of specific pressure differentials. The principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the~~

~~buffer area across the line of demarcation into the ante-area. The displacement concept may not be used to maintain buffer area requirements for sterile compounds which originate from any ingredient that was at any time non-sterile, regardless of intervening sterilization of the ingredient, for hazardous compounds, or for chemotherapy compounds.~~

~~(c)~~(d) "Bulk drug substance" means any substance that, when used in the preparation of a compounded drug preparation, processing, or packaging of a drug, ~~becomes~~ is an active ingredient or a finished dosage form of the drug, but the term does not include any intermediate used in the synthesis of such substances.

~~(f)~~(e) "Cleanroom or clean area or buffer area" means a ~~physically separate~~ room or area ~~with walls and doors~~ with HEPA-filtered air that provides ~~at least an~~ ISO Class 7 or better air quality where the primary engineering control (PEC) is physically located.

(1) For nonhazardous compounding a ~~A minimum differential~~ 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 ~~at least~~ 0.01 to 0.03 inches of water column relative to all adjacent spaces is required.

~~(h)~~(f) "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 ~~volatile~~ hazardous drugs are prepared, the exhaust air from the isolator ~~should~~ shall be appropriately removed by properly designed external building ventilation. This external venting should be dedicated to one BSC or CACI. Air within the CACI shall not be re-circulated nor turbulent.

(g) "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 re-circulated nor turbulent.

~~(i)~~(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35~~-6~~ degrees to 46~~-4~~ degrees F).

~~(j)~~(i) "Controlled freezer temperature" means -25 degrees to -10 degrees C (-13 degrees to 14 degrees F) or at a range otherwise specified by the pharmaceutical manufacturer(s) for that product.

~~(k)~~(j) "Controlled room temperature" means 20 degrees to 25 degrees C (68 degrees to 77 degrees F).

~~(l)~~(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

~~(m)~~(l) "Daily" means occurring every day ~~that a~~ the pharmacy is operating, except when daily monitoring of refrigerator and freezer temperature are required, then daily means every 24 hours.

~~(n)~~(m) "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.

~~(n)~~~~(o)~~(n) "Dosage unit" means a quantity sufficient for one administration to one patient~~,~~ ~~except that for self-administered ophthalmic drops, a quantity sufficient for 30 days or less shall be considered one dosage unit~~.

~~(a)~~~~(o)~~~~(p)~~(o) "Equipment" means items that must be calibrated, maintained or periodically certified.

~~(p)~~~~(q)~~(p) "First air" means the air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

~~(q)~~~~(r)~~(q) "Gloved fingertip sampling" means a process whereby compounding personnel lightly press each fingertip and thumb of each hand onto appropriate growth media, which are then incubated at a temperature and for a time period conducive to multiplication of microorganisms, and then examined for growth of microorganisms.

~~(r)~~~~(s)~~(r) "Hazardous" 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.

~~(b)~~~~(c)~~~~(t)~~(s) "Integrity" means retention of potency until the ~~expiration~~ beyond use date ~~noted~~ provided on the label, so long as the preparation is stored and handled according to the label directions ~~after it is dispensed~~.

~~(t)~~~~(u)~~(t) "Lot" means one or more compounded drug preparation(s) prepared during one uninterrupted continuous cycle of compounding from one or more common active ingredient(s).

~~(u)~~~~(v)~~(u) "Media-fill test" means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby ~~that mimics~~ compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. ~~to demonstrate the competency of compounding personnel in aseptic techniques.~~ The media-fill test must mimic the most complex compounding procedures performed by the pharmacy ~~that aseptic techniques of compounding personnel or processes routinely employed do not result in microbial contamination. To be valid, media-fill tests must be conducted on both the most routine and the most challenging compounding procedures performed~~.

~~(v)~~~~(w)~~(v) "Non-sterile-to-sterile batch" means any compounded drug preparation containing two (2) or more dosage units with any ingredient that was at any time non-sterile, regardless of intervening sterilization of that ingredient.

~~(w)~~~~(x)~~(w) "Parenteral" means a preparation of drugs administered in a manner other than through the digestive tract. ~~This includes, but is not limited to, injection through one or more layers of skin, administration into the eye, and by inhalation.~~ It does not include topical, sublingual, rectal or buccal routes of administration.

~~(x)~~~~(y)~~(x) "Personal protective equipment" means clothing or devices that protect the employee from exposure to ~~drug products~~ 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.

~~(c)~~~~(y)~~~~(z)~~(y) "Potency" means active ingredient strength within +/- 10% (or the range specified in USP37-NF32, 37th Revision, Through 2nd Supplement Effective December 1, 2014) of the labeled amount. Sterile injectable products compounded solely from commercially manufactured sterile pharmaceutical products in a health care facility licensed under section 1250 of the Health and Safety Code are exempt from this definition. For those exempt, the range ~~may~~ shall be calculated and defined in the master formula.

~~(z)~~~~(aa)~~(z) "Preparation" means a drug or nutrient compounded in a licensed pharmacy; the preparation may or may not be sterile.

~~(aa)~~~~(ab)~~(aa) "Prescriber's office" or "prescriber office" means an office or suite of offices in which a prescriber regularly sees patients for outpatient diagnosis and treatment. This definition does not include any hospital, pharmacy, or other facility, whether or not separately licensed, that may be affiliated with, adjacent to, or co-owned by, the prescriber's practice environment.

~~(ab)~~~~(ac)~~(ab) "Primary Engineering Control (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 ~~the exposure of critical sites when~~ 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.

~~(ac)~~~~(ad)~~(ac) "Process validation" means demonstrating that when a process is repeated within specified limits, the process will consistently produce preparations complying with predetermined requirements. If any aspect of the process is changed, the process would need to be revalidated.

~~(ad)~~~~(ae)~~(ad) "Product" means a commercially manufactured drug or nutrient evaluated for safety and efficacy by the FDA.

~~(d)~~~~(ae)~~~~(af)~~(ae) "Quality" means the absence of harmful levels of contaminants, including filth, putrid, or decomposed substances, ~~and~~ the absence of active ingredients other than those listed on the label, and the absence of inactive ingredients other than those listed on the master formula ~~record~~ document.

~~(af)~~~~(ag)~~(af) "Segregated sterile compounding area" 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 three feet of a PEC. The segregated sterile compounding area shall be restricted to preparing ~~non-hazardous~~ of sterile-to-sterile compounded preparations.

(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 its meeting the requirements listed in section 1751.4(f)(1)-(3), the assigned BUD shall comply with section 1751.8(a-b) or (d) ~~(b)~~.

~~(e)~~(ag) "Strength" means amount of active ingredient per unit of a compounded drug ~~product~~ preparation.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.2 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.2. Compounding Limitations and Requirements; Self-Assessment.

(a) Except as specified in (b) and (c), no drug ~~product~~ preparation shall be compounded prior to receipt by a pharmacy of a valid prescription for an individual patient where the prescriber has approved use of a compounded drug ~~product~~ preparation either orally or in writing. Where approval is given orally, that approval shall be noted on the prescription prior to compounding.

(b) A pharmacy may prepare and store a limited quantity of a compounded drug ~~product~~ preparation in advance of receipt of a patient-specific prescription where and solely in such quantity as is necessary to ensure continuity of care for an identified population of patients of the pharmacy based on a documented history of prescriptions for that patient population.

(c) A "reasonable quantity" ~~as used in~~ that may be furnished to a prescriber for office use by the prescriber as authorized by Business and Professions Code section 4052, subdivision (a)(1), means that amount of compounded drug ~~product~~ preparation that:

(1) ~~I~~Is ordered by the prescriber or the prescriber's agent ~~and paid for by the prescriber at a price that fairly reflects the fair market value of each drug preparation,~~ using a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient that is sufficient for ~~either~~ office administration ~~or application to patients in the prescriber's office, or for distribution of not more than~~ ~~or~~ ~~furnishing of a 72-hour supply~~ ~~to the prescriber's patients, as estimated by the prescriber~~; and

(2) Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; and

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or for furnishing of not more than ~~a 72-hour supply for human medical practices, or~~ a 120-hour

supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

~~(2)~~(4) That the pharmacist has a credible basis for concluding it is a reasonable quantity for office use ~~the quantity provided for office use is reasonable~~ considering the intended use of the compounded medication and the nature of the prescriber's practice; and

~~(3)~~ (5) ~~for~~ With regard to any individual prescriber to whom the pharmacy furnishes, and with regard to ~~for~~ all prescribers to whom the pharmacy furnishes, ~~taken as a whole,~~ is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug ~~product~~ preparation; and

(6) Does not exceed an amount the pharmacy can reasonably and safely compound.

(d) No pharmacy or pharmacist shall compound a drug preparation that:

(1) Is classified by the FDA as demonstrably difficult to compound;

(2) Appears on an FDA list of drugs that have been withdrawn or removed from the market because such drugs or components of such drugs have been found to be unsafe or not effective; or

(3) Is a copy or essentially a copy of one or more commercially available drug products, unless that drug product appears on an ASHP (American Society of Health-System Pharmacists) or FDA list of drugs that are in short supply at the time of compounding and at the time of dispense, and the compounding of that drug preparation is justified by a specific, documented medical need made known to the pharmacist prior to compounding. The pharmacy shall retain a copy of the documentation of the shortage and the specific medical need in the pharmacy records for three years from the date of receipt of the documentation.

~~(d)~~(e) A drug ~~product~~ preparation shall not be compounded until the pharmacy has first prepared a written master formula ~~record~~ document that includes at least the following elements:

(1) Active ingredients to be used.

(2) Equipment to be used.

(3) ~~Expiration dating requirements.~~ The maximum allowable beyond use date for the preparation, and the rationale or reference source justifying its determination.

(4) Inactive ingredients to be used.

(5) ~~Process and/or procedure~~ Specific and essential compounding steps used to prepare the drug.

(6) Quality reviews required at each step in preparation of the drug.

(7) Post-compounding process or procedures required, if any.

(8) Instructions for storage and handling of the compounded drug preparation.

~~(e)~~(f) Where a pharmacy does not routinely compound a particular drug ~~product~~ preparation, the master formula record for that ~~product~~ preparation may be recorded on the prescription document itself.

~~(f)~~(g) The pharmacist performing or supervising compounding is responsible for the integrity, potency, quality, and labeled strength of a compounded drug ~~product~~ preparation until ~~it~~ the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed.

~~(g)~~(h) All chemicals, bulk drug substances, drug products, and other components used for drug compounding shall be stored and used according to compendia~~l~~ and other applicable requirements to maintain their integrity, potency, quality, and labeled strength.

~~(h)~~(i) Every compounded drug ~~product~~ preparation shall be given a~~n expiration~~ beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, ~~.~~ and determined based on the professional judgment of the pharmacist performing or supervising the compounding. ~~, in the professional judgment of the pharmacist performing or supervising the compounding, it should not be used, stored, transported, or administration begun.~~

(1) For non-sterile compounded drug preparation(s), the beyond use date ~~This "beyond use date" of the compounded drug product preparation~~ shall not exceed any of the following: ~~180 days from preparation or~~

(A) the shortest expiration date or beyond use date of any ~~component~~ ingredient in the compounded drug ~~product~~ preparation, ~~nor shall it exceed 180 days~~

(B) the chemical stability of any one ingredient in the compounded drug preparation;

(C) the chemical stability of the combination of all ingredients in the compounded drug preparation,

(D) 180 days for non-aqueous formulations,

(E) 14 days for water-containing oral formulations, and

(F) 30 days for water-containing topical/dermal and mucosal liquid and semisolid formulations.

~~from preparation~~

(2) For sterile compounded drug preparations, the beyond use date shall not exceed any of the following:

(A) The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug product preparation,

(B) The chemical stability of any one ingredient in the sterile compounded drug preparation,

(C) The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

(D) The beyond use date assigned for sterility in section 1751.8.

(3) Extension of a beyond use date is only allowable when supported by the following:

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

~~unless a longer later date is supported by stability studies of~~

(4) In addition to the requirements of paragraph three (3), the ~~finished~~ drugs or compounded drug ~~products~~ preparations tested and studied shall be ~~using~~ ~~the same~~ identical ~~components~~ in ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation.

(5) Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist.

~~(i)~~(j) The pharmacist performing or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug ~~product~~ preparation.

~~(j)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the

pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed by the board (Incorporated by reference is "Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment" Form 17M-39 Rev. 02/12.) as required by Section 1715 of Title 16, Division 17, of the California Code of Regulations. That form contains a first section applicable to all compounding, and a second section applicable to sterile injectable compounding. The first section must be completed by the pharmacist-in-charge before any compounding is performed in the pharmacy. The second section must be completed by the pharmacist-in-charge before any sterile ~~injectable~~ compounding is performed in the pharmacy. The applicable sections of the self-assessment shall subsequently be completed before July 1 of each odd-numbered year, within 30 days of the start date of a new pharmacist-in-charge or change of location, and within 30 days of the issuance of a new pharmacy license. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

~~(k)~~(l) Packages of ingredients, both active and inactive, that lack a supplier's expiration date are subject to the following limitations:

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy. ~~unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions, and~~

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy~~, unless either appropriate and documented inspection or analytical testing indicates that the ingredient has retained its purity and quality for use in compounded drug preparations, considering the container in which it is packaged and the storage conditions~~.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code, Sections 1735, 1735.1, 1735.8, and 1751.1-1751.8 of Title 16, Division 17, of the California Code of Regulations.

To Amend § 1735.3 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.3. ~~Records~~ Recordkeeping ~~of~~ for Compounded Drug ~~Products~~ Preparations.

(a) For each compounded drug ~~product~~ preparation, ~~the~~ pharmacy records shall include:

(1) The master formula ~~record~~ document.

(2) A compounding log consisting of a single document containing all of the following: ~~The compounding document shall include the following:~~

(A) Name and Strength of the compounded drug preparation.

~~(2)~~(A)(B) The date the drug ~~product~~ preparation was compounded.

~~(3)~~(B)(C) The identity of ~~the~~ any pharmacy personnel ~~who compounded the~~ engaged in compounding the drug ~~product~~ preparation.

~~(4)~~(C)(D) The identity of the pharmacist reviewing the final drug ~~product~~ preparation.

~~(5)~~(D)(E) The quantity of each ~~component~~ ingredient used in compounding the drug ~~product~~ preparation.

~~(6)~~(E)(F) The manufacturer, expiration date and lot number of each component. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. If the manufacturer does not supply an expiration date for any component, the records shall include the date of receipt of the component in the pharmacy, and the limitations of section 1735.2, subdivision (k) shall apply.

(i) Exempt from the requirements in this paragraph (1735.3(a)(2)(E)) are sterile ~~products~~ preparations compounded ~~on a one-time basis~~ in a single lot for administration within seventy-two (72) hours to a~~n in~~patient in a health care facility licensed under section 1250 of the Health and Safety Code and stored in accordance with standards for "Redispensed CSPs" found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (~~35~~ 37th Revision, Effective ~~May~~ December 1, ~~2012~~ 2014), hereby incorporated by reference~~, to an inpatient in a health care facility licensed under section 1250 of the Health and Safety Code~~.

~~(7)~~(F)(G) A pharmacy-assigned unique reference or lot number for the compounded drug ~~product~~ preparation.

~~(8)~~(G)(H) The ~~expiration~~ beyond use date or beyond use date and time of the final compounded drug ~~product~~ preparation, expressed in the compounding ~~record~~ document in a standard date and time format.

~~(9)~~(H)(I) The final quantity or amount of drug ~~product~~ preparation compounded for dispensing.

(J) Documentation of quality reviews and required post-compounding process and procedures.

(b) Pharmacies shall maintain records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, drug products, and components used in compounding.

(c) Active ingredients shall be obtained from a supplier registered with the Food and Drug Administration (FDA). All other ~~C~~chemicals, bulk drug substances, and drug products~~, and components~~ used to compound drug ~~products~~ preparations shall be obtained, whenever possible, from ~~reliable~~ FDA- registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products~~, and components~~ used in compounding. Certificates of purity or analysis are not required for drug products that are approved by the FDA. Any certificates of purity or analysis acquired by the pharmacy shall be matched to the corresponding ~~product~~ chemical, bulk drug substance, or drug products received.

(d) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was ~~created~~ last in effect. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1735.4 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.4. Labeling of Compounded Drug ~~Products~~ Preparations.

(a) Each compounded drug preparation shall be affixed with a container label prior to dispensing that contains at least:

(1) Name of the compounding pharmacy and dispensing pharmacy (if different);

(2) Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed IV solutions, the intravenous solution utilized shall be included;

(3) Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;

(4) The beyond use date for the drug preparation;

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

~~In addition to the labeling information required under Business and Professions Code section 4076 and under California Code of Regulations section 1707.5, the label of a compounded drug product preparation shall contain the generic or brand name(s) of the principal all active ingredient(s)~~.

(b) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include on the label the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5.

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient. Exempt from the requirements of this paragraph are those sterile drug preparations compounded within a health care facility solely for administration, by a licensed health care professional, to a patient of the facility. To be treated as such, the "health care facility" must be licensed under Health and Safety Code section 1250.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a

statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration beyond use date and shall not be subject to minimum font size requirements.~~

(d) Prior to dispensing drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a), (b), and (c) shall be labeled with at least the name of the compounding pharmacy and dispensing pharmacy, if different, the name(s) of the active ingredient(s), strength, volume or weight of the preparation, pharmacy reference or lot number, and beyond use date, and shall not be subject to minimum font size requirements. Once dispensed, outer packaging must comply with 1735.4(a) – (c).

(e) All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly."

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1735.5 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.5. Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding shall maintain ~~a~~ written policy~~y~~ies and procedures ~~manual~~ for compounding that establishes procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for

disciplinary action.

(b) The policy~~y~~ies and procedures ~~manual~~ shall be reviewed and such review shall be documented on an annual basis by the pharmacist-in-charge. ~~and~~ The policies and procedures ~~manual~~ shall be updated whenever changes in policies and procedures ~~processes~~ are implemented.

(c) The policy~~y~~ies and procedures ~~manual~~ shall include at least the following:

(1) Procedures for notifying staff assigned to compounding duties of any changes in ~~processes or to the~~ policy~~y~~ies or procedures ~~manual~~.

(2) ~~Documentation of a~~ A written plan for recall of a dispensed compounded drug ~~product~~ preparation where subsequent ~~verification~~ information demonstrates the potential for adverse effects with continued use ~~of a compounded drug product~~. The plan shall ensure that all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).

(3) ~~The p~~Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(4) ~~The p~~Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.

(~~4~~5) Documentation of the methodology used to ~~test~~ validate integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations. The methodology must be appropriate to compounded drug preparations.

(~~5~~6) Documentation of the methodology and rationale or reference source used to determine appropriate ~~expiration~~ beyond use dates for compounded drug ~~products~~ preparations.

(7) Dates and signatures reflecting all annual reviews of the policies and procedures ~~manual~~ by the pharmacist-in-charge.

(8) Dates and signatures accompanying any revisions to the policies and procedures ~~manual~~ approved by the pharmacist-in-charge.

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and

daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

(10) Policies and procedures regarding ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.

(11) Policies and procedures for proper garbing when compounding with hazardous products. This shall include when to utilize double shoe covers.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, ~~and~~ 4127, and 4301, Business and Professions Code.

To Amend § 1735.6 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.6. Compounding Facilities and Equipment.

(a) Any pharmacy engaged in compounding shall maintain written documentation regarding the facilities and equipment necessary for safe and accurate compounding of ~~ed~~ compounded drug ~~products~~ 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 ~~products~~ preparations shall be stored, used, ~~and~~ maintained, and cleaned in accordance with manufacturers' specifications.

(c) Any equipment that weighs, measures, or transfers ingredients used to compound drug ~~products~~ 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 writing~~ 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 ~~12~~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 ~~at least~~ 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 [insert effective date upon adoption] 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.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code.

Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.7 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.7. Training of Compounding Staff.

(a) A pharmacy engaged in compounding shall maintain documentation ~~that demonstrates~~ demonstrating that personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation ~~that~~ demonstrating that all personnel involved in compounding ~~was~~ are trained in all aspects of

policies and procedures. This training shall include but is not limited to support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacist and all others whose jobs are related to the ~~sterile~~ compounding process. ~~Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding. Additionally, documentation demonstrating that staff have been trained on all policies and procedures shall be maintained.~~

(b) The pharmacy shall develop and maintain an ongoing competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug ~~product~~ preparation.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1735.8 in Article 4.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1735.8. Compounding Quality Assurance.

(a) Any pharmacy engaged in compounding shall maintain, as part of its written policies and procedures, a written quality assurance plan designed to monitor and ensure the integrity, potency, quality, and labeled strength of compounded drug ~~products~~ preparations.

(b) The quality assurance plan shall include written procedures for verification, monitoring, and review of the adequacy of the compounding processes and shall also include written documentation of review of those processes by qualified pharmacy personnel.

(c) The quality assurance plan shall include written standards for qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality, and labeled

strength, including the frequency of testing~~, analysis of compounded drug products preparations~~. All qualitative and quantitative analysis reports for compounded drug ~~products~~ preparations shall be retained by the pharmacy and ~~collated~~ maintained along with the compounding log ~~record document~~ and master formula document. The quality assurance plan shall include a schedule for routine testing and analysis of specified compounded drug preparations to ensure integrity, potency, quality, and labeled strength, on at least an annual basis.

(d) The quality assurance plan shall include a written procedure for scheduled action in the event any compounded drug ~~product~~ preparation is ever discovered to be ~~below~~ outside minimum standards for integrity, potency, quality, or labeled strength.

(e) The quality assurance plan shall include a written procedure for responding to out-of-range temperature variations within the pharmacy ~~or~~ and within patient care areas of a hospital where furnished drug is returned for redispensing.

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code.

To Amend § 1751 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 7. Sterile ~~Injectable~~ Compounding

1751. Sterile ~~Injectable~~ Compounding; Compounding Area; Self-Assessment.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ 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 ~~injectable~~ compounding.

(b) Any pharmacy compounding sterile ~~injectable~~ drug ~~products~~ preparations shall have a ~~designated~~ compounding area designated for the preparation of sterile ~~injectable~~ drug ~~products~~ preparations that is in a restricted location where traffic has no impact on the

performance of the PEC(s). The ~~buffer area or~~ 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. ~~which shall meet the following standards:~~ The environments within the pharmacy shall meet the following standards:

(1) ~~Clean Room and Work Station Requirements, shall be in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(2) Walls, ceilings and floors shall be constructed in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~

~~(3) Be ventilated in a manner in accordance with Section 505.12 of Title 24, Chapter 5 of the California Code of Regulations.~~

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

~~(5)~~ (2) ~~The pharmacy shall be arranged in accordance with Section 1250 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.~~ Items related to the compounding of sterile ~~injectable~~ drug ~~products~~ preparations within the compounding area shall be stored in such a way as to maintain the integrity of an aseptic environment.

~~(6)~~ (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 ~~buffer area or~~ cleanroom, nor in a segregated sterile compounding area within three feet 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. ~~(A)~~ 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) ~~they~~ the sterile compounding area is ~~are~~ exempt from the room requirement listed in 1751(b)(3).

~~(7)~~ (4) There shall be a refrigerator and~~,/or~~ 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.

~~(c) Any pharmacy compounding a sterile injectable drug product preparation from one or more non-sterile ingredients shall comply with Business and Professions Code section 4127.7.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; Sections 1735, 1735.1-1735.8., and 1751.1-1751.8. of Title 16, Division 17, of the California Code of Regulations; and Section 18944, Health and Safety Code.

To Amend § 1751.1 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.1. Sterile ~~Injectable~~ Compounding Recordkeeping Requirements.

(a) ~~Pharmacies compounding sterile injectable products for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, amount, and date on which the products were provided to a prescriber.~~

~~(b)~~ In addition to the records required by section 1735.3 ~~and subdivision (a)~~, any pharmacy engaged in any compounding of ~~for~~ sterile drug ~~products~~ preparations ~~compounded from one or more non-sterile~~ ~~ingredients~~~~,~~ shall ~~make and~~ ~~keep~~ maintain the following records, which must be ~~must be made and kept by~~ readily retrievable, within the pharmacy:

(1) ~~The~~ Documents evidencing training and competency evaluations of employees in sterile ~~product~~ drug preparation policies and procedures.

(2) Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.

(3) Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.

(4) Results of viable ~~volumetric~~ air and surface sampling.

(5) Video of smoke studies in all ISO certified spaces.

~~(2)~~ ~~(5)~~(6) Documents indicating daily ~~recordation~~ documentation of room, ~~R~~ refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

~~(3)~~ ~~(6)~~(7) Certification(s) of the sterile compounding environment(s).

~~(7)~~(8) Documents indicating daily documentation ~~recordation~~ of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

~~(4)~~ ~~(9)~~(9) Other facility quality control ~~logs~~ records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment).

~~(5)~~ ~~(9)~~(10) Logs or other documentation of ~~I~~inspections for expired or recalled ~~pharmaceutical products or raw ingredients~~ chemicals, bulk drug substances, drug products, or other ingredients.

~~(6)~~ ~~(10)~~(11) Preparation records including the master formula document ~~work sheet~~, the preparation compounding log ~~document~~~~work sheet~~, and records of end-product evaluation testing and results.

(b) Pharmacies compounding sterile drug preparations for future use pursuant to section 1735.2 shall, in addition to those records required by section 1735.3, make and keep records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, ~~and~~ license type and number of the prescriber.

(c) Pharmacies shall maintain and retain all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only

recorded and stored electronically, on magnetic media, or in any other computerized form, the records shall be maintained as specified by Business and Professions Code section 4070 subsection (c).

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.2 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.2. Sterile ~~Injectable~~ Compounding Labeling Requirements.

In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, a pharmacy ~~which~~ that compounds sterile ~~injectable~~ drug ~~products~~ preparations shall include the following information on the label~~s~~ for each such ~~those products~~ preparation:

(a) The ~~T~~telephone number of the pharmacy. ~~, except~~ The telephone number is not required on the label for sterile ~~injectable~~ drug ~~products~~ preparations ~~dispensed~~ administered ~~for~~ to inpatients ~~of a~~ within the hospital ~~pharmacy~~.

~~(b) Name (brand or generic) and concentration strength, volume, or weight of each active ingredients contained in the sterile injectable drug product preparation.~~

(~~c~~b) Instructions for storage, ~~and~~ handling, and administration.

(~~d~~c) All ~~cytotoxic~~ hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "~~Cytotoxic~~ Hazardous – Dispose of Properly."

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, 4076 and 4127, Business and Professions Code.

To Amend § 1751.3 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.3. Sterile ~~Injectable~~ Compounding Policies and Procedures.

(a) Any pharmacy engaged in compounding sterile drug preparations shall maintain ~~a~~ written policies and procedures ~~manual~~ for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. In addition to the elements required by section 1735.5, there shall be written policies and procedures regarding the following:

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling~~.~~ and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

(3) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.

(4) Cleaning and maintenance of ISO environments and segregated compounding areas.

(5) Compounded sterile drug preparation stability and beyond use dating.

(6) Compounding, filling, and labeling of sterile drug preparations.

(7) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.

(8) Depyrogenation of glassware (if applicable)

~~(8)~~(9) Facility management including certification and maintenance of controlled environments and related equipment.

~~(9)~~(10) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.

~~(10)~~(11) Hand hygiene and garbing.

~~(11)~~(12) Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.

~~(12)~~(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations. ~~Media-fill testing procedure~~.

~~(13)~~(14) Orientation, training, and competency evaluation of staff in all aspects of the

preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique, demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.

~~(14)~~(15) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.

~~(15)~~(16) Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(16)~~(17) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

~~(17)~~(18) Proper use of equipment and supplies.

~~(18)~~(19) Quality assurance program compliant with sections 1711, 1735.8 and 1751.7.

~~(19)~~(20) Record keeping requirements.

~~(20)~~(21) Temperature monitoring in compounding and controlled storage areas.

~~(21)~~(22) The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.

~~(22)~~(23) Use of automated compounding devices (if applicable).

~~(23)~~(24) Visual inspection and other final quality checks of sterile drug preparations.

~~(a) Any pharmacy engaged in compounding sterile injectable drug products preparations shall maintain a written policyies and procedures manual for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. that includes, iIn addition to the elements required by section 1735.5, written policies and procedures regarding the following:~~

~~(1) Compounding, filling, and labeling of sterile injectable compounds drug preparations.~~

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the~~

~~intended route of administration and recommended rate of administration.~~

~~(3) Proper use of E equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable drug products Hand hygiene and garbing.~~

~~(5) Procedures for handling cytotoxic agents Media-fill testing procedure.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

~~(8) Compounded sterile drug preparation stability and beyond-use dating.~~

~~(9) Visual inspection and other final quality checks of sterile drug preparations.~~

~~(10) Use of automated compounding devices (if applicable).~~

~~(11) Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.~~

~~(12) Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments that include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique.~~

~~(13) Airflow considerations and pressure differential monitoring.~~

~~(14) Cleaning and maintenance of ISO environments and segregated compounding areas.~~

~~(15) An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.~~

~~(16) For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.~~

~~(17) Temperature monitoring in compounding and controlled storage areas.~~

~~(18) Facility management including certification and maintenance of controlled environments and related equipment.~~

~~(19) Action levels for colony forming units (CFUs) detected during viable surface testing, sampling, glove fingertip, and volumetric viable air sampling.~~

~~(b)(20) The determination and approval by a pharmacist of The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist.~~

~~(c)(21) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(22) Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

~~(23) Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.~~

(b) For lot compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ that includes, in addition to the elements required by section 1735.5 and 1751.3(a), written policies and procedures regarding the following:

(1) Use of master formula~~s~~ documents and compounding logs ~~documents work sheets~~.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain ~~a~~written policies and procedures ~~manual~~ for compounding that includes, in addition to the elements required by section 1735.5, ~~and~~ 1751.3(a), and 1751.7(e), written policies and procedures regarding the following:

(1) Process validation for chosen s~~S~~terilization methods ~~and shall include sterilization method suitability testing for each master formula document~~.

(2) End-product evaluation, quantitative, and qualitative testing.

(d)~~(1) All written p~~Policies and procedures ~~manuals and materials~~ shall be immediately available to all personnel involved in ~~these~~ compounding activities and to board inspectors.

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding

sterile ~~injectable products~~ drug preparations. ~~, and any~~ All personal involved must read all additions, revisions, and deletions to the written policies and procedures ~~must be communicated to all personnel involved in sterile compounding~~. ~~This~~ Each review must be documented by a signature and date.

~~(3) Policies and procedures must address at least the following:~~

~~(A) Competency evaluation.~~

~~(B) Storage and handling of products and supplies.~~

~~(C) Storage and delivery of final products.~~

~~(D) Process validation.~~

~~(E) Personnel access and movement of materials into and near the controlled area~~

~~(F) Use and maintenance of environmental control devices used to create the critical direct compounding area for manipulation of sterile products (e.g., laminar-airflow workstations, biological safety cabinets, class 100 cleanrooms, and barrier isolator workstations).~~

~~(G) Regular cleaning schedule for the controlled areas and any equipment in the controlled area and the alternation of disinfectants. Pharmacies subject to an institutional infection control policy may follow that policy as it relates to cleaning schedules and the alternation of disinfectants in lieu of complying with this subdivision.~~

~~(H) Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.4 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.4. Facility and Equipment Standards for Sterile ~~Injectable~~ Compounding.

(a) No sterile ~~injectable~~ drug ~~product~~ 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 ~~injectable~~ drug ~~products~~ preparations.

(b) During the compounding of ~~preparation of~~ sterile ~~injectable~~ drug ~~products~~ preparations, access to the areas designated ~~area or cleanroom~~ for compounding must be limited to those individuals who are properly attired.

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

(d) ~~Cleaning and disinfecting surfaces in the ISO Class 5 PEC shall occur frequently, including:~~ 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, work table 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, work table 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 ~~(at least every 30 minutes)~~, including:

(1) At the beginning of each shift;

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

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d)~~ ~~(e)~~ ~~Exterior workbench surfaces and other hard surfaces in the designated area, such as~~

~~walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination. Counters, cleanable work surfaces and floors shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent daily. Walls, ceilings, storage shelving, tables and stools shall be cleaned with a germicidal detergent and water and disinfected with a suitable agent monthly. Cleaning and disinfecting shall occur after any unanticipated event that could increase the risk of contamination.~~

~~(e)~~ (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~~1~~, Revised ~~January 31, 2012~~May 20, 2015). Certification records must be retained for at least 3 years. Unidirectional ~~c~~compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 ~~buffer area or~~ cleanroom if the isolator is certified to meet~~s~~ 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 ~~or compounding aseptic containment isolators~~ that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 ~~buffer area~~ 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 ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented.The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-1~~3~~1, Revised ~~January 31, 2012~~May 20, 2015). ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ 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~~, complete with~~. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and ~~two layers of gloves with the outermost glove tested to meet~~ two pairs of sterile ASTM D6978-05 standard gloves. ~~Where the documentation provided by CACI manufacturer does not require garbing, only the two glove requirement shall apply.~~

(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.

~~(i)~~(j) Viable surface sampling shall be done at least ~~quarterly~~ every six months for all sterile-to-sterile compounding and ~~monthly~~ quarterly for all non-sterile-to-sterile compounding. ~~Volumetric~~ Viable air sampling shall be done by ~~impaction~~ 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 ~~volumetric~~ 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 s~~S~~urface 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.

~~(i)~~(k) The sterile compounding area ~~is~~in the pharmacy shall have a comfortable and well-lighted working environment, which includes a room temperature of 20-2~~3~~4 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).

Note: Authority Cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052 and 4127, Business and Professions Code; and Section 18944, Health and Safety Code.

To Amend § 1751.5 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.5. Sterile ~~Injectable~~ Compounding Attire.

~~(a) When preparing cytotoxic agents, gowns and gloves shall be worn.~~

~~(b)~~ (a) When compounding sterile drug ~~products~~ preparations ~~from one or more non-sterile ingredients~~ the following standards must be met:

(1) ~~Cleanroom garb~~ Personal protective equipment consisting of a ~~low~~ non-shedding ~~coverall~~ gown, head cover, face mask, facial hair covers (if applicable), and shoe covers must be worn inside the designated area at all times~~, unless the compounding aseptic isolator or compounding aseptic containment isolator manufacturer can provide written documentation, based on validated environmental testing, that any component of the personal protective equipment or personnel cleansing is not required~~. For hazardous compounding double shoe covers are required.

(2) ~~Cleanroom garb~~ Personal protective equipment must be donned and removed ~~outside the designated area~~ in an ante-area or immediately outside the segregated compounding area.

(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.

~~(3)~~ (4) Compounding personnel shall not wear any wrist, ~~H~~hand, finger, ~~and~~ or ~~wrist~~ other visible ~~jewelry or piercing must be eliminated~~ jewelry, piercing, headphones, earbuds, or personal electronic device. ~~If jewelry cannot be removed then it must be thoroughly cleaned and covered with a sterile glove.~~

~~(4) Head and facial hair must be kept out of the critical area or be covered.~~

(5) ~~Gloves made of low-shedding materials are required.~~ 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 ~~buffer area 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.

~~(c) The requirements of subdivision (b) do not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.~~

(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). ~~Exceptions are as listed in 1751.4(g).~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.6 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.6 ~~Training of Sterile Injectable Compounding Staff, Patient, and Caregiver.~~ **Sterile Compounding Consultation; Training of Sterile Compounding Staff**.

(a) Consultation shall be available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile ~~injectable~~ drug ~~products~~ preparations and related supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and

demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

(c) Records of training and demonstrated competence shall be available for each individual and shall be retained for three years beyond the period of employment.

(d) The pharmacist-in-charge shall be responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations.

(e) Pharmacies that compound sterile drug ~~products from one or more non-sterile ingredients~~ preparations must comply with the following training requirements:

(1) The pharmacy must establish and follow a written program of training and performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following:

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

(C) Sterile ~~product~~ preparation compounding documentation.

(D) Quality assurance procedures.

(E) Aseptic preparation procedures ~~using media-fill tests which are as complicated as the most complex manipulations performed by staff and which contain the same amount or greater of volume transferred during the selected manipulations~~.

(F) Proper hand hygiene, gowning and gloving technique.

(G) General conduct in the controlled area (aseptic area practices).

(H) Cleaning, sanitizing, and maintaining of the equipment and ~~used in~~ the controlled area.

(I) Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.

(J) Container, equipment, and closure system selection.

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performs by the

individual. Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations. Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. Each person's proficiency and continuing training needs must be reassessed at least every 12 months. Results of these assessments must be documented and retained in the pharmacy for three years.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.7 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.7. Sterile ~~Injectable~~ Compounding Quality Assurance and Process Validation.

(a) Any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations shall maintain, as part of its written policies and procedures, a written quality assurance plan including, in addition to the elements required by section 1735.8, a documented, ongoing quality assurance program that monitors personnel performance, equipment, and facilities. The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that it meets required specifications. The ~~Q~~quality ~~A~~assurance ~~P~~program shall include at least the following:

(1) Procedures for ~~C~~cleaning and sanitization of the ~~parenteral medication~~ sterile preparation area.

~~(2) The storage of compounded sterile injectable products in the pharmacy and periodic documentation of refrigerator temperature.~~

~~(3)~~(2) Actions to be taken in the event of a drug recall.

~~(4)~~(3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

(b)(1) The pharmacy and each individual involved in the compounding of sterile drug preparations must successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. 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 representative of the types of manipulations, products and batch sizes the individual is expected to prepare and include a media-fill test. The validation process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater amount of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be used in the testing. Media used must have demonstrated the ability to support and promote growth. Completed medium samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then each individual's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated.

(2) Each individual's competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients.

(3) The pharmacy's validation process on aseptic technique and aseptic area practices must be revalidated whenever:

(A) the quality assurance program yields an unacceptable result,

(B) there is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner that affects airflow or traffic patterns, or when improper aseptic techniques are observed.

(4) The pharmacy must document the validation and revalidation process.

~~Each individual involved in the preparation of sterile injectable drug products preparations must first successfully demonstrate competency by successfully performing aseptic media-fill~~

~~tests complete a validation process on technique before being allowed to prepare sterile injectable drug products preparations. 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 representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The media-fill testing process shall be as complicated as the most complex manipulations performed by staff and contain the same amount or greater of volume transferred during the compounding process. The same personnel, procedures, equipment, and materials must be involved. Media used must have demonstrated the ability to support and promote growth. Completed medium media samples must be incubated in a manner consistent with the manufacturer's recommendations. If microbial growth is detected, then the employee's sterile preparation process must be evaluated, corrective action taken and documented, and the validation process media-fill testing repeated. Personnel competency must be revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile products from non-sterile ingredients. Aseptic work practice assessments via media-fill tests must be revalidated, as appropriate to the circumstance or personnel found to be deficient, whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented~~.

(c) All sterile compounding personnel must successfully complete an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, ~~all compounding personnel~~ each individual who may be required to do so in practice must successfully complete a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations.

(d) Re-evaluation of garbing and gloving competency shall occur at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months

for personnel compounding products from non-sterile ingredients.

~~(c)~~ (e)(1) Batch-produced sterile ~~injectable~~ drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), ~~non-sterile-to-sterile batch drug preparations~~ shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogen~~,~~ per USP chapter 85 limits~~,~~ before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are ~~non-injectable~~ topical ophthalmic and inhalation preparation.

(~~1~~2) The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens:

(A) Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

(B) Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients Non-sterile-to-sterile batch drug preparations shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens, per USP chapter 85 limits, before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile.~~

~~(d) Batch-produced sterile to sterile transfers shall be subject to periodic testing through process validation for sterility as determined by the pharmacist-in-charge and described in the written policies and procedures.~~

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.8 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

In conformity with and in addition to the requirements and limitations of section 1735.2, subdivision (h), every sterile compounded drug preparation shall be given and labeled with a beyond use date that does not exceed the shortest expiration date or beyond use date of any ingredient in sterile compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation ~~the expiration date or beyond use date provided by the manufacturer for any component in the preparation~~, and that, in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia – National Formulary (USP37-NF32) Through 2nd Supplement (37th Revision, Effective December 1, 2014), hereby incorporated by reference, that would justify ~~a more~~ an extended beyond use date, conforms to the following limitations:

(a) The beyond use date shall specify that storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; and

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and

not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

(b) The beyond use date shall specify that storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 ~~buffer area or~~ cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and

(2) The compounding process involves complex aseptic manipulations other than the single-volume transfer; and

(3) The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days ~~at controlled freezer temperature~~ in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies: ~~including manufactured preparations not intended for sterile routes of administration, or non-sterile devices, before terminal sterilization, or where the sterile compounded drug preparation lacks effective antimicrobial preservatives.~~

~~For the purposes of this subdivision, "non-sterile" includes sterile contents of commercially manufactured preparations, sterile surfaces of devices, and containers for the preparation,~~

~~transfer, sterilization, and packaging of compounded sterile preparations, that are exposed to worse than ISO Class 5 air quality for more than one hour.~~

(1) The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI ~~or CACI~~ which meets the requirements in 1751.4(f)(1)-(3).

(d) The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply:

(1) The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

(2) The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

(3) The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use"

preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 ~~buffer area or~~ cleanroom, with an ante-area. ~~(1)~~ Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

(f) The beyond use date for any compounded allergen extracts shall be the earliest manufacturer expiration date of the individual allergen extracts.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add § 1751.9 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1751.9 Single-Dose and Multi-Dose Containers; Limitations on Use

(a) Single-dose ampules are for immediate use only, and once opened shall not be stored for any time period.

(b) Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within the following time limit, depending on the environment:

(1) When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour;

(2) When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container must remain within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

(3) If the puncture time is not noted on the container, the container must immediately be discarded.

(c) Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications shall be used in its entirety or its remaining contents shall be labeled with a beyond use date ~~BUD~~ and discarded within twenty eight (28) days from initial opening or puncture. Any multi-dose container not stored according to the manufacturer's specifications shall be discarded immediately upon identification of such storage circumstance. If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container must immediately be discarded.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.8.~~ 1751.10. Sterile ~~Injectable~~ Compounding Reference Materials.

In any pharmacy engaged in compounding sterile ~~injectable~~ drug ~~products~~ preparations, there shall be current and appropriate reference materials regarding the compounding of sterile ~~injectable~~ drug ~~products~~ preparations located in or immediately available to the pharmacy.

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

To Add Article 7.5 of Division 17 of Title 16 of the California Code of Regulations to read as follow

Article 7.5 Furnishing for Home Administration

To Amend § 1751.10 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.10.~~ 1752. Furnishing to Parenteral Patient at Home.

Subject to all provisions of this article, a pharmacist may carry and furnish to a patient at home dangerous drugs, other than controlled substances, and devices for parenteral therapy when the dangerous drug or device is one currently prescribed for the patient.

Authority cited: Section 4005, Business and Professions Code. Reference: Section 4005, Business and Professions Code.

To Amend § 1751.11 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.11.~~ 1753. Furnishing to Home Health Agencies and Licensed Hospices.

Subject to the following conditions, a licensed pharmacy may furnish to a home health agency licensed under provisions of Chapter 8 (commencing with section 1725 of Division 2 of the Health and Safety Code) or to a hospice licensed under provisions of Chapter 8.5 (commencing with section 1745 of Division 2 of the Health and Safety Code) dangerous drugs for parenteral therapy other than controlled substances, in a portable container for furnishing to patients at home for emergency treatment or adjustment of parenteral drug therapy by the home health agency or licensed hospice.

(a) The pharmacy, having ownership and responsibility for the portable containers, shall ensure that each portable container is:

(1) furnished by a registered pharmacist;

(2) sealed in such a manner that a tamper-proof seal must be broken to gain access to the drugs;

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times

when not in the pharmacy;

(4) labeled on the outside of the container with a list of the contents;

(5) maintained at an appropriate temperature according to United States Pharmacopeia Standards (1995, 23rd Revision), and protected at all times from extreme temperatures that could damage the contents.

(b) The portable container may contain up to:

(1) 1000mL of 0.9% sodium chloride intravenous infusion in containers of a size determined by the pharmacy;

(2) 1000mL of 5% dextrose in water injection in containers of a size determined by the pharmacy;

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

(A) heparin sodium lock flush 100 units/mL;

(B) heparin sodium lock flush 10 units/mL;

(C) epinephrine HCl solution 1:1,000;

(D) epinephrine HCl solution 1:10,000;

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

(G) normal saline, preserved, up to 30 mL vials;

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

(N) insulin (human) 100 units/mL;

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

(5) The pharmacy shall ensure that the specific dangerous drugs and quantities to be included in the portable container are listed in the home health agency's or licensed hospice's policyies and procedures.

(c) The pharmacy shall not supply a portable container to a home health agency or licensed hospice which does not:

(1) implement and maintain policies and procedures for:

(A) the storage, temperature stability and transportation of the portable container;

(B) the furnishing of dangerous drugs from the portable container upon the written or oral authorization of a prescriber; and

(C) a specific treatment protocol for the administration of each medication contained in the portable container.

(2) have the policies, procedures and protocols reviewed and revised (as needed) annually by a group of professional personnel including a physician and surgeon, a pharmacist and a registered nurse.

(d) A copy of these policies, procedures and protocols shall be maintained by the furnishing pharmacy from each home health agency or licensed hospice for which the pharmacy furnishes portable containers.

(e) In cases where a drug has been administered to a patient pursuant to the oral order of a licensed prescriber, the pharmacy shall ensure that the oral order is immediately written down by the registered nurse or pharmacist and communicated by copy or fax within 24 hours to the furnishing pharmacy, with a copy of the prescriber-signed document forwarded to the dispensing pharmacy within 20 days.

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an

inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container. (h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

(i) The furnishing pharmacy shall maintain a current inventory and record of all items placed into and furnished from the portable container.

Note: Authority cited: Sections 4005 and ~~and~~ 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

To Amend § 1751.12 in Article 7 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

~~1751.12~~ 1754. Obligations of a Pharmacy Furnishing Portable Containers.

(a) A licensed pharmacy shall not issue portable containers to any home health agency or licensed hospice unless the home health agency or licensed hospice complies with provisions of section ~~1751.11~~ 1753.

(b) A licensed pharmacy shall cease to furnish portable containers to a home health agency or licensed hospice if the home health agency or licensed hospice does not comply with provisions of section ~~1751.11~~ 1753.

Note: Authority cited: Sections 4005 and 4057, Business and Professions Code. Reference: Sections 4040, 4057, 4081 and 4332, Business and Professions Code.

Physical Plant Requirements in Proposed Board of Pharmacy Compounding Regulations 11/17/2015
And Proposed USP 797 Sept 2015
And Proposed USP 800
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists ****

BOARD OF PHARMACY REGULATIONS CCR§1735
Effective January 1, 2017
NON-HAZARDOUS DRUGS (Low and Medium Risk)

SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	PRIMARY ENGINEERING CONTROL (PEC) (Sterile Compounding Hoods)	Beyond Use Dates		Comments
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with Unidirectional Flow** • **HEPA-filtered first air** • **Non-turbulent**	**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**	**APPLIES TO ALL**
≥ISO Class 7 cleanroom with ISO 8 or better ante-area • No sink in cleanroom • Sink in Ante • 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 to the ante area, from floor to ceiling and wall to wall CCR §1735.1(e)(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. 1751.1(a)(8)
Segregated Sterile Compounding Area • Any preparation area that is not ISO classed, >ISO 7, 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)	• Compounding Aseptic Isolators (CAI) • Mfg of CAI has documentation meeting 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)	• 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
	• Laminar Flow Hood • Biological Safety Cabinet with unidirectional flow • 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)
	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	1 hour from time of 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 the immediate need.

Physical Plant Requirements in Proposed Board of Pharmacy Compounding Regulations 11/17/2015
And Proposed USP 797 Sept 2015
And Proposed USP 800
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists ****

PROPOSED USP 797 NON-HAZARDOUS DRUGS Effective July 1,2018			
SECONDARY ENGINEERING CONTROL • **Temp = or < 20 C** • **Humidity < 60%** • **Controlled through HVAC** • **Air enters HEPA filter in the ceiling of buffer room and returns low on the wall**	**PRIMARY ENGINEERING CONTROL (PEC)** **ISO 5 with Unidirectional Flow**	**BEYOND USE DATES**	
		Category 1	**Comments**
Segregated Compounding Area (SCA) • **Not ISO classified** • **Buffer/ante not meeting ISO 7/8 respectively** • **Buffer/ante fails surface sampling** • **Away from significant traffic flow** • **Away from unsealed doors/windows that connect to outdoor** • **Perimeter must be defined** • **Sink must be 1 meter from PEC** • **Not adjacent to construction, warehouse, or food prep**	ISO Class 5 PEC: • Laminar Air Flow System (LAFS) • Biological Safety Cabinet (BSC) • Restricted Access Barrier System (RABS), can be CAI or CACI • Isolator	**12 hours at Room Temp*** **24 hours at Cold Temp (Refrigerator)****	• Recertification every 6 months • Endotoxin and Sterility testing not required for products • No shipping or external cartons allowed in SCA
		Category 2	**Comments**
PEC in ISO 7 Buffer Room • **with ISO 8 or better Ante, separated from surrounding unclassified area** • **Buffer and Ante must be separate rooms with walls and doors, and controls to prevent low quality air into controlled areas** • **Sink in Ante** • **Buffer and Ante must have ACPH = or >30, at least 15 must be HEPA filtered fresh air vs recirculated air** • **Pressure differential at least 0.02"wc to separate each ISO classified area and from Ante to general pharmacy area**	ISO Class 5 PEC: • Laminar Air Flow System (LAFS) • Biological Safety Cabinet (BSC) • Restricted Access Barrier System (RABS), can be CAI or CACI	**SEE CHART BELOW FOR CATEGORY 2 BUD**	• Recertification every 6 months • No tacky mats in ISO classified areas • Document Pressure Differential or velocity daily or use continuous recording device • No shipping or external cartons allowed in buffer/ante • Endotoxin testing required for CSP compounded from non-sterile ingredient(s)
PEC in ISO 8 area • **Sink can be in ISO 8 area 1 meter from PEC** • **must have ACPH = 15 must be HEPA filtered fresh air vs recirculated air** • **Pressure differential at least 0.02"wc to separate each ISO classified area and to general unclassified area**	• Isolator (must meet standards see lines 505-511)		

BEYOND USE DAYS (BUD) IN # OF DAYS – PROPOSED USP 797

July 1, 2018

Method of Sterilization A=Aseptic Preparation T=Terminal Sterilization	Sterility Testing	Preservative Added	Controlled Room Temperature*	Controlled Cold Temperature** (Refrigerator)	Controlled Freezer Temperature***
A	No	No	4 days (Non-sterile to Sterile) (96 hours)	7 days (Non-sterile to Sterile)	45 days (Non-sterile to Sterile)
			6 days(Sterile to Sterile)	9 days (Sterile to Sterile)	45 days(Sterile to Sterile)
A	No	YES	28 days	42 days	45 days
A	YES	No	28 days	42 days	45 days
A	YES	YES	42 days	42 days	45 days
T	No	No	14 days	28 days	45 days
T	No	YES	28 days	42 days	45 days
T	YES	No	28 days	42 days	45 days
T	YES	YES	42 days	42 days	45 days

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

****Controlled Cold Temp (Refrigerator): 2 to 8 degrees C, 35 to 46 degrees F**

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

Physical Plant Requirements in Proposed Board of Pharmacy Compounding Regulations 11/17/2015
And Proposed USP 797 Sept 2015
And Proposed USP 800
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists ****

BOARD OF PHARMACY REGULATIONS CCR§1735 Effective January 1, 2017 HAZARDOUS DRUGS				
		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 dedicated to 1 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 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 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 at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft from 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 Isolators (CACI) with unidirectional flow. 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 at least q 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with 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				
Transfer Devices				
The use of transfer devices (minibag plus, AddVantage, etc.) are not considered compounding and therefore a PEC is not required; however, the use of proper aseptic technique is required.				

Physical Plant Requirements in Proposed Board of Pharmacy Compounding Regulations 11/17/2015
And Proposed USP 797 Sept 2015
And Proposed USP 800
Interpretations by the California Hospital Association Medication Safety Committee and the California Society of Health-System Pharmacists ****

PROPOSED USP 800 HAZARDOUS DRUGS				
SECONDARY ENGINEERING CONTROL **Externally vented through HEPA filtration**	**PRIMARY ENGINEERING CONTROL** **C-PECs ISO class 5 Negative Pressure unidirectional flow** **C-PECs externally vented**	**BEYOND USE DATES**		**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 Freezer Temp ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Freezer Temp***	• Requires negative pressure ISO 5 C-PEC • C-PEC and C-SEC externally vented • Eyewash readily available
• **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 HEPA filtered air** • **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	

* 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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 20, 2016

Robert Nakamura
Senior Safety Engineer
DOSH Research and Standards Health Unit
Cal/OSHA
Elihu Harris State Building
1515 Clay Street
Oakland, CA 94612

Dear Mr. Nakamura:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the comments on the draft document Cal/OSHA developed as part of the Antineoplastic Drug Handling Advisory Committee. CHA appreciates Cal/OSHA's effort to meet the requirements of AB 1202 (2013) and provide guidance to healthcare providers on the employee safety aspects of antineoplastic drug handling. California hospitals take very seriously our duty to provide a safe, healthy environment for our patients as well as our staff and look forward to working with you on this project. In an effort to provide support and assistance in development of a workable and effective regulation, we provide the comments below.

A. Timing of the Regulation

CHA's primary concern with the draft regulation is the timing. As has been discussed at the two Advisory Committee meetings held thus far, there are several significant pending developments that will have a direct impact on the very subject matter of the proposed regulations. Specifically, new USP Chapter 800 "Hazardous Drugs – Handling in Healthcare Settings" will be officially published on February 1, 2016 with an official implementation date of July 1, 2018. In addition, the California Board of Pharmacy is in the process of amending Title 16, California Code of Regulations, Sections 1755 et seq. and 1751 et seq. relating to sterile compounding of hazardous drugs, which necessarily involves handling those drugs. Finally, the National Institute of Occupational Safety and Health (NIOSH) is currently updating its guidance. While each of these activities is slightly different in their focus, they clearly overlap.

Consistent with, and in furtherance of, Cal/OSHA Standard Board's goal to develop regulations that are "enforceable, reasonable, understandable, and contribute directly to the safety and health of California employees" we believe the current draft regulations are premature. It is CHA's belief that the Cal/OSHA regulations would be most operational and effective if they are drafted once these other activities have been finalized and a concerted effort is made to reconcile these various regulations and guidance. This approach is consistent with the

legislative intent underlying AB 1202. The Senate Rules Committee analysis reflects that the bill gives Cal/OSHA discretion to "determine a reasonable time for facilities to implement new requirements imposed by the adopted standard/" Thus, unlike some other recent legislation containing a statutory deadline for adoption of regulations, AB 1202 gave Cal/OSHA the authority to determine the appropriate timing for the new regulations.

As such, we have limited our comments below to several high level issues identified in the current draft discussion document. We are happy to meet with Cal/OSHA staff at any time to review our specific concerns with the draft language.

B. Evidence-Based Standards

CHA member hospitals have provided input on the draft discussion document. What was notable was the experts agreed that there is currently no evidence-based standard for evaluating the level at which occupational exposure is harmful. Given this reality, we believe care must be taken to specify clear parameters so that the safety obligations are consistent with the level of risk involved.

C. Identification of Antineoplastic Drugs

Subsection (c)(1) require the employer to conduct a written inventory of antineoplastic drugs used in the workplace that "shall include, but not be limited to, antineoplastic drugs listed in the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014 and reprinted in Appendix A We have two concerns with this language. First, because the NIOSH standard also applies to other hazardous drugs, it is not clear that this inventory is limited to antineoplastic drugs. Moreover, NIOSH updates the list every 2 years because new drugs are always being introduced to the market. The 2014 list will quickly become outdated. In fact, NIOSH has already proposed a 2016 list. The NIOSH Alert does recommend creating your own process to review new drugs during time lag of when these lists are published. We assume that is what is meant by "including but not limited to." However, to avoid confusion, we recommend that the language be changed as follows:

> shall include antineoplastic drugs listed on the most current NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings as well as any antineoplastic drugs that the healthcare provider has identified.

Moving forward, CHA is ready to assist Cal/OSHA as it develops regulations and enforcement policies in an effort to provide employees with a safe work environment. Thank you for the opportunity to submit this information. We look forward to continuing to work with you.

Sincerely,

Gail M. Blanchard-Saiger
Vice-President, Labor & Employment

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

March 28, 2016

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

BY ELECTRONIC CORRESPONDENCE

RE: Prescription Drug Take-Back Programs, Adoption of New Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5 and 1776.6 of Division 17 of Title 16 of the California Code of Regulations (CCR)

Dear Ms. Martinez:

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully offers the following comments for consideration to the proposed adoption of the new Article 9.1 and Sections 1776, 1776.1, 1776.2, 1776.3, 1776.4, 1776.5 and 1776.6 of CCR Title 16, Division 17.

In light of the rising epidemic of opioid abuse, along with the need to protect the environment from hazardous waste disposal, the board of pharmacy has drafted salient regulations to enhance the availability of safe and effective drug take-back programs across the state. CHA applauds the intent, particularly with the proposed implementation of a voluntary pharmacy take-back program that will support all sites to individually and fully evaluate costs, security risks and benefit to their communities.

Opioid abuse continues to be a national health problem. From 1999-2014, more than 165,000 persons died from overdose related to opioid pain medication in the United States. While other top leading causes of death such as heart disease and cancer have decreased substantially, the death rate associated with opioid abuse has increased significantly. In 2011, there were an estimated 420,000 emergency department visits related to abuse of narcotics (Drug Abuse Network). Clearly, CHA and its member hospitals are supportive of efforts to prevent death and decrease prescription drug related mortality and morbidity.

To combat the growing misuse of prescription drugs, the Office of the National Drug Control Policy (ONDCP) released a Prescription Drug Abuse Plan outlining a four pronged approach consisting of education, monitoring, proper medication disposal and enforcement. CHA and its corporate regional members, along with Cal ACEP have endorsed the San Diego Safe Pain Medicine Prescribing Guidelines and have worked to educate members over the past several

years on effectively managing pain issues with emergency and urgent care patients. CHA's Medication Safety Committee, developed and disseminated "Recommendations for Improving Safety of Opioid Use" tool, and also endorsed and worked closely with the Department of Justice to encourage the use of the state's prescription drug monitoring program, "CURES" (Controlled Utilization Review and Evaluation System). In an effort to work alongside stakeholders and the Board of Pharmacy to support the aforementioned four pronged approach to opioid drug abuse prevention, CHA is also committed to addressing proper medication disposal processes that make medication collection accessible, easy, cost effective and sustainable. The states "CalRecycle" program, has developed model programs for the collection and proper disposal of unused or expired home-generated pharmaceuticals. Minimum criteria includes those mentioned by the ONDCP along with additional criteria such as board reports on waste amounts, actions for compliance failure, etc.

Drug take-back programs can be classified as either "event based" or "ongoing", with the most notable example being the Drug Enforcement Agency (DEA) regularly scheduled collections on fixed dates. Other sporadic ongoing programs exist that offer a form of continuous medication collection , featuring either fixed drop off locations at pharmacies, police stations or mail back options. Drug take-back program initiation and implementation has been sluggish, even after the Drug Enforcement Administration (DEA) announced last year that pharmacies nationwide could accept and destroy unwanted prescription drugs. While over 9,000 drug take-back services exist across the state, safety, security and cost issues prevent pharmacies from willingly adding services. And CHA notes there is limited data on the impact and effectiveness of take-back programs and their effect on drug abuse. Nonetheless, CHA is firmly committed to public safety and prevention of opioid abuse and is supportive of drug take-back programs that meet model program criteria.

While CHA and its member hospitals do not see hospital/clinic pharmacies as the most appropriate site for establishing drug take-back programs, we support the draft regulations voluntary status for sites in these settings, as there may be unique community circumstances or programs where the hospital/clinic pharmacy is the most appropriate setting. Several of these hospital sites exist today as collection sites for licensed waste management services, components of larger county and district programs with comprehensive waste disposal services in multiple sites within a locale. Overall, however, CHA supports a multipronged approach with heavy emphasis on product stewardship where drug manufacturers play a lead role in funding and handling of their own environmentally harmful products.

CHA has three specific comments on the regulations listed below:

1. Proposed Section 16 CCR Section 1776.1 Pharmacies:
   Pharmacies may assist patients seeking to destroy unwanted, previously dispensed prescription drugs as provided in this article. Provision of such services is voluntary.

   Recommendation: CHA reiterates its strong position on maintaining voluntary participation in these programs. CHA does not envision hospital/clinic pharmacies to be an appropriate site for establishing drug take back programs; however, there may be

unique community circumstances where the hospital/clinic pharmacy is an appropriate setting.

2. Proposed Section 16 CCR Section 1776.3 Collection Receptacles in Pharmacies:
In hospitals/clinics with a pharmacy on the premises, the collection receptacle must be located in an area that is regularly monitored by employees and not in the proximity of emergency or urgent care. When the supervising pharmacy is closed, the collection receptacle shall be locked so that drugs may not be deposited into the collection receptacle. When the collection receptacle is locked, the supervising pharmacy shall ensure that the collection receptacle is also physically blocked from patient access by some means.

   Recommendation: CHA recommends removing, "and not in the proximity of emergency or urgent care". While CHA suspects that most hospital pharmacies will not participate in this program, there are several drug take-back programs in hospitals presently that have collection receptacles in their emergency departments. While emergency or urgent care departments may not be the most appropriate site for a collection receptacle, it may be the most appropriate area relative to regular employee monitoring and internal hospital safety and security.

3. Proposed Section 16 CCR Section 1776.3 Collection Receptacles in Pharmacies:
General Comment: As stated in 16 CCR Section 1776 Prescription Drug Take-Back Programs: Authorization, and throughout the proposed regulations: "Federal, state and other laws prohibit the deposit in drug take-back receptacles of the following: medical sharps and needles (e.g. insulin syringes), iodine containing medications, mercury containing thermometers, radiopharmaceuticals, hazardous medications and compressed cylinders." CHA offers, that inevitably, inappropriate items will end up in the containers even with appropriate signage, etc.

   Recommendation: CHA suggests adding a section to address what processes occur when inappropriate items or damaged items are found in the transition of the sealed liners to the licensed DEA registered reverse distributor.

4. General Regulatory Comments: Costs
The Board of Pharmacy Initial Statement of Reason outlines costs for drug take-back services in pharmacies. While costs are outlined for liners and receptacles, there is underreporting of the actual costs to develop a hospital/clinic based drug take-back program.

   Recommendation: Additional pharmacy and security labor costs, along with program development and maintenance costs need to be included to estimate actual costs.

5. General Regulatory Comments: Efficacy
While the severity of the prescription drug abuse problem continues to mount, there is no question that multiple approaches to combat the issue are warranted. Little data is

available on the impact and effectiveness of drug take-back programs. Obviously, drug take-back programs will reduce the available supply of prescription drugs; however, voluntary programs are unlikely to draw participation from individuals inclined towards diversion and non-medical use. A study done in 2012 showed that "most individuals diverting unused drugs originally obtain those drugs from a single doctor, highlighting doctors as the ultimate source of the drug surplus rather than the family medicine cabinet". This is another reason why CHA and its member hospitals are heavily involved in the state's prescription drug maintenance program, CURES, that proactively monitors prescribing behavior.

Recommendation: Pilot studies be performed to determine which medications are collected, assess take-backs true costs and link program elements to understand the relationship between prescription opioid abuse and take-back programs so that scarce resources can be targeted at the most appropriate arenas to prevent opioid drug abuse.

In conclusion, CHA appreciates the opportunity to comment on these regulations and provide an overview representative of its 400 member hospitals. We are especially appreciative of the overall theme of hospital/clinic pharmacy voluntary participation as these programs are not evidenced based and pose significant cost, security, and safety risks for our patients and communities.

Sincerely:

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

BJB:rf

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

November 30, 2015

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

BY ELECTRONIC CORRESPONDENCE

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

Dear Ms. Martinez:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Respectfully Submitted:

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

BJB:rf

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

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

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

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Section	BOP Wording	CHA Proposed Wording	CHA Rationale
	loss reports and alert pharmacies and clinics of high theft controlled substances that may not be Schedule II. As regular inventory is being completed on Schedule II controlled substances, those wishing to divert controlled substances may change their focus to non-Schedule II in order to avoid detection, an example of this is Promethazine with Codeine cough syrup. Promethazine with Codeine has a high potential for abuse, but it is not Schedule II. By requiring an inventory of at least one non-schedule II, the Board will be able to reduce the theft and misuse of an additional controlled substance. Finally, as the pharmacist-in-charge or consultant pharmacist may not be the person performing the actual inventory, this subdivision requires that those who performed the inventory sign and date the Inventory Report, and that it be countersigned by the pharmacist-in-change or consultant pharmacist to ensure they are aware and accountable for the inventory. By requiring the signing and countersigning of the Inventory Report, Board inspectors will know who completed the inventory during an inspection.		technology. Examples of automated dispensing cabinets (ADCs) inventory practices utilized in various facilities: • Use of biometric identification to access ADCs • Use of "blind counts" when removing controlled substances which eliminates the possibility of confirmation bias in the counting process and automatically records any discrepancies • Use of "blind counts" when restocking the ADCs • Required resolution of any controlled substance discrepancies on a daily basis by the nurses, and verification (oversight) by pharmacy that the process has been completed (including reviewing the rationale documented during the resolution process) • Physical inventory of controlled substances in the ADCs on a regular basis by the nurses utilizing "blind counts." • Daily monitoring ADC overrides to ensure there is a valid prescriber order for the medication that was removed • Regular review of oversight reports, e.g. ADC Users created; Cancelled transactions, to detect suspicious activity and prevent diversion • Use of specialized computer software (Pandora) to analyze patterns of controlled substances removal from ADCs and identify suspicious activity and/or users to prevent diversion • Perpetual inventory of all controlled substances in the pharmacy utilizing specialized computer software (C-II Safe). This software also tracks all controlled

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			substances removed from the pharmacy and stocked in the ADCs and communicates with the ADCs to verify the controlled substances that left the pharmacy were subsequently stocked in the ADCs. • Review and approval of all Pharmacy orders for controlled substances from wholesalers/suppliers by a Pharmacy Manager • Verification by a Pharmacy Manager that all controlled substances received in the Pharmacy from a wholesaler/supplier are entered in to the specialized tracking software • Use of "blind counts" when adding and/or dispensing controlled substance from the Pharmacy inventory specialized computer tracking software As evidenced by the aforementioned numerous examples, each hospital, depending on size and resource availability must devise its individualized policy and plans for controlled substance reconciliation and inventory outside the inpatient pharmacy vault.
1715.65(c)(1)	"The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be **readily retrievable for three years**." This requirement is added so that the Inventory Report will be readily available for review by Board inspectors as defined in Business and Professions Code (B&P) section 4105(a). The three year time frame is defined in B&P section 4105(c) and is maintained in this proposal.	No Comment	
1715.65(c)(2)	"The biennial inventory of controlled substances required by federal law may	No Comment	

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

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

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

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

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

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

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

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

Controlled Substances Best Practices for Health-Systems
DRAFT

The following elements of controlled substances management represent building blocks for best practices that would support accountability and patient safety across the medication use process. These elements could be further elaborated and used as the basis for an organizational gap analysis with the goal of implementing processes to enhance accountability and reduce the potential for diversion.

- Accountability from ordering to administration including wastage
    - Ordering and receipt authority
    - Storage security from receipt to secure pharmacy location
    - Closed loop reconciliation: central storage to decentralized locations including diagnostic and procedural areas and clinics
- Pharmacy perpetual inventory systems
- Robust documentation of receipts, dispenses, disposal, transfers
- Security/access control systems
    - Passwords
    - Biometrics
    - HR integration to account for LOAs, separations, etc
- MD/Allied Health Professional medication order accountability
    - Monitoring and evaluation of overrides
- Standard requirements for documentation of administration on EMAR
- Training health professionals on use
- Monitoring use and thresholds for investigation: leveraging existing technologies
    - Evaluation of use vs pain scales
    - Time of removal vs administration vs wastage
    - Wastage accountability: verifying individual witnessed waste
    - Accountability for returns to automated dispensing cabinets
    - Use of blind counts
    - Requirements for periodic physical inventory of ADC
- Standardized protocol for investigation
- Behavioral monitoring
- Recommendations re: structure of controlled medication surveillance teams
    - Pharmacy: pharmacist(s), technician(s)
    - Nurses
    - Anesthesiologist
    - Risk Management
    - Security
- Reporting to executive leadership and regulatory agencies
- Knowledge and application of state and federal requirements

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Reconciliation and Inventory Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform reconciliation and inventory functions to prevent the loss of controlled substances.
(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all reconciliations and inventories taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the reconciliation and inventory reports required by this section.
(c) Perform a Periodic Inventory: A pharmacy or clinic shall compile an Inventory Report of specific controlled substances at least every three months. The compilation of this Inventory Report shall require a physical count, not an estimate, of all quantities of federal Schedule II controlled substances and at least one additional controlled substance which may be specified by the board each year as based upon loss reports made to the board in the prior year. The Inventory Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or consultant pharmacist.
    (1) The original or copy of the signed controlled substances Inventory Report shall be kept in the pharmacy or clinic and be readily retrievable for three years.
    (2) The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided:
        (A) A physical count of all controlled substances is performed, not an estimated count of how much medication is in a container.
        (B) The federal Drug Enforcement Administration biennial inventory was taken no more than three months from the last inventory required by this section.
(d) A new pharmacist-in-charge of the pharmacy shall complete an inventory as required by subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
(e) Reconciliation with Inventory Report: The pharmacy or clinic shall review all acquisitions and dispositions of controlled substances as part of the inventory process to determine the expected stock of each controlled substance on hand, based on the prior Inventory Report. Records used to compile each reconciliation shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
    (1) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration.
    (2) Likely causes of overages shall be identified in writing and retained.

(3) Should the reconciliation identify controlled substances which had been in the inventory of the pharmacy or clinic during the prior six-month period, but for which there is no stock at the time of the physical count, the pharmacist-in-charge or consultant pharmacist shall determine there has been a loss of these controlled substances. These losses shall be reported in the manner specified by paragraph 1.

(f) Adjustments to the Inventory Report shall be made following reconciliation, only after the reporting and documenting of any losses or accounting made for overages.

(1) Each adjustment to the Inventory Report made to correct the stock on hand count shall be annotated to show any adjustment in the number of controlled substances on hand in the pharmacy or clinic, and who made the annotation, and the date.

(2) The pharmacist-in-charge or consultant pharmacist shall countersign the adjusted Inventory Report.

(3) The original Inventory Report and amended Inventory Report following reconciliation shall be readily retrievable in the pharmacy or clinic for three years.

(g) The pharmacist-in-charge of a hospital pharmacy or of a pharmacy servicing skilled nursing homes where an automated drug delivery system is in use shall review at least once each month all controlled substances removed from or added into each automated drug delivery machine operated by the pharmacy. Any discrepancy or unusual access identified shall be investigated. Controlled drugs inappropriately accessed or removed from the automated delivery shall be reported to the board within 14 days.

(h) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses, including installation of cameras, relocation of the controlled drugs to a more secure location within the pharmacy, or daily inventory counts of the drugs where shortages are continuing.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

Medication Safety Toolkit Manual

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

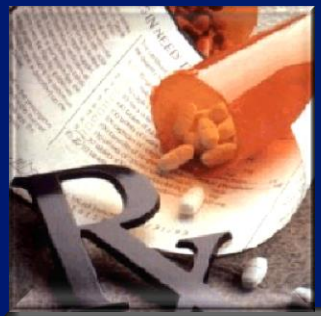
Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
	Cover, Back Cover								

DEA
U.S. Drug Enforcement Administration

Secure and Responsible Drug Disposal Act of 2010

Practice Greenhealth

Arlington, Virginia



November 17, 2015

The United States Department of Justice

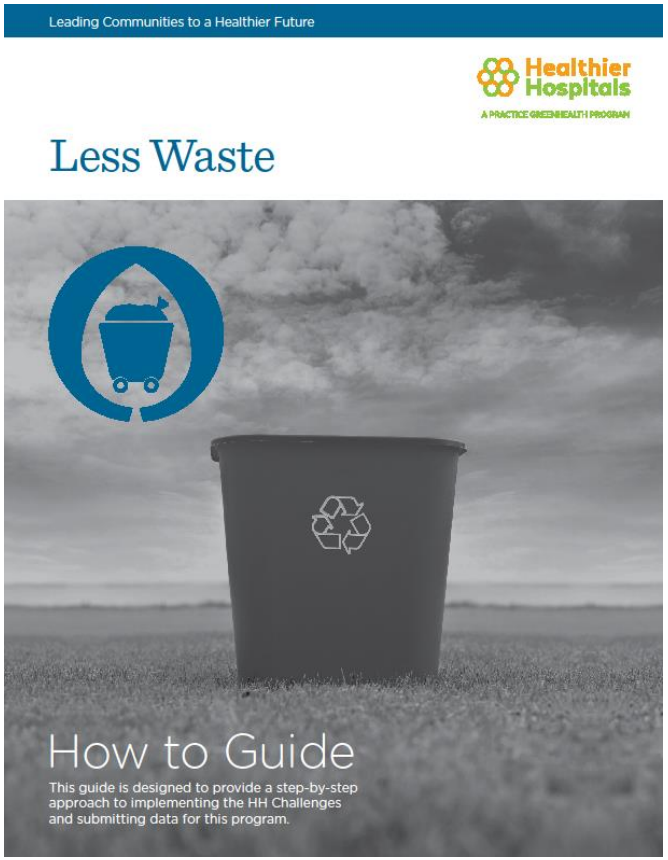
Drug Enforcement Administration

Ruth A. Carter, Chief
Liaison and Policy Section
Office of Diversion Control

Less waste toolkit

- Case Studies
- How-To Guides
- Defining Materials and Streams
- Webinars & Sharing Calls
- Power Point with Script

- https://practicegreenhealth.org/topics/less-waste



Tomorrow – November 18 at 1 eastern
How to Conduct a Waste Baseline

PGH Awards Season!

Practice Greenhealth
ENVIRONMENTAL EXCELLENCE AWARDS

- 2016 award applications available this month.
- Completed applications due late February 2016.

Welcome

jhoward@practicegreenhealth.org

www.practicegreenhealth.org

Ruth Carter, Chief, Drug Enforcement Administration

Learning Objectives

Explain disposal regulations

Define controlled substance inventory

Define pharmaceutical wastage

Define Non-retrievable

Secure and Responsible Drug Disposal Act of 2010

The Problem: Easy Access

Ultimate User

Ultimate user means as "a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household."

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- Disposal in Trash (ONDCP method); or
- Flushing (FDA opioids and select CSs)
- National Take-back Event (DEA)
- Transfer to Law Enforcement
- (Police Station Receptacles or local Take-back events)
- DEA

Secure and Responsible Drug Disposal Act of 2010

- ✓ Ultimate users will now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.

- ✓ Expected benefit to the public by:
  - Decreasing the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
  - Protecting the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.

Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

  21 USC §§ 822(f) & (g)

- Registrants authorized to collect:
  - Manufacturers
  - Distributors
  - Reverse Distributors
  - Narcotic Treatment Programs
  - Hospitals/clinics with an on-site pharmacy
  - Retail Pharmacies

  21 CFR § 1317.40

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.

Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances …**they expanded them**
- Any method of pharmaceutical disposal that was valid for **ultimate users** prior to these regulations remains valid
- Participation is voluntary
- The DEA may not require any person to establish or operate a disposal program

21 USC §§ 822(g)(2)

Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR 1307.12 & 1307.21

- New part 1317 contains the requirements on:
  - disposal procedures;
    - registrant inventory
    - collected substances
  - collection of pharmaceutical controlled substances from ultimate users;
  - return and recall; and
  - destruction of controlled substances

Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR §§ 1317.35 and 1317.65

Collection

Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) & (4) and 21 CFR § 1300.01(b)

Collection Receptacles

Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants **shall not dispose of stock/inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)

Collection at LTCF

- A registered hospital/clinic with an **on-site pharmacy** or a registered retail pharmacy may request modification of their registration to become an authorized collector to maintain a collection receptacle at a LTCF (§ 1317.80).

- Request must include:
  - Name and physical location of each LTCF at which a collection receptacle will be operated

- **No fee** is required for this modification request.

21 CFR §§ 1301.51(b)(2) and (c)

Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- **LTCF** – located in secure area regularly monitored by LTCF employees.
- **Hospital/clinic** – located in an area regularly monitored by employees---**not i**n proximity of where emergency or urgent care is provided.
- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)

Design of Collection Receptacles

Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

21 CFR § 1317.75(e)

Design of Collection Receptacles

- Outer container must display a sign stating only Schedule II-V and non- controlled substances are acceptable substances.
- Substances Not Permitted to be collected:
  - Schedule I controlled substances,
  - Controlled substances that were not lawfully possessed by the ultimate user, and
  - All other illicit substances (including marijuana in states like CO and WA)

21 CFR § 1317.75(e)

Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)

Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together
- Must have method of on-site destruction

21 CFR § 1317.70 (b)

Registrant Disposal

Registrant Disposal - Inventory

Practitioner & Non-Practitioner may **dispose of inventory:**

- Prompt on-site destruction
- Prompt delivery to **reverse distributor** by common or contract carrier or reverse distributor pick-up
- Return and recall : Prompt delivery by common or contract carrier or pick-up at the registered location

Practitioner may **also** request assistance from the SAC

Non-practitioner may **also** transport by its own means

21 CFR § 1317.05(a) and (b)

DEA Form 41

- Form 41 shall be used to record the **destruction of all controlled substances, including controlled substances acquired from collectors.**
  - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
  - Exceptions for DEA Form 41:
    - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
    - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41

21 C.F.R. §.1304.21(e)

Abandoned Controlled Substances

- Circumstances when there is no authorized person to dispose of controlled substances
  - School
  - Summer camp
  - Hospital
- Return to ultimate user is not feasible
- Options
  - Contact law enforcement or DEA
  - Destroy on-site

79 FR 53546 (Disposal Final Rule)

Pharmaceutical Wastage

Pharmaceutical Wastage

- **Not** subject to 21 CFR § Part 1317
  - Destruction does not have to be "non-retrievable"
  - DEA Form 41 must not be utilized

- Dispensing must be recorded as a record

21 CFR § 1304.22(c)

- Clarification memorandum on DEA website at www.deaDiversion.usdoj.gov

Requirements for Destruction of Controlled Substances

Destruction of Controlled Substances

All controlled substances destroyed by a registrant or caused to be destroyed by a registrant shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered **non-retrievable**

21 CFR § 1317.90

Non-retrievable means the condition or state to which a controlled substance shall be rendered following a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes

21 CFR § 1300.05

Destruction of Controlled Substances

- Destruction shall be in accordance with the following requirements:
  - Transfer to registrant or person authorized to accept for destruction
  - Transport to a registered location
  - Transport to a non-registered location for destruction
  - On-site destruction

21 CFR § 1317.95

Destruction of Controlled Substances

Transfer and transport for destruction

- Transportation directly to registered location or destruction location
- 2 employees accompany the controlled substances to location
- 2 employees load & unload or observe load & unload until transfer is complete

21 CFR § 1317.95(b) and (c)

Destruction Procedures

- 2 employees of the registrant shall handle or observe the handling of any controlled substance until it is rendered non-retrievable, and
- 2 employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

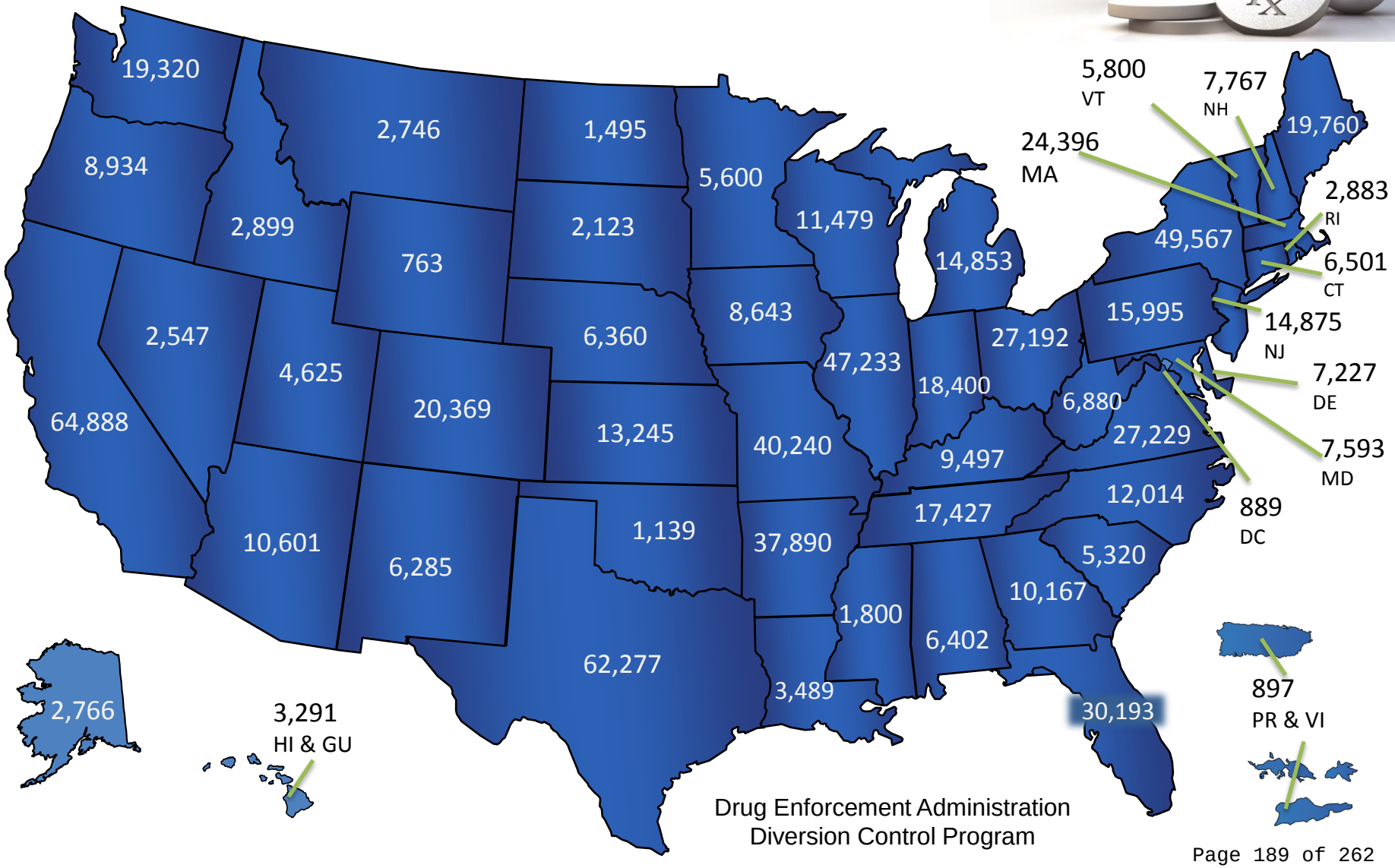
21 CFR § 1317.95(c) and (d)

National Take Back Initiative
September 26, 2015

10:00 AM – 2:00 PM

10th National Take Back Day: September 26, 2015

Total Weight Collected (pounds): 742,771 (371 Tons)



Drug Enforcement Administration
Diversion Control Program

DEA Web-based Resources

Office of Diversion Control

www.deadiversion.usdoj.gov

DEA Web-based Resources

www.DEA.gov

DEA Web-based Resources

www.JustThinkTwice.com

DEA Web-based Resources

www.GetSmartAboutDrugs.com

Ruth.A.Carter@usdoj.gov

Department of Toxic Substances Control

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Secretary for
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Edmund G. Brown Jr.
Governor

HAZARDOUS WASTE PHARMACEUTICALS RULE COMMENTS

I. General Comments of Structure of the Proposal

EPA has proposed a set of alternative management rules for pharmaceuticals for some persons, but not all persons who manage hazardous waste pharmaceuticals under RCRA. EPA has chosen to place these standards in 40 CFR part 266. Historically EPA has used part 266 for recyclable materials and, more specifically for materials that are subject to less than full hazardous waste regulatory standards because some form of recycling or resource recovery was occurring. Most current 40 CFR part 266 standards provide rules that are less stringent than the traditional hazardous waste generator and facility standards. However, EPA has decided the proposed rules are more stringent standards for generators of hazardous waste pharmaceuticals. EPA's placement of these standards in part 266 seems to deviate from its past practices and appears to be incongruous with most regulators' understandings of EPA's regulatory schema. EPA's proposal to place these standards in Part 266 (not the standards themselves, but their placement) is very confusing. After reviewing the proposal, it appears that EPA has made the following decisions:

- handlers of hazardous waste pharmaceuticals should be regulated largely as generators
- "reverse distributors" is a misnomer
- only minimal, if any recycling, reuse or resource recovery is occurring via "*reverse distribution,"*
- a more stringent set of rules is required for hazardous waste pharmaceuticals and their generators.

DTSC concludes that EPA should consider an entirely different schema for the proposed rule. The outline of the proposed rule should be based on the following general comments which serve to create two sets of generator standards for these persons (generators). Further elaboration on these general comments may be found in the specific comments section below.

Inasmuch as EPA admits in the preamble, reverse distributorship is (and has been) a fiction for too long. As EPA describes in the preamble, these entities are really an extension of the primary generator; in most cases, a "secondary generator". Therefore, DTSC recommends EPA adopt a regulatory schema, patterned after the Generator Improvements Proposed Rule that places one set of standard each for the two entities; Primary and Secondary Generators of Pharmaceuticals. In Part 262,

Standards Applicable to Generators of Hazardous Wastes, which are entitled Standards for Primary and Standards for Secondary, Generators of Hazardous Waste Pharmaceuticals, would appear as:

- Standards for VSQGs
- Standards for SQGs
- Standards for LQGs
- Standards for Primary Generators of Pharmaceuticals, including Healthcare, Retail and Pharmaceutical Manufacturing and Distributing generators, (i.e., all who would send pharmaceutical wastes to these "secondary generator" entities)
- Standards for Secondary Generators of Hazardous Waste Pharmaceuticals.

In conjunction with the above, DTSC would recommend that EPA then place the definition of pharmaceutical in 40 CFR 260.10 and would amend 40 CFR 261.2 to define, as solid waste, "any *pharmaceutical*, as defined, that, in addition to the above methods of discard, is sent to a Secondary Generator of Hazardous Waste Pharmaceuticals." The applicability sections of Part 262 would, of course, direct all primary generators to follow a single set of standards for their ordinary hazardous wastes (as either a VSQG, SQG, or LQG) and the tailored Standards for Primary Generators of Pharmaceuticals for their pharmaceutical wastes (proposed 40 CFR 266.503 -.507, as applicable). The latter would not count toward the ordinary hazardous waste generator status. However, the regulations could provide the option to follow either the applicable full hazardous waste rules or the (new) tailored rules. EPA's proposed 40 CFR "Reverse Distributor" Standards would be contained in the *Standards for Secondary Generators of Hazardous Waste Pharmaceuticals* section; however, with changes from the proposal to remove the *potentially creditable* and *non-creditable labels* categorization issues (see elaboration below), and (to remove) "is it a waste or not confusion" (it all is), and most importantly to end the *reverse distribution*/*reuse* fiction for good.

DTSC recommends EPA eliminate the definitions of *potentially creditable* and *non-creditable hazardous waste pharmaceuticals*. Simply put, as EPA has defined these terms, no person can visually discern, nor determine, the difference between one or more hazardous waste pharmaceuticals and tell which definition applies. However, EPA has defined a workable schema with regard to its proposed definition "Evaluated Hazardous Waste Pharmaceutical" and only needs to also define "Unevaluated Waste Pharmaceutical" and a regulatory standard that provides a means to distinguish the two and to complete a workable structure, around which EPA can attach most (if not all) of its proposed management standards for hazardous waste pharmaceuticals.

California, other states and EPA have all dealt with part 266 subpart F unobservable and unenforceable standard of "economically significant amounts." DTSC recommends that EPA recognize such standards are not practicable regulatory waste management standards and, especially in this context, where no significant recovery or reuse is occurring, are unwarranted. DTSC asks EPA to not unnecessarily confuse the regulations with issues of business credit. DTSC asks EPA to adopt a set of clear

waste management standards that ensures the safe handling of hazardous waste pharmaceuticals (creditable or not) that can be applied and enforced without, unobservable, unmeasurable economic variables that have no relevance to the safe handling of the hazardous wastes.

DTSC believes its proposal herein makes this possible while not making credit and other issues of business part of the hazardous waste regulatory standards. DTSC urges EPA to revise its proposal to incorporate a simpler perspective. DTSC suggest EPA address the following questions:

- What are the necessary waste handling standards?
- Can businesses evaluate materials for credit (or not)?
- May businesses conduct such transactions (as well as other business transactions) while complying with these waste handling standards?
-

DTSC asks EPA to re-examine its proposed rule from this simpler perspective.

Under this revised schema, the Primary Generators (i.e., hospital, doctor's office, LTCF, or retailer, etc.) would send the waste pharmaceuticals, in accordance with EPA's proposed standards, to the Secondary Generators for "evaluation". (Unlike EPA's use of the word, the *evaluation* is the completion of the generator's hazardous waste determination – not a business evaluation of credit or some other business concern.)

The Primary Generator standards would be largely the proposed part 266.502/503 standards combined. However, the shipments could/would include both hazardous and non-hazardous pharmaceuticals as long as they were in: 1) un-opened, 2) original packaging, and 3) largely intact packaging. This regulatory standard will clearly set the scope of which hazardous waste pharmaceuticals primary generators (retailers and healthcare and research facilities, etc.) may send to Secondary Generators. DTSC proposes EPA add a labeling requirement with an EPA-specified, color-coded (e.g., orange) label containing the words (Primary sent: date).

The Secondary Generators would then complete the *evaluations* and would apply either: 1) an EPA-specified (color-coded) label with date, for an Evaluated Hazardous Waste Pharmaceutical, or 2) another EPA-specified second e.g., orange label (symbolizing moving forward for evaluation) containing the words (R.D. sent: date). In this system, there would be one set of standards for all Primary Pharmaceuticals Waste Generators and for all Secondary Generators who send pharmaceutical hazardous wastes forward for evaluation. These would be duplicative and appear in both of the new part 262 sections.

There would also be one set of rules for all "evaluated hazardous waste pharmaceuticals" (i.e., for those wastes for which the hazardous waste determinations were completed) for all generators. Only hazardous waste pharmaceuticals meeting the unused, unopened, original packaging standard would be eligible for moving forward to evaluation. Any other "hazardous waste pharmaceuticals," e.g. used IV

bags with residues would be exactly that "hazardous wastes!" (These *non-creditable hazardous waste pharmaceuticals* - a definition that says/does nothing would not fall under any other confusing definition. If they did not meet the standard as eligible for sending forward for evaluation, these hazardous wastes would be regulated at the primary generators site and would be sent to TSDFs using a manifest, but they may get the benefit of alternate waste counting rules, alternate accumulation time limits, etc.

DTSC recommends that EPA address the following:

- Codify the Controlled Substances provision in either 40 CFR 261.4(a)(next number) or in new (g),
- EPA codify the Prohibition of Sewering (proposed 266.503) in each of the applicable sections.
- Re-locate the various more universal proposed empty-container provisions (266.507) into one or more new subsections in 40 CFR 261.7.

DTSC believes other generators, such as research laboratories, Universities, R&D facilities, etc. may have an equivalent need for these the above provisions. For example, if a manufacturing facility administers an injection or a pill of a finished pharmaceutical product to a test animal as part of its product testing protocol, would the fully dispensed syringe or blister pack be any less likely to qualify for, or any less deserving of, the empty container exemption? Likewise, are there not circumstances where freeing controlled substance hazardous wastes from RCRA constraints (when managed under DEA's safeguards)? As with the discussion above, if the waste management standards are relevant to the waste and are protective, then why limit them to one, two, or a few industry sectors?

In summary, DTSC believes that EPA can better implement its proposed rule by placing almost all of the proposed provisions in The Standards for Generators, along with what the Agency is doing in its Generator Improvements Rule. Codification in part 262 will better clarify for all generators of waste pharmaceuticals (not just healthcare sector parties) that some pharmaceutical hazardous wastes are RCRA regulated hazardous wastes and that generators of these hazardous waste are subject to generator standards. However, DTSC also believes codification in part 262 does not preclude EPA from tailoring standards to certain groups of generator entities. Lastly, it appears EPA may have missed opportunities to set standards for pharmaceuticals and related hazardous wastes, such as emptied syringes, for other sectors that handle like hazardous wastes.

II. Specific Comments

Note: In general DTSC supports that the more stringent standards in proposed 266.502 be adopted for Primary Generators sending hazardous waste pharmaceuticals to Secondary Generators who will complete the hazardous waste determinations for the pharmaceutical hazardous wastes. However, for simplification and greater clarity

for all pharmaceutical hazardous waste generators, DTSC suggest the standards in 266 .502 and 266.503 be combined into one set of standards

1. **Dietary Supplements**
   DTSC is not aware of any dietary supplements that are RCRA hazardous wastes when discarded. Absent any specific factual examples, DTSC opposes the amendments to include them at this time. However, DTSC suggests EPA may consider adopting a petition procedure to include dietary supplements and other like-materials on a case-by-case basis.

2. **Credit and Creditable Waste**
   DTSC believes the credit is not well enough understood by regulators to serve as an informed basis for a regulatory schema, for regulatory definitions, nor for regulatory enforcement activities. If EPA adopts a schema based on all or in part upon *a potential for credit*, what is to stop manufacturers from charging retailers $0.02 extra and then returning $0.01 as a credit on every item? In that event, all items would become potentially creditable. As EPA discusses, there is very little actual reuse and/or resource recovery occurring in the waste pharmaceutical arena. Therefore, it seems to DTSC, that EPA has made the correct choice in deciding that hazardous waste pharmaceuticals moving forward for evaluation are hazardous wastes (credit or no credit). Yet, incongruously, EPA has exempted hazardous waste pharmaceuticals destined for reverse distributors exempt from its proposed standards in part 266 subpart P. [See proposed 40 CFR 266.501(d)((1)(ii)]. DTSC recommends EPA not build a regulatory schema around this less than fully understood credit concept.

   Primary Generators may not have the knowledge to readily complete the hazardous waste determination for the waste pharmaceuticals. The Secondary Generators (a.k.a. reverse distributors, a false term) may be able to do a better job of this hazardous waste management step. EPA can adopt a regulatory schema that allows Primary Generators to presume (all) the pharmaceutical wastes are hazardous wastes and allow them to send them under tailored hazardous waste management standards to the Secondary Generators, who, in turn, complete the hazardous waste determinations. These Secondary Generators can also be allowed to operate under their own set of tailored hazardous waste management standards. If these entities also make a credit determination at the same time, that falls outside the scope of the RCRA regulations.

3. **Proposed Definition of non-Creditable Hazardous Waste Pharmaceutical**
   As mentioned above, the proposed definition appears to be a non-definition that is unnecessary and that is not really used in the proposed regulations. With this definition, it appears EPA is trying to define (or limit) which hazardous wastes are ineligible to be sent forward for evaluation by more knowledgeable Secondary Generators. DTSC recommends EPA simply set a clear regulatory standard, such as: "1) un-opened, 2) in original packaging, and 3) largely intact packaging" that can entirely eliminate this confusing issue. According to EPA's preamble, the

healthcare generators do not know which wastes are credit worthy and which are not. If that is indeed fact, then how can EPA expect generators and inspectors to comply with such a standard or definition? DTSC believes that generators and inspectors alike, could not function under this proposed standard. It is therefore recommended that this definition (and this concept) be removed from the final rule. ~~In the~~ Alternatively, EPA could adopt a clear listing of those items which EPA believes are non-creditable hazardous waste pharmaceuticals, including presumably all used, adulterated, and/or damaged hazardous waste pharmaceuticals.

At a minimum, the rule would be much more enforceable if EPA re-defined non-creditable HWP as: "any pharmaceutical waste not meeting the criteria in the definition of potentially creditable HWP." Although this is circular in nature, at least the definition would then specify some enforceable standard other than a generator's (perhaps wishful) expectation. In the final analysis, the only parts of these definitions that have real/actionable meaning are the following:

- unused,
- unexpired,
- expired for less than one year, and/or
- in sound packaging with original labeling capable of identification for hazardous waste purposes.

Any exclusion, exemption, tailored, and/or relaxed standards EPA wishes to devise for hazardous waste pharmaceuticals, including those eligible for and/or being sent for evaluation, can be clearly drafted and stated using those terms alone without reference to or creating a more elaborate economic euphemism or tautology.

4. **Proposed Definitions of Evaluated and Potentially Creditable Hazardous Waste Pharmaceuticals**

As mentioned above, DTSC does not know enough about this so called evaluation for credit or this credit to understand EPA's definitions or proposal. However, DTSC does believe a Secondary Generator can possibly simultaneously make this "business-credit determination" outside the scope of RCRA while also completing the RCRA step of making a hazardous waste determination for the Primary Generator. In light of this fact, DTSC recommends that EPA eliminate the creditable and non-creditable terms and concepts from the regulations and, instead define the process in terms of the "*evaluation*" and clarify that EPA is allowing the Secondary Generator to make the hazardous waste determination on behalf of the former generators. DTSC believes the rules can be practicable and enforceable as long as eligible pharmaceutical wastes moving forward for evaluation can be tracked and timed and distinguished from those which that have been evaluated. DTSC agrees with allowing a short timeframe, such as the proposed 21 days, to allow the hazardous waste determination to be completed. Regardless of the exact words codified by EPA in the final rule, the primary distinction in DTSC's opinion is that those wastes yet to be evaluated have incomplete hazardous waste determinations, whereas those that have been

evaluated are hazardous wastes with known RCRA listings, characteristics, waste codes and understood LDR requirements.

Therefore, DTSC proposes the following definition for Evaluated Hazardous Waste Pharmaceutical: A hazardous waste pharmaceutical received from a Primary Generator (of hazardous waste pharmaceuticals) that has been evaluated by the Secondary Generator (within 30 days of receipt – optional text), and that will not be sent to another Secondary Generator for further evaluation (i.e. for further hazardous waste identification).

5. **Proposed Definition of non-Pharmaceutical Hazardous Waste**
DTSC believes this definition is unnecessary if EPA adopts the schema suggested above. If so, the applicability sections in Part 262 can easily clarify that hazardous waste pharmaceuticals are subject to the two (new) sections for pharmaceutical waste generators and that all other hazardous wastes remain subject to the traditional generator standards (for VSQGs, SQG, and LQGs) without this definition.

6. **Proposed Definition of Pharmaceutical Reverse Distributor**
DTSC believes the discussion in section 11. of pp. 58025 of the preamble illustrates that this term is not related to RCRA hazardous waste management activities. As already noted, it also appears to be a falsehood that materials are actually returning up the supply chain in any significant quantities. As such, DTSC opposes the adoption of this term. DTSC recommends that EPA better identify, clarify, and then define the hazardous waste handling or management role this entity plays in the system if it does adopt this term into regulation. Please see the general comments above.

7. **Intersection of Controlled Substance and Hazardous Waste Pharmaceutical**
California's regulations have, for years, contained a limited, conditional exclusion for controlled substances that are incinerated. As noted above, DTSC believes this sort of exclusion in 40 CFR 261.4, provided the conditions are adequate, and is the best way to address the interface of these two controlling statutes. EPA might also consider excluding just the four known controlled substances if it wishes to be very narrow in the scope of such an exclusion. As noted in other areas, there are likely other parties (outside healthcare) that may benefit from such rules. For example, what if a person delivers such controlled substances to a Sherriff's Office for lack of any better alternative? The Sherriff may not fall within the scope of the current proposal or subpart 266. Re-locating the proposed rules as more generic exclusions in 261.4 (and 261.7 for syringes) appears to be a more versatile structure than the EPA proposal.

8. **Proposed Definitions of Long Term Care Facilities (LTCFs) and CESQG**
Based upon the preamble, most LTCFs are CESQGs. As such they would not be subject to the proposed rules. DTSC recommends that EPA consider amending 40 CFR 261.5 to exclude pharmaceutical hazardous wastes from the exemption

categorically and instead subject those generators to the (new) rules suggested (see above, Standards for Primary Generators of Pharmaceuticals) for their pharmaceutical hazardous wastes. Of course, these generators would still be VSQGs (CESQGs) for their ordinary hazardous wastes. Given EPA's explanations of the need for these rules and for its many more stringent aspects, this approach appears to be the most uniform solution to the LTCF situation. I.e., rather than amend 40 CFR 261.5 to require sending their wastes to a part 266 regulated entity, DTSC recommends EPA subject these entities to part 266 (as a Primary Generator) for their pharmaceutical wastes.

9. **Notification Using 8700-12 for Generator (Primary and Secondary)**
   DTSC supports requiring notifications by generators, including health care facilities and others managing hazardous waste pharmaceuticals subject to the new rules. As mentioned above, including subjecting CESQGs (VSQGs) to these standards and requiring notifications form these entities as well. Without such notification, the anti-Sewering rule will likely not be enforced.

10. **Training Requirements for Generators**
    Consistent with DTSC's above comments, DTSC recommends EPA apply the lower (SQG) training requirements to all Primary Generators and the higher (LQG) training standards to all Secondary Generators who complete the hazardous waste determinations, and who apply EPA hazardous waste numbers and make decisions about LDR applicability.

11. **Hazardous Waste Determinations**
    DTSC supports not requiring Primary Generators to assign waste numbers and determine LDR standards as long as it is a condition of the set of alternate generator standards for pharmaceutical hazardous wastes which requires those wastes be sent to a Secondary Generator who becomes responsible for those determinations. As with the co-generator policy, EPA could suggest or require a contractual agreement between the two parties as part of its final rule.

12. **Accumulation Areas**
    DTSC supports the use of working areas for accumulation containers and supports the divergence from CAAs and SAAs. However, DTSC recommends that facilities be required to maintain a list and map of all containers/locations (so that no containers/ locations are forgotten) if the number of locations/containers exceeds nine.

13. **Container Standards**
    DTSC supports relaxed container standards, but would prefer to see that cloth and plastic sacks or bags not be allowable, unless they are used as part of a packaging system that has a rigid component as part of the container.

14. **Labeling for Primary Generators**
    DTSC supports the labeling of containers as "Hazardous Waste Pharmaceuticals" and not requiring hazardous waste numbers for containers moving forward for evaluation. DTSC recommends that EPA-specified, color coded, date shipped labels be required as discussed above. This will facilitate the identification of "yet- to-be-evaluated" containers by receiving facilities and by inspectors in the field.

15. **Accumulation Time Limit**
    DTSC supports the longer accumulation time limit to allow transportation efficiencies. However, DTSC recommend that the limit be amended to include "up to one year or 6000kg, whichever occurs first." DTSC suggests EPA may find some other quantity equates to what is a cost effective quantity.

16. **LDRs**
    DTSC supports not requiring Primary Generators to complete LDR evaluations (how could they without EPA waste codes?) as long as it is a condition of the set of alternate generator standards for pharmaceutical hazardous wastes which requires those wastes be sent to a Secondary Generator who becomes responsible for those determinations on behalf of the Primary Generators.

17. **Manifesting**
    DTSC recommends manifests be used to track hazardous waste pharmaceuticals from Primary Generators to Secondary Generators without waste code, by EPA creating a single unique code. Primary Generators would use a single unique code when making such shipments to Secondary Generators who will complete the hazardous waste determinations on behalf of the primary generators. EPA should also clarify that Secondary Generators are allowed to accept these manifested hazardous waste shipments. (The preamble suggests it is not allowable under current regulations for a non-permitted TSDF, yet no citation was provided and no clear prohibition can be found in the regulations, in DTSC's opinion. A simple regulation stating: "notwithstanding section 26x.xx, Secondary Generators may receive ..." would be very helpful for all.)

18. **Records Retention**
    DTSC supports keeping records for three years. In this comment document, this would apply to manifests and exception reports. Primary Generators who send their hazardous waste pharmaceuticals to Secondary Generators who complete the hazardous waste determinations would not have to keep records of their decision to follow the hazardous presumption. Instead, the Secondary Generators would maintain the records for the final hazardous waste determinations on behalf of the Primary Generator.

19. **Releases**
    DTSC supports the 266.502(k) proposal.

20. **LTCF Self-generated Hazardous Wastes**
    DTSC is neutral on the requirement to inventory and collect the self-generated (household) hazardous waste pharmaceuticals from residents. The wording could be included to clarify that if a LTCF does accept these hazardous wastes from its residents, then it must manage them per these rules. This is necessary because EPA says HHW remains its exclusion/status into the future.

21. **CESQG Wastes Acceptance by LTCFS**
    Please see comment 8 above. DTSC recommends CESQGs be subject to the proposed standards themselves.

Note: the following specific comments build upon the above comments by further clarifying certain aspects for the Secondary Generators as DTSC has proposed they be called (i.e., the evaluators). For the most part, the waste handling standards for safe handling should be essentially same. Certain clarification are made herein, where circumstances at the second locations may be slightly different.

22. **Potentially Creditable Pharmaceuticals as Products**
    DTSC agrees with and supports EPA's recent findings that these pharmaceutical wastes are hazardous wastes and are not products. ~~DTSC agrees believes that the~~ Evidence placed before DTSC and regulatory agencies ~~supports~~ shows that the pharmaceuticals are not being reclaimed, nor reused in any significant quantities. DTSC supports EPA's rescission [revocation] of its previous guidance documents in the final rule. In line with EPA's findings, DTSC strongly recommends, as previously mentioned above, a line item amendment to 40 CFR 261.2 clarifying that pharmaceuticals, as defined in 260.10 are wastes when sent to Secondary Generators for completion of the hazardous waste determination by trained, skilled and more knowledgeable persons. If ultimately EPA retains the "potentially creditable" moniker, DTSC strongly suggests that EPA add that moniker to the line item discussed above.

    Under EPA's current proposal when one steps through the regulations, starting on page 58083, as proposed (without reading and using any preamble discussion), the the following will/may occur:

    A healthcare generator, who is uneducated in hazardous waste rules, will deem all pharmaceutical material potentially creditable because this person does not know otherwise, and would like to receive credit In part 261 there is no reason to believe these items are wastes; the generator does not know anything about disposal, reuse, or reclamation. It may be worthy of credit instead of regarded as a waste. Then, in part 262, the generator reads nothing to indicate potentially creditable items are not products, but instead are hazardous wastes. If the generator does turn to part 266, the generator will see nothing in the definition section that would indicate the "potentially creditable materials" are hazardous wastes, but will be left with the final definition of potentially creditable *hazardous*

wastes. Despite that phrase, the generator will see that it is not regulated via 266.501(d)(1)(ii), supporting that the material are unregulated.
In light of the above impact, DTSC asks EPA to consider it alternative approach designating two kinds of regulated generators for hazardous waste pharmaceuticals.

23. **Hazardous Waste Determinations for Evaluators (Secondary Generators)**
DTSC recommends that the standards for secondary generators require completion and documentation of the hazardous waste determinations for the waste pharmaceuticals these entities receive under a presumption of being hazardous. DTSC suggests the final regulations could require a contractual agreement that specifies that these entities will complete this action and will return documentation of such completion to the Primary Generators. DTSC supports a relatively short timeframe, 21 days, as proposed by EPA, for such completion and a labeling or marking requirement as discussed above, upon completion.

24. **Accumulation Time Limit & Labeling**
DTSC would apply the same standard as in comment 11 above. However, DTSC expects the secondary generators would reach the proposed quantity limit of 6,000 kg (or another value set by EPA) much sooner. Still, the standard for safe handling should not differ in DTSC's mind; the wastes have not changed chemically or physically during the transfer from one location to the other. Containers should be labeled Hazardous Waste Pharmaceuticals. Once evaluated, hazardous waste labels should be affixed within three days.

25. **Sewer Disposal Prohibition**
DTS supports this prohibition applying to all entities managing hazardous waste pharmaceuticals, including VSQGs (CESQGs) SQGs, LQGS, TSDFs, and of course Primary and Secondary Generators as described herein. For SQGs and LQGs, this prohibition need only be codified in those sections of Part 262 if EPA decides to allow generators the option of following the traditional hazardous waste rules or the new rules for pharmaceuticals. If the rules for hazardous waste pharmaceuticals are not optional under the applicability section of part 262, then this prohibition need not appear in the SQG and LQG sections (currently proposed 262.16 and 262.17). To re-iterate, DTSC believes EPA should utilize its CWA authority to exclude hazardous waste pharmaceuticals from the 40 CFR part 261.5 exemption and should also simultaneously codify the sewering prohibition in that section. EPA could also use its solid waste (Subtitle D) authorities, perhaps.

26. **DEA and Empty Container Exclusions**
See above. No additional comments.

27. **Sending Evaluated Hazardous Waste Pharmaceuticals to TSDFs**
DTSC believes the Secondary Generators should be subject to the same pre-transport standards and transportation standards as are LQGs (i.e., in proposed 262.17). To reiterate, DTSC supports shipping hazardous waste pharmaceuticals to Secondary Generators under manifests as well with a new single waste code promulgated by EPA for his purpose (presumed hazardous pharmaceuticals shipped for evaluation, EPA hazardous Waste # XYZ1.

28. **Imports and Exports**
DTSC supports EPA's proposal to apply the existing hazardous waste rules for Imports and Exports of hazardous waste pharmaceuticals, for both Primary and Secondary Generators, as discussed herein.

29. **Notification for Secondary Generators**
DTSC supports EPA amending the 8700-12 form and requiring notifications of activities for all Secondary Generators who accept hazardous waste pharmaceuticals under manifest and complete the hazardous waste determinations on behalf of the Primary Generators of pharmaceutical hazardous wastes.

30. **Inventories for Secondary Generators**
DTSC supports EPA's proposal to require inventories and to make copies available to inspectors, as well as applicable portions available to Primary Generators they contract with.

31. **Security**
DTSC supports EPA's proposal, in proposed 266.510(a)(3), for security for Secondary Generators of hazardous waste pharmaceuticals.

32. **Accumulation Time Limit**
Please, see comment 24 above.

33. **Contingency Plan, and Closure**
DTSC supports applying the newly proposed, and to hopefully be revised, Contingency Plan and Closure requirements for LQGs to Secondary Generators.

34. **Reporting and Recordkeeping**
DTSC supports un-manifested waste reports and all recordkeeping proposed by EPA. DTSC also recommends maintaining for three years: copies of all completed hazardous waste determinations made on behalf of Primary Generators and copies of all submitted 8700-12 forms regarding pharmaceutical hazardous waste handling.

35. **Sending Hazardous Waste to another Secondary Generator**
DTSC recommends that the standards for a Secondary Generator clearly state that a Secondary Generator that sends hazardous waste pharmaceuticals to another Secondary Generator for Evaluation becomes the Primary Generator and is

subject the "Standards for Primary Generators of Pharmaceuticals," as proposed in these comments, just as a TSDF may be subject to part 262 under the present regulations.

36. **Additional standards for Secondary Generators**
DTSC supports EPA's application and adoption of all of the additional standards in proposed 266.510(c) and (d) to Secondary Generators of hazardous waste pharmaceuticals as DTSC has described that entity herein.

37. **Part 268 Standards**
DTSC supports EPA's proposal to amend the LDR standards accordingly to the proposed rules.

38. **Part 273 Prohibition**
DTSC supports EPA's proposal to regulate health care industry generators as well as other industrial generators of hazardous waste pharmaceuticals under tailored generator standards and not under the universal waste rules. However, DTSC questions the extent of the prohibition as proposed. DTSC suggests that EPA revise the proposed 66273.80(d) prohibition to allow for States to adopt universal waste rules including household hazardous wastes and possibly CESQG hazardous wastes into their universal waste rules as this rule may facilitate collection programs that have objectives that are directly in synch with the stated goals of EPA's proposed rule. DTSC understands that EPA views it RCRA rules with the 261.4(b)(1) exclusion in mind. However, DTSC would like to point out to EPA that not all states implement this type of exclusion, nor does the 40 CFR 273.8(b)(1) provision operate consistently with this RCRA exclusion. In addition, EPA's creation of the universal waste rule has spurred the creation of states UWRs. The prohibition as drafted could have impacts that potentially negatively impact states efforts to collect hazardous waste pharmaceuticals, both RCRA and non-RCRA.

CA AB 26

AUTHOR: Jones-Sawyer [D]
TITLE: Medical Cannabis
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 12/01/2014
LAST AMEND: 01/25/2016
DISPOSITION: Pending
LOCATION: Senate Business, Professions & Economic Development Committee
SUMMARY:

Requires a licensee under the Medical Marijuana Regulation and Safety Act to institute a training program for the licensee's agents and employees regarding compliance. Requires an application for licensure include a description of the applicant's program. Makes the licensing authority responsible for approving and regulating programs. Prohibits approving a apprenticeship program. Authorizes a fee for program approval. Provides for deposit of said fees in a related account.

STATUS:

02/04/2016 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 73

AUTHOR: Waldron [R]
TITLE: Patient Access to Prescribed Antiretroviral Drugs
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 12/18/2014
LAST AMEND: 01/05/2016
DISPOSITION: Pending
LOCATION: Senate Health Committee
SUMMARY:

Provides, to the extent permitted by federal law, that if medically necessary antiretroviral drugs used in the treatment of HIV/AIDS is prescribed by a Medi-Cal beneficiary's treating provider for that purpose, and coverage for that drug is denied by a Medi-Cal managed care plan in which the beneficiary is enrolled, that denial shall be reviewed in accordance with these provisions. Provides the conditions under which that patient would be entitled to an automatic urgent appeal.

STATUS:

02/04/2016 To SENATE Committee on HEALTH.
INDEX: 63, 89
ISSUES: AK*, AO, BJ
LOBBYIST: AH, BG*
POSITION: F

CA AB 1069

AUTHOR: Gordon [D]
TITLE: Prescription Drugs: Collection and Distribution
FISCAL COMMITTEE: no
URGENCY CLAUSE: no

INTRODUCED:	02/26/2015
LAST AMEND:	07/01/2015
DISPOSITION:	Pending - Carryover
LOCATION:	Senate Appropriations Committee

SUMMARY:

Authorizes an entity participating in the medication repository and distribution program to transfer eligible donated medication to a participating entity in any other county. Prohibits such entity from transferring more than a specified percentage of its donated medications annually. Authorizes medication donated to the program to be maintained in new, properly labeled containers. Prohibits donated medication from being repackaged more than twice. Makes a technical, nonsubstantive change.

STATUS:

07/06/2015	From SENATE Committee on BUSINESS, PROFESSIONS AND ECON. DEVELOPMENT: Do pass to Committee on APPROPRIATIONS. (7-0)
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1575

AUTHOR:	Bonta [D]
TITLE:	Medical Cannabis
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/04/2016
LAST AMEND:	03/18/2016
DISPOSITION:	Pending
COMMITTEE:	Assembly Business and Professions Committee
HEARING:	04/12/2016 9:30 am

SUMMARY:

Requires the Board of Equalization to form an advisory group to examine strategies such as integrated point-of-sale systems with State track and trace systems, and other measures that will improve financial monitoring of medical cannabis businesses. Requires creation of a financial monitoring system. Prohibits a city, county, or city and county from adopting an ordinance for packaging safety standards exceeding statewide standards. Requires the Department of Public Health to establish such standards.

STATUS:

03/18/2016	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1668

AUTHOR:	Calderon I [D]
TITLE:	Investigational Drugs,Biological Products and Devices
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/15/2016

LAST AMEND:	03/07/2016
DISPOSITION:	Pending
COMMITTEE:	Assembly Appropriations Committee
HEARING:	04/06/2016 9:00 am

SUMMARY:

Permits a manufacturer of an investigational drug, biological product, or device to make the product available to eligible patients with life-threatening conditions. Authorizes a health benefit plan to provide coverage for any investigational drug, biological product, or device. Prohibits disciplinary action against any physician for a related recommendation. Prohibits using such recommendation as the basis for excluding a physician from Medicaid or Medicare certification.

STATUS:

03/29/2016	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS: Do pass to Committee on APPROPRIATIONS. (14-0)
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1831

AUTHOR:	Low [D]
TITLE:	Health Care Coverage: Prescription Drugs: Refills
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/09/2016
DISPOSITION:	Pending
LOCATION:	Assembly Health Committee

SUMMARY:

Requires a health care service plan contract or health insurance policy that provides coverage for prescription drug benefits to allow for early refills of covered topical opthalmic products at a specified percentage of the predicted days of use.

STATUS:

02/25/2016	To ASSEMBLY Committee on HEALTH.
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 1977

AUTHOR:	Wood [D]
TITLE:	Prescriptions: Health Coverage: Opiod Analgesics
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/16/2016
LAST AMEND:	03/30/2016
DISPOSITION:	Pending
COMMITTEE:	Assembly Health Committee
HEARING:	04/12/2016 1:30 pm

SUMMARY:

Limits the supply of such analgesic that may be prescribed for pain due to surgery. Requires an individual or group health care service plan or disability insurance policy to provide coverage on its formulary, drug list, or other lists of

for at least one abuse deterrent opioid analgesic drug product per opioid analgesic active ingredient. Provides the total amount of copayments and coinsurance an enrollee or insured is required to pay for brand name abuse-deterrent opioid analgesic drug products.

STATUS:

03/30/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/30/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 39, 89
ISSUES: BJ, DG, DJP*, DP
LOBBYIST: AH
POSITION: F

CA AB 2050

AUTHOR: Steinorth [R]
TITLE: Health Care Coverage: Prescription Drugs: Refills
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/17/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
COMMITTEE: Assembly Health Committee
HEARING: 04/19/2016 1:30 pm
SUMMARY:

Requires a health care service plan or health insurance policy that provides coverage for prescription drug benefits to implement a medication synchronization policy for the dispensing of prescription drugs so that prescriptions that are refilled at the same frequency may be filled concurrently.

STATUS:

03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 39, 89
ISSUES: BJ, DG, DJP*, DP
LOBBYIST: AH
POSITION: F

CA AB 2095

AUTHOR: Allen T [R]
TITLE: Medi-Cal: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/17/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
COMMITTEE: Assembly Health Committee
HEARING: 04/12/2016 1:30 pm
SUMMARY:

Requires the Legislative Analyst's Office to conduct or cause to be conducted a study comparing the purchase or administration of brand name prescription medications through the Medi-Cal program to the purchase or administration of biosimilars through the Medi-Cal program. Requires the study to cover specified fiscal years.

STATUS:

03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 65, 89
ISSUES: AK*, AO, BJ, DP
LOBBYIST: AH, BG*
POSITION: F

CA AB 2144

AUTHOR: Rodriguez [D]
TITLE: Pharmacy: Prescriptions
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/17/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
LOCATION: Assembly Health Committee
SUMMARY:

Revises specified patient information provisions of existing law to require that a health facility require each patient to acknowledge in writing that the patient has received information regarding drugs given to the patient at the time of discharge including the use and storage of each drug, the precautions, and relevant warnings, and the importance of compliance with directions. Makes a nonsubstantive change to a provisions of existing law regarding substitution of an alternative biological product.

STATUS:

03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 2385

AUTHOR: Jones-Sawyer [D]
TITLE: Medical Marijuana Regulation and Safety Act: Measure D
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/18/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Permits licensing authorities under the Medical Marijuana Regulation and Safety Act from requiring a local license, permit, or other authorization, and would require a State license, if the applicant meets all of the requirements of the Act and specified criteria relating to a special measure approved by the voters in the City of Los Angeles. Provides a license pursuant to State provisions has the same force and effect as licenses issued to licensees not subject to the above-described exception.

STATUS:

	03/18/2016	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.
	03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.
	INDEX:	89
	ISSUES:	BJ*, DP
	LOBBYIST:	AH
	POSITION:	F

CA AB 2400

AUTHOR:	Nazarian [D]
TITLE:	Prescription Drug Coverage: Prior Authorization
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
LAST AMEND:	03/17/2016
DISPOSITION:	Pending
LOCATION:	Assembly Second Reading File

SUMMARY:

Specifies that an external exception request may be file in lieu of a grievance with a health care service plan or health insurer regarding nonformulary drugs, following an adverse benefit determination. Requires any plan or insurer grievance system process or a plan or insurer internal process to require the resolution of grievances or complaints that involve the disapproval of a request for a formulary drug within a specified time period for both nonurgent and if exigent circumstances exist.

STATUS:

03/29/2016	From ASSEMBLY Committee on HEALTH: Do pass as amended to Committee on APPROPRIATIONS. (13-2)
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*, DP
LOBBYIST:	AH
POSITION:	F

CA AB 2436

AUTHOR:	Hernandez R [D]
TITLE:	Health Care Coverage and Disclosures
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
DISPOSITION:	Pending
COMMITTEE:	Assembly Health Committee
HEARING:	04/12/2016 1:30 pm

SUMMARY:

Requires a health care service plan contract or a policy of health insurance that provides coverage for prescription drug benefits to notify the enrollee or insured of information related to the cost of a prescription drug at the time that the drug is purchased or delivered.

STATUS:

03/08/2016	To ASSEMBLY Committee on HEALTH.
INDEX:	39, 89
ISSUES:	BJ, DG, DJP*
LOBBYIST:	AH
POSITION:	F

CA AB 2592

AUTHOR: Cooper [D]
TITLE: Controlled Substances: Medicine Packages: Grants
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/19/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
COMMITTEE: Assembly Health Committee
HEARING: 04/05/2016 1:30 pm
SUMMARY:

Requires the State Department of Public Health to implement the Opioid Abuse Prevention Pilot Program to award grants to combat opioid abuse and improve the safe prescribing of opioids. Requires a pharmacy that applies for and receives a grant to offer all patients who are prescribed an opioid a medicine locking closure package.

STATUS:

03/18/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 2679

AUTHOR: Cooley [D]
TITLE: Marijuana: Regulation: Research
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/19/2016
LAST AMEND: 03/18/2016
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Amends the Medical Marijuana Regulation and Safety Act which requires each licensing authority to prepare and submit an annual report. Requires that report to include the number of appeals from the denial of a State license or other disciplinary actions taken, the average time spent on appeals, and the number of complaints regarding licensees. Specifies studies of the University of California to ascertain medical safety and efficacy of marijuana to include the effect of marijuana on motor skills.

STATUS:

03/18/2016	From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.
03/18/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA AB 2712

AUTHOR: Chiu [D]
TITLE: Pharmacies: Medi-Cal Program Participation

FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/19/2016
LAST AMEND:	03/28/2016
DISPOSITION:	Pending
LOCATION:	Assembly Health Committee

SUMMARY:

Relates to pharmacies and Medi-Cal program participation. Relates to any patient upon presentation of a valid prescription for the patient and evidence of residency in California. Provide that the term covered by insurance does not apply to a prescription for a specific medication prescribed for a patient that is not included on the drug formulary maintained by that patient's health care service plan or health insurer, and for which the patient is prepared to pay cash.

STATUS:

03/28/2016	From ASSEMBLY Committee on HEALTH with author's amendments.
03/28/2016	In ASSEMBLY. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX:	65, 89
ISSUES:	AK, AO*, BJ, DP
LOBBYIST:	AH, BG*
POSITION:	PR

CA SB 149

AUTHOR:	Stone [R]
TITLE:	Investigational Drugs: Biological Products or Devices
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	01/29/2015
LAST AMEND:	07/13/2015
DISPOSITION:	Pending - Carryover
LOCATION:	Assembly Appropriations Committee

SUMMARY:

Permits a manufacturer of an investigational drug, biological product, or device to make the product available to certain patients with an immediately life-threatening disease or condition. Provides the Medical Practice Act does not require a health benefit plan or governmental agency to provide coverage for the cost of such products made available under these provisions. Authorizes a health benefit plan to provide coverage for such products. Prohibits action against a physician for making a recommendation.

STATUS:

08/27/2015	In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.

INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F, X

CA SB 423

AUTHOR:	Bates [R]
TITLE:	Retail Nonprescription Surplus Products: Reuse
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	yes
INTRODUCED:	02/25/2015
LAST AMEND:	08/31/2015

DISPOSITION: Pending - Carryover
LOCATION: ASSEMBLY
SUMMARY:

Amends the Medical Waste Management Act. Establishes criteria for the handling and management of retail nonprescription pharmaceutical surplus products if a reasonable determination for reuse has been made or when such determination for reuse cannot be made but the product has been recalled as required by law. Authorizes the adoption of regulations as deemed necessary to establish standards for the proper and safe handling of retail non prescription pharmaceutical surplus products.

STATUS:

09/01/2015 In SENATE. Read third time, urgency clause adopted. Passed SENATE. *****To ASSEMBLY. (40-0)

INDEX: 75, 89
ISSUES: BJ, CLH*, DP
LOBBYIST: AH, KAS*
POSITION: F

CA SB 435

AUTHOR: Pan [D]
TITLE: Medical Marijuana: Personal Cultivation
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/25/2015
LAST AMEND: 01/19/2016
DISPOSITION: Pending
LOCATION: Assembly Health Committee
SUMMARY:

Amends existing law that exempts certain persons from the State license requirements for permitting the cultivation of marijuana under the Medical Marijuana Cultivation Program to provide that an exemption from these requirements does not limit or prevent a city, county, or city and county from exercising its police power authority under a specified portion of the State Constitution.

STATUS:

01/20/2016 In ASSEMBLY Committee on HEALTH: Not heard.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: F

CA SB 447

AUTHOR: Allen [D]
TITLE: Medi-Cal: Clinics: Enrollment Applications
FISCAL COMMITTEE: yes
URGENCY CLAUSE: no
INTRODUCED: 02/25/2015
LAST AMEND: 08/24/2015
DISPOSITION: Pending - Carryover
LOCATION: Assembly Appropriations Committee
SUMMARY:

Eliminates the requirement that the State Department of Health Care Services approve an application for enrollment in the PACT Program. Requires specified health facilities to submit an application to the State Department of Public Health. Requires a clinic not enrolled in the Medi-Cal program to submit an

application for enrollment in both programs. Requires a clinic already under Medi-Cal to apply for the PACT Program. Provides the time period for application review. Requires development of related forms.

STATUS:

08/26/2015 In ASSEMBLY Committee on APPROPRIATIONS: Not heard.

INDEX: 65, 89

ISSUES: AK, AO*, BJ, DP

LOBBYIST: AH, BG*

POSITION: F

CA SB 482

AUTHOR: Lara [D]

TITLE: Controlled Substances: CURES Database

FISCAL COMMITTEE: yes

URGENCY CLAUSE: no

INTRODUCED: 02/26/2015

LAST AMEND: 04/30/2015

DISPOSITION: Pending - Carryover

LOCATION: ASSEMBLY

SUMMARY:

Requires all prescribers and dispensers of Schedule II or Schedule III controlled substances, to consult a patient's electronic history in the Controlled Substance Utilization Review and Evaluation System database before prescribing the controlled substance to the patient for the first time. Requires the prescribed to consult the database at least annually when the substance remains part of the patient's treatment. Failure to use the database is cause for licensing board disciplinary action.

STATUS:

05/28/2015 In SENATE. Read third time. Passed SENATE. *****To ASSEMBLY. (28-11)

INDEX: 89

ISSUES: BJ, DP*

LOBBYIST: AH

POSITION: F

CA SB 992

AUTHOR: Fuller [R]

TITLE: Pharmacy Practice

FISCAL COMMITTEE: no

URGENCY CLAUSE: no

INTRODUCED: 02/10/2016

DISPOSITION: Pending

LOCATION: Senate Rules Committee

SUMMARY:

Makes a technical, no nonsubstantive changes to a provision declaring that pharmacists are health care providers.

STATUS:

02/18/2016 To SENATE Committee on RULES.

INDEX: 89

ISSUES: BJ*, DP

LOBBYIST: AH

POSITION: F

CA SB 1193

AUTHOR: Hill [D]

TITLE: California State Board of Pharmacy

FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
DISPOSITION:	Pending
COMMITTEE:	Senate Business, Professions & Economic Development Committee
HEARING:	04/18/2016

SUMMARY:

Extends the Pharmacy Law that provides for the licensure and regulation of the practice of pharmacy by the California State Board of Pharmacy, which is within the Department of Consumer Affairs. Authorizes the board to appoint, with the approval of the Director of Consumer Affairs, an executive officer, as specified.

STATUS:

03/03/2016	To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1229

AUTHOR:	Jackson [D]
TITLE:	Home-Generated Pharmaceutical Waste
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
LAST AMEND:	03/28/2016
DISPOSITION:	Pending
LOCATION:	Senate Environmental Quality Committee

SUMMARY:

Provides that a collector is not liable for civil damages, or subject to criminal prosecution, for maintaining a secure drug take-back bin on its premises if the collector takes specified steps, including that the collector regularly inspects the area surrounding the secure drug take-back bin for potential tampering or diversion, to ensure the health and safety of consumers and employees and the proper disposal in the waste stream of home-generated pharmaceutical waste contained in the bins.

STATUS:

03/28/2016	From SENATE Committee on ENVIRONMENTAL QUALITY with author's amendments.
03/28/2016	In SENATE. Read second time and amended. Re-referred to Committee on ENVIRONMENTAL QUALITY.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

CA SB 1230

AUTHOR:	Stone [R]
TITLE:	Pharmacies: Compounding
FISCAL COMMITTEE:	yes
URGENCY CLAUSE:	no
INTRODUCED:	02/18/2016
DISPOSITION:	Pending
COMMITTEE:	Senate Business, Professions & Economic Development

Committee

HEARING: 04/11/2016

SUMMARY:

Authorizes a pharmacy that provides compounding services to provide to a clinic commercial products that are unique and otherwise unavailable to the clinic, if the compounding pharmacy and the clinic have entered into a professional compounding services agreement to provide nonpatient-specific compounded medications that cannot be planned for prospectively.

STATUS:

03/03/2016 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.

INDEX: 89

ISSUES: BJ*, DP

LOBBYIST: AH

POSITION: F

CA SB 1346

AUTHOR: Allen [D]

TITLE: Pharmacists: Drug Labeling

FISCAL COMMITTEE: yes

URGENCY CLAUSE: no

INTRODUCED: 02/19/2016

DISPOSITION: Pending

LOCATION: Senate Business, Professions & Economic Development Committee

SUMMARY:

Relates to drug labeling. Authorizes a pharmacist to offer a patient, as an alternative to a printer paper medication guide for a prescription drug, the electronic delivery of the medication guide. Authorizes a pharmacist to deliver the medication guide by electronic means if the patient chooses electronic delivery. Authorizes the board to exempt a drug from that authorization by regulation.

STATUS:

03/03/2016 To SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT.

INDEX: 89

ISSUES: BJ*, DP

LOBBYIST: AH

POSITION: F

CA SB 1454

AUTHOR: Stone [R]

TITLE: Pharmacy

FISCAL COMMITTEE: no

URGENCY CLAUSE: no

INTRODUCED: 02/19/2016

LAST AMEND: 03/31/2016

DISPOSITION: Pending

LOCATION: Senate Rules Committee

SUMMARY:

Prohibits a pharmacy benefits manager from requiring that a pharmacist or pharmacy provide reimbursement to the pharmacy benefit manager for the costs of any drug dispensed to a patient that was property adjudicated, except upon a showing of fraud or malfeasance. Requires any improper reimbursement during a specified time period, to be refunded to the pharmacist or pharmacy.

STATUS:	
03/31/2016	From SENATE Committee on RULES with author's amendments.
03/31/2016	In SENATE. Read second time and amended. Re-referred to Committee on RULES.
INDEX:	89
ISSUES:	BJ*, DP
LOBBYIST:	AH
POSITION:	F

From: Shane, Rita Pharm.D. [mailto:Rita.Shane@cshs.org]
Sent: Wednesday, March 23, 2016 3:27 PM
To: BJ Bartleson; Doug.C.O'Brien@kp.org; Paulsen, Lynn (Lynn.Paulsen@ucsf.edu); Jeannette Hanni; Candace Fong; 'Low, Christine'; 'Stephens, Sarah'; 'susan.reed@ah.org'
Cc: Youmbi, Karen V
Subject: RE: Remarks for AB 2144

Here are our comments. Thanks to Karen Youmbi for her assistance in compiling the information.

- **Patient written acknowledgement of receipt of discharge instructions**
  - Health facilities may have other means to ensure patient receive medication counseling at discharge (e.g. Electronic health record prevents changes in pt status until counseling is complete)
  - **Assessment:** Requiring written acknowledgment does not appear to provide additional benefit in ensuring patient are counseled when other processes already exist for this purpose
- **Biological substitution**
  - Ability to substitute for lower cost alternative supports global healthcare cost reduction initiatives
  - Requirement to inform provider within 5 days of substitution appears unwarranted when substitution is performed using an FDA-approved interchangeable product
    - Interchangeable biological products have been shown to have no clinically meaningful differences from the reference biological product and are expected to produce the same clinical result in any given patient
  - Relevant background
    - ASHP Policy 1509: "Approval of biosimilar medications" states: To oppose any state legislation that would require a pharmacist to notify a prescriber when a biosimilar deemed to be interchangeable by the FDA is dispensed
    - FDA:
      - Interchangeable products are both biosimilar to an FDA-approved reference product, and can be expected to produce the same clinical result as the reference product in any given patient. An interchangeable product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.
      - In addition, for a biological product that is administered more than once to an individual, the risk in terms of safety or efficacy of alternating or switching between the biological product and the reference product will not be greater than the risk of using the reference product without alternating or switching
      - Because interchangeable products have met additional criteria for approval, they may be substituted at the pharmacy without the intervention of a healthcare provider
  - Use of an interchangeable product would not be expected to increase the risk to patients when compared to the reference product – informing the prescriber of this substitution would not be expected to result in a change in the clinical management of the patient
  - **Assessment:** Based on the FDA and ASHP policy language, we recommend that pharmacists should not be required to notify the prescribers when substituting with interchangeable biological products. It would be prudent for the pharmacist to notify the prescriber when substitution is performed with a biosimilar that is not deemed interchangeable.

CHA Medication Safety Pharmacy Bill Discussion Guide

4/6/2016

1. **Medical Cannabis - What are pharmacists seeing in the hospital setting relative to medical cannabis? What happens to a patient who is on this at home and is hospitalized? What happens when a patient has it on their person when admitted?**

   AB 26 – license to institute a training program on compliance

   AB 1575 – Board of Equalization to form an advisory group

   AB 2385- LA medical marijuana business immunity

   AB 2679 – amends the medical marijuana regulation and safety act to require their reporting to include the number of appeals from denials of a state license, etc.

   SB 435 – exempts certain persons from state license requirements

2. **Medication /Drug Access/Coverage – Do these coverage issues extend beyond your own hospital system formularies? Do they cause a delay in practice, etc? Particularly with HIV, Hep C or oncology drugs?**

   AB 73 – any denials of antiretroviral drugs used in the treatment of HIV/AIDS shall be reviewed

   AB 1831 – requires a health care services plan to allow for early refills of topical ophthalmic products

   AB 2095 – requires the LAO to conduct a study comparing the purchase or administration of brand name prescription medications through the Medi-Cal program to the purchase or administration of biosimilars through the Medi-Cal program.

   AB 2400 – an external exception request may be filed in lieu of a grievance with a health care service plan/insurer regarding nonformulary drugs, following an adverse benefit determination.

   AB 2436 – requires a health care plan that provides coverage for prescription drug benefits to notify the enrollee of information related to the cost of a prescription drug at the time that the drug is purchased or delivered.

   AB 2712 – relates to pharmacies and Medi-Cal program participation and patient that presents with a valid prescription for the patient and evidence of residency in CA. Specific drug formulary requirements – *Does this affect any member outpatient pharmacies?*

   SB 447 – Eliminates the requirement that the State Department of Health Care Services approve an application for enrollment in the PACT program.

   SB 1454- Prohibits a pharmacy benefits manager from requiring that a pharmacist or pharmacy provide reimbursement to the pharmacy benefit manager for the costs of any drug dispensed to a patient.

3. **Prescription Drugs: Collection and Distribution**

   AB 1069 – authorizes an entity participating in the medication repository and distribution program to transfer eligible donated medications to a participating entity in any other county. *Does this affect members?*

   AB 2050 – requires a health care service plan or policy to implement a medication synchronization policy for the dispensing of prescription drugs so that prescriptions that are refilled at the same frequency may be filled concurrently. *Explain?*

4. Investigational Drugs – Has our position changed this year on investigational drugs?

AB 1668 – permits a manufacturer of an investigational drug, biologic product, etc. to make the product available to eligible patients with life threatening conditions

SB 149 - permits a manufacturer to make investigational drug, other available, and includes the provision that does not require the health benefit plan to provide coverage for the cost

5. Drug Waste

SB 423 - amends the Medical Waste Management Act. Established criteria for the handling and management of retail nonprescription pharmaceutical surplus products if a reasonable determination for reuse has been made or when such determination for reuse cannot be made but the product has been recalled as required by law,

SB 1229 – provides that a collector who maintains a secure drug take back bin on its premises will not be held liable for civil damages or subject to criminal prosecution

6. Opioids

AB 1977 - limits the supply of analgesics that may be prescribed for pain due to surgery. Requires an individual or group plan for at least one abuse deterrent opioid analgesic drug product per opioid analgesic active ingredient.

AB 2592 – requires CDPH to implement the Opioid Abuse Prevention Pilot Program to award grands to combat opioid abuse and improve safe prescribing of opioids.

SB 482 - requires all prescribers and dispensers of the Schedule II or Schedule III controlled substances to consult a patient's electronic history in CURES before prescribing and requires the prescribed to consult the database at least annually when the substance remains part of the patient's treatment. Failure to use the database is cause for licensing board disciplinary action.

7. General

AB 2144- revises specified patient information provisions of existing law to require that a health facility require each patient to acknowledge in writing that the patient has received information regarding drugs given to the patient at the time of discharge including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. *See notes from Cedars*

SB 992 – technical changes to a provision declaring that pharmacists are health care providers

SB 1193 – Board of Pharmacy Sunset bill

SB 1346 – authorized a pharmacist to offer a patient, as an alternative to a printer paper medication guide for a prescription drug, the electronic delivery of the medication guide by electronic means.

8. Compounding

SB 1230 - authorizes a pharmacy that provides compounding services to provide to a clinic commercial products that are unique and otherwise unavailable to the clinic if they have entered into a professional services agreement.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

January 27, 2016

TO: CHA Board of Trustees

FROM: Jeannette Hanni, R.Ph, MPA, FCSHP and Candace Fong, Pharm.D.
Co-Chairs, CHA Medication Safety Committee

SUBJECT: Medication Safety Committee

The Medication Safety Committee (Committee) provides a forum for diverse multidisciplinary health care organizations, including 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 acts as a source of pharmacy and medication safety expertise, provides a venue for the coordination of medication safety activities, and makes recommendations for medication related legislation and regulations. Statewide pharmacy, nursing and medication experts comprise the committee membership.

The Committee met on January 8, 2016, and discussed the following.

A. Board of Pharmacy Sterile Compounding Regulations, Article 4.5,7.5 of Division 17 of Article 16 California Code of Regulations, Section 1735 et seq., and 1751.

The Committee and the Sterile Compounding Workgroup have negotiated rigorously over the past year with the Board of Pharmacy and other stakeholders to modify and create a well-balanced set of sterile compounding regulations. The Committee had a majority of its proposals honored including the addition of program flexibility consideration for hospitals and health systems that will not meet the proposed regulations for physical plant and or venting issues, or who will not meet changes by the regulatory mandated date. The proposed requirements for a separate negative pressure room for all hazardous sterile drug compounding, and the requirement for external venting, will require many hospitals to assess and review necessary physical plant changes and ventilation reconfiguration, along with potential purchase or procurement of new or modified equipment to perform successfully under the revised guidelines. The proposed guidelines are in full alignment with the revised U.S. Pharmacopeial Convention 800 guidance.

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Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

The proposed regulations should be completed this year. In the meantime, the Committee is organizing educational tools, FAQ's, and a member webinar.

B. Board of Pharmacy Reconciliation and Inventory Report of Controlled Substances, Section 1715.65 of Article 2 of Division 17 of Title 16

The Committee submitted comments on these regulations that would require a periodic physical reconciliation and inventory at least every three months of all Schedule II controlled substances, and at least one additional controlled substance as identified by the board based on drug loss reports. While pharmacy leaders agree that physical inventory of the pharmacy vault every three months is reasonable, the area of greatest concern with the proposed regulations is the requirement to physically inventory automatic dispensing cabinets (ADC). A physical inventory of ADCs is not necessarily the best method to identify or limit diversion, depending on the respective ADC technology and hospital policies. Physical inventory of ADCs should not be mandated due to the fiscal impact and availability of other equivalent if not more successful methods deployed such as biometric identification, blind counts and controlled substance software, etc.

C. CURES 2.0 Browser Advisory Group

The state's prescription drug management program (PDMP), the Controlled Substance Utilization Review and Evaluation System, CURES, is being upgraded to a 2.0 platform to offer significantly improved user experience and features in a number of added functionalities. The system release, however, requires the need for a contemporary browser such as Internet Explorer 11 or above, Safari, Firefox or Chrome. The Committee formed an advisory group to work collaboratively with the Department of Justice to enhance hospital adoption of the program and full use of the system by appropriate providers by July 1, 2016.

D. FDA Drug Quality and Security Act

The Food and Drug Administration (FDA) Drug Quality and Security Act was signed into law in 2013 and affects all pharmacies, manufacturers and wholesalers to prevent suspect or illegitimate pharmaceutical products from entering the U.S. pharmaceutical supply chain. While the law went into effect July 1, 2015, enforcement will not officially begin for Dispensers until March 1, 2016. The Committee is developing FAQ's and other educational materials for CHA member distribution.

BJB:rf/nr

February 10, 2016

Opioid Crisis Puts Pharmacists on the Front Line, Pressed to Serve As Drug Cops

By John M. Glionna

GRAND PRAIRIE, Texas — Pharmacist Joe Harmison has been burglarized so many times, he protects his business with a siren-and-strobe-light security system. He keeps his most potent pain pills locked in a gun safe, in a room protected by a steel door.

Still, he was hit with two attempted break-ins in two days last month.

It's the price he pays for running a pharmacy as an opioid epidemic sweeps the United States.

The crisis has upended many lives. Pharmacists, however, are in an especially tough position, pulled between patients in dire need of relief and people addicted to opioids who will stop at nothing to get their hands on the drugs. More than 4 million Americans abuse prescription painkillers, federal data show, and such gnawing need has fueled a thriving black market.

From behind their counters, pharmacists are increasingly, and controversially, called upon to play drug cop — to turn away abusers, to reject phony prescriptions, and to protect their inventory of pills from criminals who see pharmacies as an easy target.

"It's a role that's been given to us, and many pharmacists choose to embrace it, while others run as far away and as fast as they can," Harmison said.

"People say, 'It's not fun. It's not what I signed on for.' But the way I see it, it's what I'm supposed to do. I'm entrusted with these chemicals," he said. "Not to be judicious would not be fulfilling my oath."

A gregarious 69-year-old with a soft Texas drawl, Harmison challenges prescriptions written by doctors from fly-by-night clinics. He flatly turns away some customers, like the guy who drove to this town on the outskirts of Dallas in a vehicle with Louisiana license plates and presented a prescription written by a doctor in Houston, 300 miles away. Not only that, the guy insisted on paying cash.

"I've told people, 'It looks like this prescription has been altered. I suggest you turn around and get out of here because I am going to call the cops,'" Harmison said.

He knows he's putting himself in danger by turning away addicts who want pills. He points to marks on the frame of his pharmacy's steel door — gouges where intruders have tried to wedge their way past and get at the drugs. These people are determined. Some could come back, angry and armed. "And that," he said, "I don't need."

But he's willing to take the risk — in the name of both protecting his integrity and the public health.

An arrest at the pharmacy counter

Others aren't so sure.

The expectation that they act as watchdogs has sent ripples of controversy among the nation's 300,000 pharmacists. Some worry that they'll hurt legitimate patients by denying them medication they desperately need. Challenging criminals could also put a pharmacist's life at risk or tie him up as a witness in lengthy trials.

"Every time I pick up a pharmacist magazine I read where some pharmacist is caught up in a legal battle because they had to play drug cop," one pharmacist wrote on the blog Pharm QD."I mean seriously, we are pharmacists, not the" Drug Enforcement Administration.

Another wrote that there isn't enough time to play detective: "Our attentions should be with the patients, anyway."

Richard Logan believes they're wrong. He has the street credentials to show he's serious about tackling prescription drug abuse: He's both a pharmacist and a working detective — an investigator in a multiagency drug task force for Mississippi and Scott counties in southeast Missouri.

"My colleagues do not want to do what I do," said Logan, 63. "There have been multiple occasions where I have badged people at my pharmacy counter and arrested them right there."

He relishes slapping those handcuffs on offenders.

"When I see someone trying to abuse the system, in my mind they're standing in the way of patients who really need those drugs," he said. "They're bastardizing the good work that pharmacists are trying to do. So, yeah, putting the cuffs on them feels pretty darn good."

Not long ago, Logan helped track a doctor who was writing illegal scripts for Schedule II drugs such as OxyContin, Demerol, and Vicodin, which are classified as having high potential for abuse. When the day came for the arrest, his colleagues let him take the doctor down.

"I'll arrest a doctor, nurse, or pharmacist," he said. "I have a photo I keep on my cell phone with this physician bent over his vehicle as I put the cuffs on him. It's one of my proudest moments."

Other pharmacists also take the issue personally.

"Those people with bad scripts could be selling these drugs to my kids, or to someone who might get so high they run over one of my kids," said Frank Iannarone III, a pharmacist in Madison, N.J.

Empathy for the daily battles with pain

The other day, as Harmison sipped a cup of afternoon tea, his cell phone rang with a call from a local detective.

The cop was following up on an attempted burglary of his pharmacy last month. Surveillance cameras caught the criminals wearing gloves, face masks, and hooded sweatshirts as they tried to dismantle Harmison's security system. The intruders returned one night later, this time entering the pharmacy to search for drugs. The break-in was foiled by the steel door leading to the dispensing room.

Harmison was lucky: Another nearby pharmacy had also recently been hit, and there the bad guys made off with medications carrying a street value of about $1 million.

As the detective talked, Harmison nodded a few times. He hung up with a sigh. "I think it's gonna go nowhere," he said of his case. "There's nothing to go on."

Though he's frustrated by all the fraudulent prescriptions that come his way, Harmison sees the legitimate need for these powerful drugs every day. The patients who need them are the customers he serves every day in his pharmacy, a converted physician's office tucked away in a business complex across the street from Texas General Hospital here in Grand Prairie, a western suburb of Dallas.

Harmison knows most of his customers by name and has studied the details of their diseases — the cancer or other maladies that make each waking hour a battle of pain so acute it often threatens their sanity.

He doesn't want to make it harder for these patients to get the relief they need.

That's why he's has testified before Congress against proposals to toughen access to the medications he dispenses.

“There are people who really need this drug, who do good just to get out of bed with their terminal illnesses,” he said. “Do you really want them to have to get to their doctor every time they need a refill?”

Harmison stood before the computer in his dispensary, filling prescriptions beneath shelved bottles of antibiotics and muscle relaxants. He’s comfortable as drug cop. But he also wants to continue to be the friendly neighborhood pharmacist of Grand Prairie.

Friends have suggested he put bars on his windows and doors. He won’t do it. “If I have to do that, I’m retiring, I’m going home,” he said. “I am not going to work inside a cell.”

This story comes from STAT, a national publication focused on telling compelling stories about health, medicine, and scientific discovery.

McDermott Will & Emery

FDA Takes Further Steps to Curb Opioid Abuse

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Required Black Box Warnings on Immediate Release Opioids

Closely following on recent efforts undertaken by states and the Centers for Disease Control to curb opioid abuse (review further here and here), the U.S. Food and Drug Administration (FDA) last week announced that it will require black box warnings on immediate-release opioids highlighting the risk of "misuse, abuse, addiction, overdose and death," to combat what the agency described as an epidemic of addiction.

Ninety percent of opioids prescribed are immediate-release, which are usually taken every four to six hours. The remaining ten percent, extended-release/long-acting (ER/LA) opioids, are typically viewed as more prone to abuse because they include more opioid per tablet. The FDA added a black box warning for ER/LA opioids in 2013.

The new FDA black box requirements will apply to drugs such as hydrocodone, oxycodone and other frequently prescribed immediate release painkillers. The labels will include a variety of warnings about the risk of addiction, misuse, overdose and death. There are a number of required warnings regarding interactions with other medications and the effect of opioids on patients with certain conditions.

The FDA stated said that the labels will likely be approved and finalized by the end of the year and that no recall will be necessary. The new labels will affect 87 brand-name drugs and 141 generics—ranging from acetaminophen-opioid combinations to intravenous therapy formulations.

Draft Guidance Promoting Generic Abuse-Deterrent Opioids

The FDA also issued draft guidance which it noted is intended to support the manufacturing industry in the development of generic versions of opioids with abuse-deterrent formulations (ADF). Abuse deterrent mechanisms make certain types of abuse—such as crushing or dissolving tables so as to snort or inject the contents—less effective. The FDA seeks comments from stakeholders on the draft guidance, due June 25, 2016.

The FDA had already required all sponsors of brand name products with approved abuse-deterrent labeling to conduct long-term epidemiological studies to assess their effectiveness in reducing abuse.

The FDA has noted that it plans to hold public meetings related to opioid abuse issues.

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High Costs For Drugs Used By A Few Are Starting To Add Up

Updated February 5, 20165:12 PM ET **Published** February 5, 20161:13 PM ET
Pauline Bartolone, CALmatters

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Multiple sclerosis pill Tecfidera is on the top 10 list of most costly specialty drugs, as measured by overall spending, for California's health benefit system for public workers and retirees. ***John/Flickr***

The cystic fibrosis drug Orkambi can help people with specific genetic mutations breathe better, but treatment with the pill comes with a hefty sticker price — $259,000 a year.

Orkambi, which was approved by the Food and Drug Administration last July, is expected to take almost $36 million from California's general fund this fiscal year and next. That cost estimate doesn't include any discounts the state may receive from drug manufacturers.

Seventy-four Californians with health coverage under the Department of Health Care Services are expected to receive the drug in the current fiscal year. In the next one, 220 people are expected to get it, some of whom may be the same patients as this year.

Orkambi is listed on the specialty tier of drug categories in some private health plans. That category is typically reserved for high-cost drugs or, in the federal government's view, for drugs that cost more than $600 a month and are used by a small proportion of patients.

Specialty drugs are already proving to be a financial burden on one California agency, the California Public Employees' Retirement System, which purchases health benefits for active and retired state workers. CalPERS says that specialty drugs made up less than 1 percent of all prescriptions for its members but accounted for 30 percent of the total drug costs in 2014.

Drugmakers say the health benefits from specialty drugs justify their cost.
"Patients are gaining access to medicines that are better treating their diseases or frankly even curing them," said Priscilla VanderVeer, deputy vice president of communications at the Pharmaceutical Research and Manufacturers of America. "Patients are now healthier. They're more productive. They're functioning."

VanderVeer said companies price drugs not just on the cost of production, but on the value the industry believes the drug brings to the health care system, such as efficacy, improvements in quality of life or length of life and the extent to which the medical need for a drug has gone unmet.

The price of the drug also accounts for the cost of developing other drugs and the high risk that a particular drug won't make it to market, VanderVeer said. Only 12 percent of drugs that go through clinical trials get approved, according to PhRMA.

Finally, she said, the sticker price doesn't reflect the final price paid for the drug, which can be heavily discounted through negotiations or because of mandated rebates for Medicaid programs.

Drugmakers are following the money, said Joel Hay, professor of pharmaceutical economics and policy at University of Southern California. Companies invest in specialty drugs that target a small population because their high price tags can be spread over a large insurance pool, he said.

Even though specialty drugs are "ridiculously expensive per treatment episode," Hay said, the cost for each member in a health plan is "just a few cents." Raising the price 10 cents on a diabetes drug, for example, would have a bigger budget impact, he said, because more people have diabetes than cystic fibrosis.

Hay says manufacturers are now less inclined to invest in drugs that treat millions of people, because there is more pushback on price. "Drug companies are for-profit companies obligated to make money for their stockholders," Hay said. "They're not virtuous charitable organizations."

Drugmakers are also investing more in treating uncommon illnesses because there is less competition and therefore more opportunity for profit, said Dr. Helene Lipton, professor of health policy at the School of Pharmacy and Institute for Health Policy Studies at the University of California, San Francisco.

The high price of the drugs affects patients, she noted, because health plans put controls on the drugs so that they're used as a last resort.

"That may mean going through two or more rounds of care with other medications before being able to use the specialty drug," Lipton said.

Still, it's not just specialty drugs that are straining health plans' budgets, said Steve Miller, chief medical officer at Express Scripts, a pharmaceutical benefits manager that negotiates drug coverage for 7.5 million Californians.

"The price of drugs is just continuing to go up," said Miller, explaining that the trend is due to both new high-cost drugs coming on the market, and mark-ups of old drugs.

There has been an explosion of drugs costing $100,000 a year over the past decade, for things like cystic fibrosis and cancer, Miller said. And there was a 127 percent price increase of branded drugs that had been on the market between 2008 and 2014, he says.

A California ballot initiative scheduled to go before voters this November aims to rein in drug costs by limiting the amount the state pays for a drug to no more than the lowest price paid for the same drug by the U.S. Department of Veterans Affairs.

A version of this story appeared first on KQED's State of Health blog. CALmatters is a nonprofit journalism venture dedicated to explaining state policies and politics. Pauline Bartolone wrote this article while participating in the California Data Fellowship, *a program of the* *Center for Health Journalism* *at USC's Annenberg School of Journalism.*

Barolone will be exploring how the cost of specialty drugs' affects patient access. If you are a chronic disease patient who is either taking a specialty drug or having difficulty getting the right one, she would like to hear from you. Reach her on Twitter @pbartolone *or* pauline@calmatters.org.

Annals of Internal Medicine

POSITION PAPER

Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians

Hilary Daniel, BS, for the Health and Public Policy Committee of the American College of Physicians*

This American College of Physicians position paper, initiated and written by its Health and Public Policy Committee and approved by the Board of Regents on 16 February 2016, reports policy recommendations from the American College of Physicians to address the escalating costs of prescription drugs in the United States. Prescription drugs play an important part in treating and preventing disease. However, the United States often pays more for some prescription drugs than other developed countries, and the high price and increasing costs associated with prescription medication is a major concern for patients, physicians, and payers. Pharmaceutical companies have considerable flexibility in how they price drugs, and the costs that payers and patients see are dependent on how payers are able to negotiate discounts or rebates. Beyond setting list prices are issues of regulatory approval, patents and intellectual property, assessment of value and cost-effectiveness, and health plan drug benefits. These issues are linked, and comprehensive efforts will be needed to affect how drugs are priced in the United States.

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For author affiliation, see end of text.
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High-profile cases of high-priced drugs entering the market and price increases for traditional, generic, specialty, and biologic medications have thrust the issues of prescription drug price, value, and spending to the forefront of health care discussions. In a Kaiser Family Foundation poll, over 70% of those surveyed felt that drug prices were too high and that companies were too concerned about making profits (1). Patients, physicians, payers, and politicians have taken notice of the potential effect of drug price on access to needed medications and are asking questions not only about how pharmaceutical companies determine a drug's price, but also how we can better assess the pricing, cost, and value of a drug. Pricing (the base price of a drug before negotiations, rebates, and discounts), cost (the actual dollar amount paid by patients, health plans, or the government for a drug), and value (the benefit of a drug relative to its cost) are intertwined, and as policymakers look for solutions, they must consider all 3 issues in order to understand the broader implications of policies or regulatory action.

The benefits associated with prescription drugs cannot be ignored. The drive to create new drugs and seek improved treatments has resulted in a broad and constantly evolving market for prescription drugs in the United States. As new developments in the diagnosis and treatment of disease are discovered, Americans are using these drugs as part of their daily lives. Today, 7 out of 10 Americans are taking at least 1 prescription drug (2). However, not all patients can absorb the out-of-pocket costs for these drugs. Approximately 18% of retail prescription drugs were paid for out of pocket in 2012, and patients used various techniques to reduce costs, including not taking a medication as prescribed (7.8%), asking the doctor for a lower-cost medication (15.1%), purchasing drugs from another country (1.6%), or using alternative therapies (4.2%) (3). Whereas drug prices are variable, demand for prescription medication is fairly inelastic.

Although the current U.S. market includes important advances in disease treatment, the United States is the only country in the 34-member Organisation for Economic Co-operation and Development (OECD) that lacks some degree of government oversight or regulation of prescription drug pricing. The OECD includes 13 countries that are considered high-income: Australia, Canada, Denmark, France, Germany, Japan, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States. Comparatively, the United States spends more on pharmaceuticals than these other high-income countries (4). An analysis of OECD data showed that the United States had the highest level of per capita spending on prescription drugs in 2010 compared with Australia, Canada, France, Germany, Switzerland, and the United Kingdom (5). In addition, the United States tends to introduce new drugs to the market faster than other countries and use these new products more, influencing increases in prescription drug spending (5). The government and private insurance companies are the primary purchasers of drugs in the United States. Medicare, Medicaid, benefits administered under the Veterans Health Administration, and private payers have different methods for obtaining prescription drugs, rebates, discounts, negotiation, and administration of drug benefits, which creates a disparate system.

After some years of slowing growth in prescription drug spending, high-cost entrants to the market and increases in the price of prescription drugs already on the market have resulted in increased growth rates, and

* This paper, written by Hilary Daniel, BS, was developed for the Health and Public Policy Committee of the American College of Physicians. Individuals who served on the Health and Public Policy Committee and contributed to the paper at the time the paper was approved by the committee were Darilyn V. Moyer, MD (*Chair*); Douglas M. DeLong, MD (*Vice-Chair*); Micah Beachy, DO; Mitch Biermann; Sue S. Bornstein, MD; James F. Bush, MD; Gregory A. Hood, MD; Carrie A. Horwitch, MD; Gregory C. Kane, MD; Robert H. Lohr, MD; Kenneth E. Olive, MD; Shakaib U. Rehman, MD; and Fatima Syed, MD. Approved by the ACP Board of Regents on 16 February 2016.

analysts expect that the United States will see the largest increase in per capita spending among the developed markets between 2013 and 2018 (6). Various components have been mentioned as contributing to the rise in prescription drug costs, including lack of pricing transparency, regulatory barriers, a shortage of comparative clinical data between the cost-effectiveness and value of a drug, health plan benefit structures, and a patent system with loopholes that allows companies to extend monopolies on brand-name drugs while lower-cost alternatives are shut out of the market. All of these issues must be dealt with to achieve meaningful change.

Addressing the many issues surrounding prescription drug pricing may not be as straightforward as unilateral action by a single actor. The research, development, regulatory, and payment systems for prescription medication are deeply intertwined, and the pressing issue of drug pricing and payment will require comprehensive efforts to increase transparency, accountability, and stewardship. Every day, physicians see how prescription drugs affect the lives of their patients. The American College of Physicians (ACP) supports policies and proposals that give patients the best available information and access to prescription medications at the lowest cost possible, while acknowledging the need for a strong pharmaceutical market that fosters investment in and development of new treatments.

This executive summary provides a synopsis of the full position paper, which appears in **Appendix 1** (available at www.annals.org).

METHODS

The ACP's Health and Public Policy Committee developed these positions and recommendations. This committee is charged with addressing issues that affect the health care of the U.S. public and the practice of internal medicine and its subspecialties. The committee identified studies, reports, surveys, relevant news articles, policy documents, and other sources of public information on the pricing of prescription drugs; cost of prescription drugs; cost of drugs to patients and payers; and other aspects of the research, development, regulation, and marketing of prescription drugs. Draft recommendations were reviewed by ACP's Board of Regents, Board of Governors, Council of Early Career Physicians, Council of Resident/Fellow Members, Council of Student Members, Council of Subspecialty Societies, and outside expert reviews. The position paper and recommendations were reviewed by the ACP Board of Regents and approved on 16 February 2016.

RECOMMENDATIONS

1. ACP supports transparency in the pricing, cost, and comparative value of all pharmaceutical products:

a. Pharmaceutical companies should disclose:

i. Actual material and production costs to regulators;

ii. Research and development costs contributing to a drug's pricing, including those drugs which were previously licensed by another company.

b. Rigorous price transparency standards should be instituted for drugs developed from taxpayer-funded basic research.

2. ACP supports elimination of restrictions of using quality-adjusted life-years (QALYs) in research funded by the Patient-Centered Outcomes Research Institute (PCORI).

3. ACP supports the following approaches to address the rapidly increasing cost of medications:

a. Allow greater flexibility by Medicare and other publicly funded health programs to negotiate volume discounts on prescription drug prices and pursue prescription drug bulk purchasing agreements (7, 8);

b. Consider legislative or regulatory measures to develop a process to reimport certain drugs manufactured in the United States, provided that the safety of the source of the reimported drug can be reasonably assured by regulators;

c. Establish policies or programs that may increase competition for brand-name and generic sole-source drugs.

4. ACP opposes extending market or data exclusivity periods beyond the current exclusivities granted to small-molecule, generic, orphan, and biologic drugs. ACP supports robust oversight and enforcement of restrictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products.

5. ACP supports research into novel approaches to encourage value-based decision making, including consideration of the following options:

a. Value frameworks;

b. Bundled payments;

c. Indication-specific pricing;

d. Evidence-based benefit designs that include explicit consideration of the pricing, cost, value, and comparative effectiveness of prescription medications included in a health plan's benefit package.

6. ACP believes payers that use tiered or restrictive formularies must ensure that patient cost-sharing for specialty drugs is not set at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. Health plans should operate in a way consistent with ACP policy on formularies and pharmacy benefit management.

7. ACP believes that biosimilar drug policy should aim to limit patient confusion between originator and biosimilar products and ensure safe use of the biosimilar product in order to promote the integration of biosimilar use into clinical practice.

CONCLUSION

Recent trends show that increases in the price of prescription drugs have drawn the interest and concern of patients, payers, government officials, and physicians, particularly in the cases of very substantial price

increases for some generic drugs, and in the price of existing brand-name drugs and specialty drugs (9). The United States often pays more than other high-income countries for the same drugs, and despite discounts, rebates, coupons, and assistance programs, high and increasing drug prices still threaten to keep patients from getting the drugs they need. Through collaboration and innovation, stakeholders have the ability to effect change by supporting transparency in how drugs are priced, developing and piloting novel approaches to evaluate and pay for drugs through evidence-based practices that reward advancements in the medical field, assuring access to needed prescription medication by not placing disproportionate economic burden on patients, encouraging informed patient participation in their health care decision making, and ensuring a truly competitive marketplace.

From the American College of Physicians, Washington, DC.

Disclaimer: The authors of this article are responsible for its contents, including any clinical or treatment recommendations.

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Appendix 1: Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians

Background

Drug Pricing in the United States

The complex factors that go into how a drug is priced can be difficult to understand and highly variable. Often, the terms "price," "cost," and "value" are used without explicit understanding of what is being referred to; small nuances in language can lead to confusion. For the purpose of this paper, "price" refers to the wholesale acquisition price or "list price" of a drug without applicable rebates, coupons, or discounts, and "cost" is the amount paid by a patient or health plan after all rebates, coupons, or discounts are applied. The concept of "value" in the biopharmaceutical field is highly variable and depends on the perceptions of clinicians and patients. Generally, the value of a drug is the benefit it provides relative to cost.

Unlike many other countries, the United States lacks regulatory authority to control the price of drugs or devices or take into account value as a coverage consideration. As a result, pharmaceutical companies may price drugs at will, and there is very little transparency or understanding of how companies arrive at the price of a drug. Representatives of the pharmaceutical manufacturing industry maintain that the price of the drug is necessary to promote continued investment in private research and development and the comparative benefit the drug provides to patients, and to encourage future innovation. However, these claims tend to conflict with available information.

The Tufts Center for the Study of Drug Development estimated that the current cost of drug development and approval in the United States is approximately $2.6 billion (10). In 2001, Tufts estimated this cost to be about $802 million (in 2000 dollars) (11). This estimate has been challenged by other researchers as being inaccurate or overstated; a 2014 article in the *New England Journal of Medicine* article criticized the Tufts figure for placing too much importance on the cost of capital ($1.2 billion, nearly one half the cost estimate), lacking transparency in the compounds and companies analyzed, and not taking into account public subsidies received by pharmaceutical companies (12).

Owing to the multifaceted nature of drug development and a high failure rate for drugs in the early stages of the development pipeline, it can be difficult to pinpoint how much money put into research and development of drugs that are abandoned or ultimately fail to gain regulatory approval is carried over into the pricing of other drugs. Most drugs that fail to make it to market do so in the preclinical phase of development; however, some companies spend considerable amounts of money for drugs that fail in late-stage trials. Pfizer invested $800 million to develop a potential blockbuster cholesterol drug, only to find that it increased the risk for death in a large-scale, 15 000-person clinical trial (13). However, as mentioned in the *New England Journal of Medicine* article, the $1.2 billion figure "[was] assessed at 10.6% per year compounded—despite the fact that bonds issues by drug companies often pay only 1% to 5%" (12). Industry advocates report that approximately 20% of marketed drugs earn back research and development costs (14).

Some analysts have challenged the claims that price is reflective of research, development, and capital costs. Funding from private companies is required to bring new drugs over the drug development "valley of death" and to market; large investments are made annually by private companies on research and development (15). However, a good deal of basic research originates through government-funded grants or agreements. In addition, publicly available financial data have given greater insight into how pharmaceutical companies use the money they spend on drugs. A study published in *PLoS Medicine* found that companies seem to spend twice as much on drug promotion as on research and development (16).

Pharmaceutical company mergers bring up several concerns regarding real investment in research and development. One example is the acquisition of Wyeth by Pfizer in 2008. Before the merger, the 2 companies spent a combined total of $12 billion on research and development. In 2013, the new company spent $6.55 billion (17). A portion of this reduction can be attributed to eliminating redundancies; however, the merger of 2 companies would decrease collective investments by nearly one half. Pharmaceutical company acquisition and subsequent increase in price of existing drugs is also notable. In the case of Daraprim (pyrimethamine), Turing Pharmaceuticals purchased the rights to the drug and subsequently increased the price. The company did not spend any money on research or development of that specific drug, but maintained that the price would go to funding research and development

of a future drug that would make Daraprim obsolete (18).

Finally, although market forces clearly play a role in keeping pricing competitive and sustainable, competition alone may not be effective in encouraging innovation or controlling costs, especially without the price transparency required for true price competition to take place. Rewarding innovation is critical to the development of new therapies. However, several drugs on market are considered "me-too" drugs—that is, drugs that are similar to products already on the market and provide little, if any, added benefit. For example, AstraZeneca originally manufactured the blockbuster acid reflux treatment Prilosec (omeprazole magnesium). When Prilosec's patent expired in 2001, the company immediately launched Nexium (esomeprazole sodium), an almost identical drug with a minor formulation change that earned the company billions more in sales.

The value of me-too drugs continues to be debated; similar drugs manufactured by competing companies may put pressure on the competitor drug to lower price or deter price increases (19). Determining new delivery systems or dosing for drugs may also result in a net gain if those methods can be used to improve future drugs. However, me-too drugs may also reduce investment in research and development or innovation.

Free-market forces are also not always effective in leveling costs in certain drug classes. Oncology drugs are an example of this: Generic versions are priced very low, whereas brand-name, patented drugs are priced high and continue to increase (20).

Increase in Spending on Prescription Drugs

In 2013, prescription drug costs accounted for 9.3% of the United States' total health expenditure, with a growth rate of 2.4% over the previous year, or approximately $263.5 billion (21). In 2014, prescription drug spending grew 12.2% to $297.7 billion and accounted for 9.9% of total health expenditures (22). Of note, the national health expenditure assessment of the percentage share of prescription drug spending does not include pharmaceutical spending in physician or hospital settings, and some have estimated that the percentage is higher (23). According to the National Health Expenditure Projection, prescription drug spending is expected to grow 5.4% for 2016-2019 and 6% for 2020-2023, owing to " . . . improving economic conditions, an expected rising trend of expensive specialty drugs being purchased through retail channels, and anticipated clinical guidelines designed to encourage drug therapies at earlier stages of treatment" (23). In 2014, total spending for health care in the United State increased 5.3%, faster than the 2.9% growth rate seen in 2013 and partially attributed to "rapid growth in spending on retail prescription drugs" (24).

The recent growth in the prescription drug spending rate is in contrast to the decline in the growth rate in drug spending experienced since 2003. By 2007, prescription drug spending growth slowed to 1.6%, despite a 9.9% average growth between 1997 and 2007 (25). Part of this slowing is the effect of the Drug Price Competition and Patent Term Restoration Act (also known as the "Hatch-Waxman Act"), passed in 1984. The Hatch-Waxman Act aimed to increase the availability of generic drugs after patent expiration by eliminating the requirement that generic drug manufacturers do the same type of clinical testing as for new brand-name drugs and by making certain adjustments to patent protections. The act was successful in speeding generic medications to market. Generic medications are relatively cheap and simple to produce, and they account for 8 in 10 prescriptions filled in the United States (26).

Generic drugs have traditionally encouraged competition and driven costs down. The patent protection for many branded drugs, including several blockbuster drugs, expired in 2012, allowing a flood of generic drugs to enter the marketplace. Several other global, high-selling drugs—including Celebrex (celecoxib), Symbicort (budesonide and formoterol), Gleevec (imatinib), and Cialis (tadalafil)— will go off patent by 2018, at which point the market will reach a lull (6). Once generic versions of widely used drugs became available, there can be considerable savings. A notable example is the case of Lipitor (atorvastatin), a cholesterol-lowering drug made by Pfizer. In the third quarter of 2011, Lipitor saw $1.97 billion in sales. After the patent on Lipitor expired in late 2011, sales of the drug dropped by almost 50%, to $841 million (27). The savings from the use of generic drugs increased 14% between 2012 and 2013, for about $30 billion in additional savings (28). To account for this loss in revenue, companies refocus on newer, brand-name drugs.

A major factor in the increase in overall spending for prescription drugs is the prevalence and rising use of high-priced specialty medications. Specialty drugs are sometimes described as "large-molecule" products, produced by using advanced techniques that require special handling and administration compared with "small-molecule" traditional drugs (29). Across the spectrum, specialty drugs are also defined as drugs that treat life-threatening or complex chronic illness; are priced at $600 per month or more; and require patient education, monitoring, and management over the course of the drug cycle (30).

Many specialty drugs are biologics, which are drugs derived from living tissues, sugars, or proteins. One of the first biologics approved in the United States was human insulin; biologics now include ground-

breaking therapies for cystic fibrosis, rheumatoid arthritis, cancer, and various chronic diseases. Although specialty drugs only accounted for 1% of prescriptions written, they made up 25% of the $263.3 billion spent on prescription drugs (31). The average daily cost of a biologic is $45, compared with $2 for traditional small-molecule drugs (32). All biologic drugs are considered specialty drugs, but not all specialty drugs are biologics.

Although many high-priced drugs are associated with use in rare diseases, small populations, or life-threatening diseases for which no alternatives exist, the market is expanding to include advancements over existing therapies in larger disease populations. Two primary examples are the hepatitis C drugs Sovaldi (sofosbuvir) and Harvoni (ledipasvir and sofosbuvir) and the recently approved class of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors that lower low-density lipoprotein cholesterol levels (33). Sovaldi and Harvoni are significant advancements over older, more toxic treatments and can reduce viral levels so effectively that some refer to the drug as a cure. Sovaldi costs $84 000 for an 8-week course of treatment, or about $1000 per pill (34). If every person infected with hepatitis C in the United States, estimated to be around 3 million, were treated with Sovaldi, it would cost hundreds of billions of dollars. Harvoni combines Sovaldi with another drug and is priced slightly higher, at around $95 000 for a 12-week course of treatment.

The PCSK9 inhibitors, which are a groundbreaking advancement in the treatment of cholesterol, must be injected once or twice a month. One of these drugs, Repatha (evolocumab), has been priced at $14 100 annually. This number does not seem high compared with the sticker shock of Sovaldi or Harvoni; however, unlike the hepatitis C drugs, which have a specific treatment cycle, PCSK9 inhibitors must be taken as maintenance therapy for an undetermined period. One of the largest pharmacy benefit managers, Express Scripts Holding Company, announced in October 2015 that they had reached an agreement with the makers of the PCSK9 inhibitors that included rebates, restrictions on who can receive the therapy, protections against price increases, and a spending cap. Express Scripts does not expect to spend more than $750 million on the drugs in 2016 (35).

Potential Contributors to Unsustainable Prescription Drug Pricing

Lack of Price, Cost, or Value Transparency

For decades, pharmaceutical manufacturers have claimed that pricing is based on research and development costs and innovation, and is well regulated by market forces. The spike in prices and increase in prices for drugs already on the market have made many stakeholders wary, especially because many of these new therapies treat small populations and there are few data to support that overall health care costs are reduced. People are particularly worried about high-priced drugs for hepatitis C, because health plans have seen increases in expenditures as a result of this particular set of drugs (36). An actuarial study by consulting firm Milliman assessed the cost to the U.S. health care system in the absence of a cure for hepatitis C. The report found that, without a cure, 350 000 more patients would be living with advanced stages of hepatitis C between 2015 and 2025, at a cost of $115 billion (37). Although some high-priced drugs may prove to decrease costs in the long run, high prices give certain drugs the perception of value without adding benefit. An analysis of oncology drugs approved between 1996 and 2014 found that the price of oncology drugs per life-year gained has increased over time (38).

Regulatory Process

Companies seeking to market a prescription drug in the United States must have the drug approved by the U.S. Food and Drug Administration (FDA), the agency charged with protecting and advancing public health and ensuring the safety and efficacy of drugs, devices, veterinary drugs, biological products, the nation's food supply, cosmetics, and products that emit radiation. It is the FDA's charge to ensure that drugs are safe and effective for their indication, but the agency is not required to take into account the value of a new drug compared with existing therapies.

Obtaining FDA approval has long been criticized by the pharmaceutical industry for being arduous, timely, and costly, delaying a drug's ability to be marketed and begin making a profit. In the early 1990s, an underfunded FDA resulted in a backlog of new drug applications and delays in new drugs reaching the U.S. market. This ultimately led to passage of the Prescription Drug User Fee Act (PDUFA), which allows the FDA to charge companies fees in exchange for being held to performance goals and approval timelines. As a result of PDUFA, the median approval times for standard and priority review drugs in fiscal year 2013 dropped to 12 months and 7.9 months, respectively, and patients have greater access to medications (39). This reduction in approval time means drugs hit the market faster and companies are quicker to recoup their investment costs. Some analysts argue that the process is still too long and costly, and there are specific concerns about generic drug applications. There is currently a backlog in generic drug applications, and generic drugs are not entering the market as quickly as had been anticipated with the passage of the Generic Drug User Fee Act, which is based in the same fee-for-timeline concept as PDUFA (40).

Drugs can move through the regulatory approval process more rapidly if they qualify for fast-track designation, accelerated approval, priority review, or breakthrough therapy designation. These approaches help expedite the process of getting lifesaving drugs for serious diseases to market. For drugs moving through the accelerated approval pathway, a drug for a serious condition filling an unmet medical need may be approved by using a surrogate end point or intermediate clinical end point (41). The number of drugs for which FDA approval is applied and granted has increased in the past decade. A report released by the FDA on novel drug approvals showed that the agency approved 45 new molecular entities in 2015—nearly double the average number of new molecular entities approved from 2006 through 2014—and 87% of these drugs were also approved on the first cycle of review, without requests from the agency for more information (42).

In addition, some classes of drugs are now approved faster in the United States than internationally. An analysis of oncology drugs approved by the FDA and its European counterpart, the European Medicines Agency, between 2003 and 2010 found that the FDA approved more brand-name oncology drugs during that time than did the European Medicines Agency (43).

The most recent PDUFA reauthorization, the FDA Safety and Innovation Act, included the newest expedited approval designation: the breakthrough therapy designation. Breakthrough therapies are those that are intended to treat serious or life-threatening disease, and for which preliminary clinical evidence shows that they provide significant improvement over existing therapies. If a drug is granted breakthrough designation, the FDA will speed the development and review of the drug, including additional communication between the FDA and the manufacturer. To date, 28 drug approvals have been designated as breakthrough therapies.

Breakthrough therapies are also more likely to be specialty drugs and carry high price tags. Drugs approved with a breakthrough therapy designation include numerous oncology drugs, Sovaldi and Harvoni, and the cystic fibrosis drug Kalydeco (ivacaftor) (44). Because these drugs are typically approved through the accelerated approval process, additional safety and efficacy reporting is required during postmarket surveillance. The FDA can require that risk evaluation and management strategies be developed for certain new drugs to address potential issues early.

Collection of postmarket data is important for the continued evaluation of safety in drugs that are approved rapidly on the basis of limited clinical trial data or surrogate end points. To date, no drugs that have been awarded breakthrough therapy designation and approved by the FDA have been removed or had approval revoked; however, the breakthrough therapy designation is relatively new, and long-term postmarket safety data are limited.

Although the number is small compared with the overall number of drugs approved by the FDA, a handful of drugs approved through the accelerated approval process have been recalled or had approval revoked for an indication—demonstrating the importance of postmarket data collection. For example, Avastin (bevacizumab) was approved in 2008 for use in combination with paclitaxel for the treatment of certain types of breast cancer. Preliminary studies found that the combination improved progression-free survival. However, follow-up studies found no difference in overall survival among patients using Avastin; on average, patients had less than 3 months of progression-free survival, and there was a high rate of severe side effects (45). The FDA revoked approval for the use of Avastin in breast cancer, although the drug is still available for the indication off-label.

Lack of Competition in the Marketplace

Drugs that gain FDA approval are granted varying marketing exclusivity periods—5 years for chemical products, 7 years for orphan drugs, and 12 years for biologics—that are a statutory provision granted to a drug if all statutory requirements are met (46). This period may run concurrently with a drug's patent protection, extend beyond the life of a patent, or expire before the patent does. Other drugs are prevented from obtaining FDA approval and entering the market before that period ends. The Affordable Care Act included the Biologics Price Competition and Innovation Act (BPCIA), which directed the FDA to establish an expedited approval pathway for biosimilar products, similar to what the Hatch-Waxman Act did for generic drugs. The BPCIA included a 12-year period of data exclusivity for biologics starting from the approval date of the product. During this period, the FDA cannot consider a biosimilar application that relies on the clinical trial data for the "originator" or "reference" biologic. The law also included provisions designed to prevent evergreening (47) (in which a pharmaceutical company producing a brand-name drug makes minor or modest changes that provide no therapeutic advantage to a drug's formulation to extend the life of the patent) and a process for resolving patent disputes (48).

The FDA does not control the length of patents or have authority to change patent terms; the U.S. Patent and Trademark Office may issue a patent to a drug at any point during development that covers various claims. The patent expires 20 years from the date of filing, although the life of a patent can be extended through new formulations of the drug, new routes of

administration, new indications, or use of the drug in combination with another drug (49).

Because patent laws can allow more flexibility than marketing and data exclusivities, pharmaceutical companies may use loopholes within the system to extend the patent protection of a drug. Product-hopping or evergreening extends the monopoly on the brand-name drug and can keep a competitor drug out of the market. In some cases of evergreening, a company will introduce a nearly identical version of a brand-name drug before patent expiration and allow the original brand-name drug's patent to expire, promoting the new drug as an improvement over the previous brand-name drug. Product-hopping; evergreening; and some pay-for-delay agreements, in which a brand-name drug company settles potential patent litigation with a manufacturer of generic drugs, effectively keeping the generic drug off the market, have been flagged as anticompetitive by the U.S. Federal Trade Commission and other government officials, although these practices remain legal.

Limited competition can also drive up the price of a medication. A recent example is price increases for naloxone. The drug, used as a treatment for opioid overdose, has been used in hospitals as an injectable drug since 1971. In the late 1990s, successful pilot programs were launched for use of naloxone outside the hospital setting by local law enforcement and community health professionals to reverse overdose. In the wake of the current heroin epidemic, police forces around the country have been authorizing the use of naloxone and training officers in how administer the drug via an intranasal spray. Although the cost of the injectable drug is minimal, only one company manufactures an intranasal form of naloxone and has raised the price from $20 to $40 per dose (50). The price increase calls into question the impact on state budgets and access to this lifesaving drug.

Increasingly, the pharmaceutical marketplace is narrowing its focus to highly innovative, biologic, or specialty drugs for which there are few, if any, competitors, creating monopolies and limiting the cost-controlling power of competition. Sovaldi and Harvoni, both made by Gilead, have had a significant impact on the hepatitis C treatment market. Although hepatitis C treatments already existed, the vast improvement over those therapies resulted in some existing drugs being withdrawn from the market (51). In its first full year on the market, Sovaldi became the second best-selling drug in the United States, at $10.3 billion in sales in 2014 (52). Harvoni generated $3.58 billion in sales in the first quarter of 2015, with $3.02 billion in the United States alone. During that period, Sovaldi sales dipped to $972 million from $2.27 billion in the first quarter of the previous year (53).

AbbVie introduced similarly priced competitor products, Viekira Pak (a multi-pill combination of dasabuvir, ombitsavir, paritaprevir, and ritonavir) and Technivie (a combination of ombitsavir, paritaprevir, and ritonavir). Although many felt that this would create a challenge to the Sovaldi-dominated market, an October 2015 warning letter from the FDA to the makers of Viekira Pak requiring an update to the label to reflect the potential for "serious liver injury mostly in patients with underlying advanced liver disease" calls into question whether the drug will have the effect that analysts thought (54).

The generic manufacturing market is becoming consolidated, and progressively some generics are being manufactured by a single company or are disappearing from the market. Single-source generics are more expensive than other generics; some health plans place these drugs in the preferred drug tier in absence of a competitor, resulting in higher costs to the patient (55, 56). Consolidation of pharmaceutical manufacturing companies may be contributing to the single-source generic problem, as well as aging factories and production issues. When a drug goes into shortage for quality issues, a company may decide that it is more expensive to correct manufacturing issues and go through the FDA process for getting the generic drug back on the market. Companies that do not already manufacture a similar drug are unlikely to produce a drug with a lower return on investment than a higher-priced brand-name drug or biologic.

Increases in the Price of Brand-Name and Generic Marketed Drugs

Increases in drug spending are related to the overall increase in drug prices at all stages of a drug's life cycle. The prices of numerous drugs have increased after coming to market, without justification or transparency. A report by Elsevier found that of a sample of 4421 drug groups, 222 groups increased in price by 100% or more over the course of 1 year, and 17 groups had price increases of more than 1000%. One of the drugs whose price increased by over 1000% is tetracycline, a common antibiotic prescribed for bacterial infections (57). The AARP Public Policy Institute found that more than one third of brand-name drugs used for chronic conditions that had been on the market since 2005 increased more than $1600 per year for 8 years (58). In addition, the retail price for commonly prescribed dermatologic drugs between 2009 and 2015 showed a considerable increase, with many of the increases occurring after 2011 (59).

One of the most recent high-profile cases of a drug price increase has been that of Daraprim. Although no companies make a generic form of the drug, Daraprim, which went off patent in 1953, recently experienced a

price increase from $13.50 per pill to $750 per pill—a 5000% increase—after it was purchased by Turing Pharmaceuticals. Despite considerable backlash from the public and media noting the practical and ethical issues behind the company's rationale for the price increase, the price of Daraprim remains unchanged.

Cancer therapies tend to be some of the highest-priced specialty drugs; 11 of the 12 cancer drugs approved by the FDA in 2012 cost $100 000 or more (60). Gleevec (imatinib), originally priced at $24,000 when it launched in 2001 (approximately $32 000 in 2015 dollars when adjusted for inflation), now costs $90 000 (60). The safety and effectiveness of the drug have not changed—only the price. Analyses of FDA-approved cancer drugs found little difference in the average wholesale price of novel cancer drugs and next-in-class drugs, suggesting that they are priced independent of novelty and simply at what the market can bear (61). Similar pricing differences are seen with multiple sclerosis drugs: The price of the first-generation disease-altering drugs has increased at an annual rate of 5 to 7 times that of inflation, despite the introduction of competitor drugs (62).

These increased prices can negatively affect the supply chain; pharmacies receive lower reimbursements than the price they must pay for the drugs, patients may not fill their prescriptions, and physicians may have to prescribe alternative therapies (63). This trend is also not confined to specialty or generic drugs: Many of the top-selling prescription drugs have also increased in price. The price of Viagra (sildenafil) increased 159% between 2007 and 2014; Xyrem (sodium oxybate) for narcolepsy increased 841%; and Humulin (insulin isophane), a diabetes medication, increased 354% (64).

The rising cost of diabetes treatment is particularly troubling to physicians and patients. According to the Centers for Disease Control and Prevention, 29 million people in the United States have diabetes, and it is estimated 387 million have diabetes worldwide (65). The American Diabetes Association estimates that the total cost of diagnosed diabetes has risen to $245 billion in 2012, from $174 billion in 2007 (66). Thirty percent of direct costs went to prescription medications to treat complications of diabetes and to antidiabetic agents and diabetes supplies. Diabetes drugs accounted for 5 of 27 branded drugs with a price increase of at least 20% between 2014 and 2015 (67). Primarily because of rising drug costs, spending on insulin and diabetes medications is expected to rise 18.3% over the next 3 years.

Lack of Available Biosimilars

Biosimilars, also referred to as "follow-on biologics," are off-brand but highly similar to reference or "originator" biologic products and are expected to help curb the prevalence of high-priced biologics. Over 700 follow-on biologics are in development worldwide, and it has been suggested that biosimilars will account for about $25 billion in sales from off-patent biologics by 2020 (68). Although sometimes referred to as the "generic" version of biologics, they are not considered by federal regulators to be generic, because the nature of the biologic drug and sensitivities to manufacturing and handling do not result in exact duplication. Some biosimilars may be deemed interchangeable with their originator product, but obtaining status as a biosimilar does not automatically indicate interchangeability—unlike generics, which are chemically identical to their brand-name counterparts.

In March 2015, the FDA approved Zarxio (filgrastim-sndz), the first biosimilar for the U.S. market, under the BPCIA biosimilar approval pathway. It was made available for sale on 2 September 2015 after legal attempts by the originator product's manufacturer to keep the drug from market failed. The drug is priced 15% lower than the originator product (69), and estimates suggest that Zarxio could save the health system $6 billion over the next decade (70). The originator product, Neupogen (filgrastim), was originally licensed in the United States in 1991.

Biosimilars have been available in Europe since 2006, and 22 biosimilars are available in the European Union. A 2013 report found that the biosimilar market in Europe has helped to improve competition and increase access to biologic medicines, although overall uptake and financial impact remains modest (69). The United States and international markets differ in their ability to regulate the cost of drugs and available research and effectiveness data; however, this example, as well as the reduction in prices and costs associated with the introduction of generic drugs in the United States, suggests future cost-savings associated with biosimilars. In addition, despite the modest gains seen in the European Union, analysts think that the United States may be faster to adopt the use of biosimilars because the European Union does not allow interchangeability (68). A RAND Corporation analysis predicts that biosimilars could lead to a $44.2 billion reduction in direct spending on biologic drugs between 2014 and 2024 (71).

Several biosimilars are in the pipeline, but it remains to be seen when these drugs will be approved and for what indications, and whether the originating manufacturers will exhaust all legal challenges in keeping the biosimilars from entering the market, as in the situation with Zarxio. Once biosimilars are available, the potential cost-savings will depend on the extent to which they are utilized; if physicians and patients are willing to use a biosimilar product instead of a biologic, cost-savings are more likely to be realized.

Paying for Prescription Drugs in Public and Private Health Plans

How health plans pay for prescription drugs varies by the insuring body: Medicaid, Medicare, and private insurers all have different policies that govern what type of agreements they can broker with pharmaceutical companies, what drugs they must provide, or what kind of discounts they can get in acquiring drugs. Pharmaceutical companies have argued that you cannot judge the price of a drug on the basis of its wholesale acquisition cost ("sticker price") because it does not reflect the actual price paid by health plans or individuals. Manufacturers often negotiate discounts with pharmacy benefit managers, state Medicaid programs, private insurers, wholesalers, and other organizations.

Medicare programs pay for drugs in distinct ways, depending on which program the enrollee uses; some programs are prohibited by statute from negotiating drug prices directly with pharmaceutical companies (72). Under traditional Medicare, Part B and certain other drugs that follow from Part B services are paid for by using a formula of the drug's average sales price plus 6% of that price. The average sales price represents an average of all rebates or discounts the pharmaceutical company charges on the commercial market (73). Medicare beneficiaries can also enroll in the Medicare Part D prescription drug benefit program, or obtain coverage through a Medicare Advantage plan.

Prices and costs in Medicare also differ depending on how and where the drug is administered. Typically, drugs are administered either at home by the patient, in which case the drug falls under the pharmacy benefit (Part D), or by physicians or health care professionals in a clinical setting, in which case the drug falls under the medical benefit (Part B). Drugs that are administered through the pharmacy benefit have generally been the lower cost of the 2 options, although recently there has been a shift and some drugs, such as some oral chemotherapy agents, cost more than those administered through the medical benefit. Oral cancer drugs were noted by one study to be the primary contributor to overall increases in Medicare specialty-drug spending in recent years (74).

State Medicaid programs reimburse pharmacies for the ingredient costs of a prescription drug and a fee to the pharmacy for those drugs provided under the pharmacy benefit. Consumer cost-sharing caps apply in Medicaid programs, and nearly all Medicaid programs and Medicaid managed care plans charge nominal copayments, which vary on the basis of the type of drug (brand-name or generic) or whether it is considered a preferred drug in the state's Medicaid program (75). Medicaid programs receive the lowest price offered to any payer outside government agencies as part of the Medicaid Drug Rebate Program and are required to cover all FDA-approved drugs. This creates unique challenges for state Medicaid plans, particularly with the introduction of sofosbuvir drugs (Sovaldi and Harvoni).

An analysis of Medicaid programs found a wide variety of protocols and preauthorization requirements before a patient is given sofosbuvir drugs as a treatment. Thirty-one states consider Sovaldi a "nonpreferred" drug, whereas 17 states designate the drug as "preferred" and do not require evidence of medical necessity. All but 2 states require prior authorization, and many states require abstinence from alcohol and illicit drugs, or both, for durations of 1 to 12 months before treatment. The analysis also found that many state Medicaid policies conflict with the recommendations of the Infectious Diseases Society of America (IDSA) and the American Association for the Study of Liver Diseases (AASLD) on the use of sofosbuvir drugs (76). The IDSA/AASLD guidelines recommend that patients abstain from alcohol or drug use but do not recommend withholding the drug until the conditions are met. Several states also require subspecialist consultation before receiving treatment. In addition, CMS issued a letter in 2015 urging state Medicaid programs to improve accessibility to hepatitis C medications (77).

Recommendations

1. ACP supports transparency in the pricing, cost, and comparative value of all pharmaceutical products:

a. Pharmaceutical companies should disclose:

i. Actual material and production costs to regulators;

ii. Research and development costs contributing to a drug's cost, including those drugs which were previously licensed by another company.

b. Rigorous price transparency standards for drugs developed from taxpayer-funded basic research.

The call for increased price transparency, especially for high-priced specialty or orphan drugs, is not new and is an important component in driving value-based incentives. The term "price transparency" has become prominent after the Daraprim pricing controversy, and it has been included as part of proposals by political candidates and echoed in the public outcry over the price of drugs.

Pricing methodologies for biomedical products are notoriously covert, and it is difficult to pinpoint to what extent a price reflects research, development, marketing, or administration costs. Pharmaceutical companies are required to disclose sale price information for a limited number of drugs. Companies report information on average sales prices for Medicare Part B drugs to CMS quarterly; however, the average sales price includes discounts, rebates, and other payments and differs from the list price. Pharmaceutical companies are often publicly held and disclose information on their research and development and marketing portfolios,

which has allowed outside analysts to review how, and how effectively, companies use their research and development budgets. The average amount that a company spends on research and development per drug may vary, depending on the number of drugs each company is developing and how many gain regulatory approval.

Pharmaceutical companies consider some information that may affect their business, including information on pricing methodology or clinical data gathered that competitors can use to develop their own strategies, as proprietary information or trade secrets. Manufacturing costs for biologic and specialty drugs are higher than those to produce traditional, small-molecule drugs. Biologics are highly sensitive to manufacturing and environmental conditions, and even innovator products can show differences in drug composition over time as a result. Biologic drugs must be produced in special facilities and use materials that can be 20 to 100 times more expensive than those used to produce small-molecule drugs (78). If certain materials required to make the drug are in shortage, this may also contribute to the price of a drug, especially in the generic market. Although these costs amount to a smaller portion of the overall price of a drug, the material and production costs of a drug are generally not considered proprietary and would be a rational first step in establishing greater transparency standards.

The ACP understands and acknowledges that marketing costs are inherent to the ability of a company to recoup the cost of investment into drugs and remain in business. However, many of the largest pharmaceutical companies are spending more on marketing and administration than they are on research and development. The practice of direct-to-consumer (DTC) advertising for prescription drugs is concerning. In accordance with existing policy, ACP believes that DTC is in appropriate because it may undermine the patient–physician relationship and foster confusion. In absence of a ban on DTC advertising, ACP supports broad efforts by federal regulators to ensure that information about a drug's effectiveness and safety, and about alternative treatments, is clearly disclosed to patients.

Although it does not represent a majority of marketing costs, DTC advertising has been shown to have a direct effect on patients asking questions about the drug with their physician. The FDA issued 3 surveys targeted at physicians and consumers that found an increase in awareness of DTC advertisements. Although these advertisements may motivate consumers to have conversations with their physicians about prescription drugs, 75% of physicians surveyed felt the DTC advertisements caused patients to think that a drug works better than it does, compared with 58% of consumers (79).

Companies that use basic research funded through the government as part of the development of a drug should be held to a high standard of pricing scrutiny. The National Institutes of Health (NIH) have historically made the largest government investments in basic research and play a key role in spurring new innovations and breakthroughs. In fiscal year 2015, the NIH invested nearly $30.3 billion in medical research (80). An analysis of publicly available data found that the NIH represented 28% of research sponsors (81). Between 1988 and 2005, federal research funding contributed to 45% of all drugs approved by the FDA and 65% of drugs that received priority review (82). Economic analyses show that NIH investments have a high return on investment in the public sector, with every dollar of NIH funding leading to an average of $2.13 in lifetime pharmaceutical sales (83). Without this assistance, the cost of discovery, research, and development on the part of pharmaceutical companies may be prohibitive. At a minimum, pharmaceutical manufacturing companies should disclose any grants, licensing agreements, or other investments by the federal government in the discovery, research, and development of the drug, in addition to material, production, and other research and development costs.

2. ACP supports eliminating the restriction of using quality-adjusted life-years (QALYs) in research funded by the Patient-Centered Outcomes Research Institute (PCORI).

More and more, physicians, patients, and other stakeholders are questioning the value of drugs relative to their price. Many of the new specialty drugs coming to the market represent real breakthroughs and benefits for patients, and the market should encourage future innovation. Those innovations do not mean that all other drugs should also be priced at the same level. Independent organizations, such as the Institute for Clinical and Economic Review and PCORI, already develop and evaluate clinical effectiveness data compared with other treatments.

Establishing an evidence base of clinical effectiveness data is the crux of transitioning to a health care system that pays for and rewards value. The PCORI is charged with funding comparative clinical effectiveness research (CER) and works to improve study methodology for CER (84). The PCORI has funded millions of dollars in head-to-head CER that can inform physicians and help patients understand all therapeutic options available as they relate to existing therapies and encourage informed decision-making and patient involvement. However, by statute, PCORI is prohibited from using QALYs as "a threshold to establish what type of health care is cost effective or recommended" (85).

A QALY is a metric of cost-effectiveness research that takes into account the quantity and quality of life associated with a treatment and assigns an index num-

ber to that treatment. Quality-adjusted life-years are commonly used in cost-utility studies to determine the cost of a treatment per QALY and compare medical interventions; however, they have been criticized for lacking sensitivity to patient preferences or goals (86). Being able to incorporate QALYs into cost-effectiveness studies will help patients and physicians compare the cost and health benefits of treatments and facilitate a better understanding of the value of different treatments. Part of a patient's overall determination of value may include the cost-effectiveness of the treatment along with the benefits or risks of a drug.

Existing ACP policy supports CER to measure the effectiveness of health care services and clinical management strategies and that all health care payers, including Medicare and other government programs, should use both comparative effectiveness and cost-effectiveness in the evaluation of a clinical intervention. The ACP policy also notes that cost should never be the sole criterion for evaluating a clinical intervention (87). Not only do comparative effectiveness data inform value judgments they can also help physicians and patients understand all available options as they relate to existing therapies, encouraging informed decision-making and involvement by patients in their health care choices.

3. ACP supports the following approaches to address the rapidly increasing cost of medications:

a. Allow greater flexibility by Medicare and other publicly funded health programs to negotiate volume discounts on prescription drug prices and pursue prescription drug bulk purchasing agreements (7, 8);

b. Consider legislative or regulatory measures to develop a process to reimport certain drugs manufactured in the United States, provided that the safety of the source of the reimported drugs can be reasonably assured by regulators;

c. Establish policies or programs that may increase competition for brand-name and generic sole-source drugs.

Whereas employer and self-insured plans are able to negotiate and use their bargaining power to lower the price of drugs, Medicare and Medicaid programs are directed by statutes that can impede their ability to obtain the best prices. When the Medicare Part D program was created in 2003, the legislation prohibited Medicare from negotiating directly with pharmaceutical companies; however, the law attempted to encourage competition and create ongoing incentives for plan sponsors to keep premiums low.

Plan sponsors negotiate rebates from drug manufacturers through pharmacy benefit managers (PBMs), third-party entities that negotiate with manufacturers on the plan's behalf. Pharmacy benefit managers have been highly effective in doing so: In 2008, the Office of the Inspector General found that Part D sponsors reported $6.5 billion in drug manufacturer rebates, or about $275 per beneficiary (88). A 2014 report by the Congressional Budget Office also found PBMs to be effective in driving down the cost of prescription drugs for beneficiaries, but suggested that the program could be strengthened by statutory changes enacted by Congress, such as requiring that Medicaid's statutory rebates be expanded to low-income Part D beneficiaries (89).

Medicare Part D pays on average more than other federal health care programs: 73% more than Medicaid and 80% more than the Veterans Health Administration. The Veterans Health Administration operates as a closed system and provides care directly to veterans. It purchases drugs and other pharmaceuticals directly from manufacturers and has a national formulary that does not exist in Medicare or Medicaid (90).

An article published in *Annals of Internal Medicine* analyzing how effective the Part D drug plan has been since its inception found a 14% increase in prescription drug use (91). In 2013, Medicare Part D spent $103.7 billion on drugs (92). The cost of Medicare Part D is likely to increase as baby boomers enter the system, and both the costs per beneficiary and overall spending on Part D are expected to increase between 2014 and 2024 (93).

The ACP has a long-standing policy of advocating for the ability of Medicare Part D to negotiate drug prices and rebates directly with pharmaceutical manufacturers as a way to keep costs to the system down. Recent estimates show that allowing Medicare Part D to negotiate prices could save $15 to $16 billion per year (94). The ACP strongly reaffirms this position.

Medicaid faces unique challenges in paying for high-priced drugs without imposing unnecessary burdens on patients and physicians. In 2014, the National Association of Medicaid Directors sent a letter to House and Senate leaders outlining the increased cost to their programs and difficulties with Sovaldi, including a lack of meaningful supplemental rebates on the drug, the conflict between the large upfront cost of the drug and Medicaid funding cycles, the frequent transition of patients on and off public insurance programs, and the lack of clinical data on the use of Sovaldi in patients with comorbidities that may alter the effectiveness of the drug (95). The group proposed looking into various federal interventions, including enhancing federal match rates for "curative" specialty drugs, mandating additional rebates from a manufacturer, and allowing Medicaid programs to "utilize cost-effectiveness research to identify whether or not a particular drug will be included in the program's formulary by granting Medicaid the flexibility to exclude products that are found to not be cost-effective" (95).

The Bipartisan Budget Act of 2015 included a provision that would increase rebates from drug manufac-

turers if the price of a generic drug increases faster than inflation. Previously, the rebate requirement was applicable only to single-source or multiple-source brand-name drugs. A review of generic drug price increases by the Office of the Inspector General found that between 1991 and 2004, 35% of the top 200 generic drugs would be eligible for a rebate and the Medicaid program would have received a total of $966 million in additional rebates (96).

The ACP has previously supported reimportation of drugs manufactured in the United States and exported for sale in other countries if the FDA can ensure the safety of the suppliers of such drugs. Under current law, drugs may only be reimported to the manufacturer of the drug in the United States, not to individuals or pharmacies. Difficulties the FDA has noted about reimported drugs include their safety, efficacy, and concentration as well as the lack of sufficient resources to ensure their safety (97).

Drugs exported to foreign countries are subject to any pricing regulations that country's government imposes (98). This may result in a lower price for a drug in the foreign country than in the United States. Quon and colleagues (99) examined the difference in brand-name drug pricing between Canadian Internet pharmacies and U.S. chain pharmacies and determined a potential savings of approximately 24% on brand-name medications. However, these savings can be variable, based on the fluctuating nature of drug pricing.

The ACP continues to support consideration of the reimportation of drugs, especially sole-source generic drugs, provided that their safety can be reasonably assured by regulators, as part of larger efforts to control the cost of prescription drugs. The ACP believes it should be a closed system, with participating pharmacies and suppliers required to meet FDA standards; have a tightly controlled and documented supply chain; not include controlled substances, biologics, or products that are infused or injected; and include adequate resources for inspections of facilities and enforcement of U.S. requirements, among others. The ACP acknowledges that drug importation is not a long-term solution to the high price of prescription medication, and there are various safety concerns about the reimportation of prescription drugs. Yet, we continue to support a careful evaluation of how existing federal importation standards may be used to encourage the reimportation of drugs to the United States, and how existing technology and recent legislative initiatives may assist in safeguarding the supply chain against counterfeiting or contamination.

It is important that policies addressing the increase in prescription drug prices cover not only new entrants to the market, but also drugs that have been on the market and may be generic or single-source drugs. The issue of single-source drugs primarily pertains to the generic market, or to drugs used to treat rare diseases with small populations. In the generic market, where drugs are reproduced inexpensively and there are relatively low profit margins, the elimination or consolidation of 1 or 2 manufacturers might have a huge effect on the production of generic drugs, potentially driving up the cost for payers and patients. In the case of Daraprim, the drug was inexpensive to produce and had a relatively low toxicity, underscoring why the dramatic price increase was so glaring.

Addressing the issue of sole-source drugs will require examination of the economic and noneconomic factors driving this trend. At the core of developing a competitive marketplace is the ability to identify and bring new therapies to market. Pharmaceutical companies spend billions of dollars each year on research that is abandoned or fails, but there are potential uses for these drugs that could be explored. The government is developing programs that would encourage companies to take drugs that have failed and find new uses for them.

The Accelerating Medicines Partnership (AMP), and the Discovering New Therapeutic Uses for Existing Molecules Initiative, also known as "New Therapeutic Uses," are public–private partnerships among the U.S. government, pharmaceutical companies, and some nonprofit organizations to test new therapeutic uses for drugs and determine how to use the existing drug development pipeline in a more efficient way. The AMP was launched in February 2014 with projects in Alzheimer disease, type 2 diabetes, rheumatoid arthritis, and lupus. All partners in the AMP have agreed to make the data and analyses from the project publicly accessible to the biomedical community (100).

The New Therapeutic Uses program "helps reengineer the research pipeline using an innovative strategy to identify new uses for assets that have undergone significant research and development by industry, including safety testing in humans" (101). One of the pilot projects found that a compound originally developed as a cancer therapy could be used to treat Alzheimer disease; because of the previous testing that had been done, investigators were able to initiate human testing within 3 months, whereas it could take as long as a decade to reach that stage under the traditional pathway (102). The AMP and New Therapeutic Uses initiatives are limited to certain disease groups currently, but may expand. The success of these programs could translate to a broader number of diseases or treatments, including diseases that have been ignored or therapies that have been allowed to be discontinued.

4. ACP opposes extending market or data exclusivity periods beyond the current exclusivities granted to small-molecule, generic, orphan, and biologic drugs. ACP supports robust oversight and enforcement of re-

strictions on product-hopping, evergreening, and pay-for-delay practices as a way to increase marketability and availability of competitor products.

Pharmaceutical companies claim that long exclusivity periods are needed to support innovation and allow a return on their investment and promote future innovation. Marketing exclusivity is granted by the FDA upon approval, during which a competitor, typically a generic drug, is prohibited from being marketed. Data exclusivity prohibits a competitor company from using the data collected by an originator company to gain approval of their drug.

In the case of biosimilars, the high cost of developing and conducting trials undermines the potential cost-savings to the manufacturer if they are required to collect new data. Congress approved a 12-year data exclusivity period for biologics under the Affordable Care Act, although some have noted that this amount of time is unnecessary (103). The President's fiscal year 2016 budget called for a reduction in data exclusivity for biologics from 12 years to 7 years in addition to prohibiting product-hopping or evergreening; in these practices, companies prevent generic competition from entering the market by making small adjustments to a drug with no real therapeutic value that grant the company longer patent protection, or they remove the drug from market, forcing patients to switch to a reformulated version of the same drug (104). The two proposals would save the federal government an estimated $16 billion over 10 years, including in Medicare and Medicaid (105).

Although providing for intellectual property protection is important to encourage innovation and introduction of medical advancements in the U.S. market, a 12-year period may not be wholly necessary. In 2009, the Federal Trade Commission (FTC) issued a report stating that a 12- to 14-year exclusivity period is unnecessary to promote innovation by biologic manufacturing companies, noting that "FOBs [follow-on biologics] are unlikely to introduce their products at price discounts beyond 10 to 30 percent. Moreover, FOBs are likely to have difficulty rapidly growing their market shares as compared to generic small-molecule drugs products. Indeed, projections are that branded biologic drugs are likely to maintain their first-mover advantages by retaining 70 to 90 percent of their market share years after FOB entry" (106).

Data exclusivity provisions were also a major issue when negotiating the Trans-Pacific Partnership (TPP). The TPP, a trade agreement between the United States and 11 other countries, establishes a 5-year mandatory minimum period of data protection and does not explicitly state a maximum (107). The agreement recognizes that the field of biologics is still generally new and included a provision that after 10 years, those party to the agreement or the commission may choose to review the provision and make changes to this time frame relative to the nature of the biologic and biosimilar markets (108). Although these provisions may be beneficial for U.S. patients by speeding the availability of lower-cost biosimilars to market, some public health organizations, including Doctors Without Borders, are concerned about the economic ramifications on TPP member countries that do not provide any data exclusivity for biologic drugs or provide for shorter terms (109). A survey of data exclusivity laws worldwide by the International Federation of Pharmaceutical Manufacturers & Associations found that of the countries with data exclusivity laws, the United States is the only one that provides 12-year data exclusivity for biologics (110). The TPP must be ratified by Congress in order to go into effect.

In 2014, the FDA issued draft guidance clarifying that the 12-year exclusivity does not apply to altered versions of already marketed biologics with a new "indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength" (111). This may combat the product-hopping that has become increasingly common in the traditional drug market. In 2013, the FTC filed an amicus brief opposing product-hopping, noting, "The potential for anticompetitive product redesign is particularly acute in the pharmaceutical industry" (112). Preventing lower-cost generic or biosimilar competitor drugs from entering the market only seeks to delay reductions in revenue for the parent company of a brand-name drug and may be detrimental to patients if the changes do not provide any measurable or meaningful benefit.

There are also concerns that pay-for-delay practices are keeping lower cost drugs out of the market. Pay-for-delay, also known as "reverse payment settlement," is a patent settlement strategy in which a patent holder pays a generic manufacturer to keep a potential generic drug off the market for a certain period. The number of pay-for-delay agreements increased from 3 in 2005 to 19 in 2009, after court decisions upheld the legality of such agreements, which prohibit generic drugs from entering the market on average nearly 17 months longer than agreements without compensation (113). In 2013, the Supreme Court ruled that although pay-for-delay agreements are not presumptively illegal, the FTC cannot be prevented from initiating legal action in regard to such agreements (114).

It is estimated that pay-for-delay agreements will cost $35 billion between 2010 and 2020. The Congressional Budget Office estimated that enacting legislation restricting pay-for-delay settlements would cut the federal deficit by $4.8 billion over 10 years (115). Proponents of pay-for-delay agreements assert that they cut short potentially lengthy and costly legal proceedings and may guarantee the entry of generics to the market (116).

It is important that pay-for-delay settlements are not exploited as a tool to keep the prices of certain drugs artificially high when suitable generic substitutes are prepared to come to market. Robust oversight of pay-for-delay agreements by the appropriate federal agencies is a cornerstone to assessing whether these agreements are valid or potentially in violation of antitrust statutes.

5. ACP supports research into novel approaches that would further value-based decision making and encourages research into policies that would tie price to innovations and clinical value. Consider the following options:

a. Value frameworks;

b. Bundled payments;

c. Indication-specific pricing;

d. Evidence-based benefit designs that include explicit consideration of the pricing, cost, value, and comparative effectiveness of prescription medications included in a health plan's benefit package.

With the great attention being paid to the price of drugs, determining how to assess the value of a drug, which patients may benefit the most from a certain drug, and the economic value of a drug has changed the conversation. Novel pilot programs have been launched, including the American Society of Clinical Oncology's (ASCO's) conceptual value framework and the Memorial Sloan Kettering Drug Abacus. The ASCO framework attempts to address relative value of new cancer therapies compared with established treatments factors, including cost, benefit, and toxicity. The Drug Abacus is a patient-led evaluation tool to measure the value of 54 new cancer drugs approved since 2001. Understanding that value means different things to different people, the Abacus takes into consideration measures of efficacy, toxicity, novelty, research and development, disease rarity, population health burden, and other factors (117).

In addition to these 2 initiatives, the American College of Cardiology and the American Heart Association, the Institute for Clinical and Economic Review, and the National Comprehensive Cancer Network have introduced programs to help patients understand the value of new therapies. An overview of these programs by Neumann and Cohen (118) notes that they will require additional refinement.

In 2015, the Center for Medicare & Medicaid Innovation (CMMI) announced the Oncology Care Model, a payment and service delivery model set to launch in 2016. Under this bundled payment model, oncologists who spend less than a benchmark figure on Medicare beneficiaries undergoing chemotherapy over a 6-month period will receive incentives; participating clinicians will also receive $160 per month per beneficiary (119). The approach may encourage the use of older, lower-priced drugs before newer, more expensive treatments with similar benefit and in turn affect drug utilization. This shift to paying for value as opposed to the number of services provided mirrors other similar shifts toward a evidence- and value-based system of health care. As these approaches are piloted and implemented, it is important to address such issues as patient preference and variability. Physicians should be included as part of the development and evaluation of these frameworks and programs to identify potential challenges and reflect the needs of the patient populations they treat.

The variability of disease and how patients react to medications makes indication-specific pricing potentially beneficial for such diseases as cancer. A study examining the improvement in survival for several cancer drugs found great variation (120). Paclitaxel holds indications for metastatic breast cancer, non–small-cell lung cancer, and pancreatic cancer. Data show that the drug improved median survival in patients with breast cancer by 0.18 year, but only 0.08 year in those with non–small-lung cancer, with similar treatment costs for each indication (120). Express Scripts has announced that they plan to work with pharmaceutical companies and develop an indication-based formulary for certain cancer drugs in 2016 (121).

As large parts of the greater health care system are embracing this value-based concept, it has been underrepresented in benefit design. With the rising prices of drugs, some are turning to methods of incorporating value into benefit frameworks. Analysts have advocated for hybrid models of novel and traditional approaches to benefit design that may bridge the divide between providing patients with the drugs they need with the high cost of these drugs, such as an integration of the medical and pharmacy benefit to keep all specialty drugs under 1 benefit (122). Payers have been hesitant to be assertive in managing spending on specialty medications because of the sensitivities involved; many of these drugs are key to living a normal, healthy life, and payers may face backlash if they institute aggressive payment strategies (123).

Innovative benefit designs can include incentives that vary by service, type of patient condition, or income (124). Evidence-based benefit design has also been advocated as a way to reduce health care costs and would be in line with the movement toward evidence-based medicine. Policies that encourage value-based benefit design can help consumers make educated choices about prescription drugs and keep costs low. Value-based benefit design uses financial incentives to increase health care quality and decrease cost by reducing barriers to maintain and improve health (125). The state of Washington has saved $20 to $30 million per year since instituting an evidence-based prescription drug program across state-administered health programs (31). Least-costly-

alternative standards may also help in controlling costs by setting a single price for a group of similar drugs and requiring consumers and patients choosing the higher-cost drug to pay the difference out of pocket (31). Another analysis measured the effect of a value-based benefit design in diabetes medications. The study found that a reduction in the copayment for diabetes medications resulted in a 30% reduction in nonadherent patients (126).

With the advent of personalized medicine and treatments in a variety of conditions from common medical conditions to chronic disease, a one-size-fits-all approach to benefit design may not be the best to address high health care costs.

6. ACP believes payers that use tiered or restrictive formularies must ensure that patient cost-sharing for specialty drugs are not set at a level that imposes a substantial economic barrier to enrollees obtaining needed medications, especially for enrollees with lower incomes. Health plans should operate in a way consistent with ACP policy on formularies and pharmacy benefit management.

Drug formularies divide prescription drugs into 4 or 5 tiers with varying levels of fixed prices (copayments) for all drugs in each tier, with the exception of the highest tier. The highest tier, typically the specialty tier, is subject to either the highest copayment or coinsurance in which the patient pays a percentage of the cost of the treatment. There has been a shift toward prescription drug plans with coinsurance in the top 2 tiers, typically the specialty tier and a nonpreferred brand tier that has no restrictions on which drugs can be placed on the tier. This can lead to higher coinsurance rates than that of the specialty tier (127). Usually, only the specialty tier has been subject to cost-sharing; all other tiers have copayments. A lawsuit recently filed against four insurers in Florida alleged discrimination against patients with HIV/AIDS for placing all HIV/AIDS drugs, including generics, in the specialty tier, which requires high levels of patient cost-sharing (128).

When health plans are faced with rising costs associated with high-priced drugs, they often look to increased cost-sharing, utilization management, or tiered formularies that place all drugs of a certain class into the highest tier, putting patients at risk for not being able to access or afford the medications they need or adhere to drug regimens properly. It is notable that an analysis by Avalere Health showed, for the first time, that all Medicare Part D prescription drug plans will use a specialty tier (128). An analysis of coverage for specialty rheumatoid arthritis drugs in Medicare Part D found that between 81% and 100% of patients were required to pay a coinsurance percentage—averaging about 30%, or between $2712 and $2774—before reaching the catastrophic phase of coverage. More than 1 in 4 Medicare beneficiaries use these disease-modifying antirheumatic drugs, and spending on them has risen sharply for Medicare Part D (129).

Increased coinsurance for all drugs in a certain class is seen with other patient populations with high drug costs, such as cancer. A 2010 study found that oncology patients taking prescription medications with an out-of-pocket cost higher than $200 were at least 3 times more likely to choose not to fill their prescriptions than those with out-of-pocket costs of $100 or less (130). Medication adherence—particularly for persons taking specialty medications, who also tend to have other health issues—is important to reducing overall health care costs. If plans want to realize these reduced costs, they need to ensure that their patients are able to complete their medication cycles as prescribed (131).

The ACP acknowledges that there are limited ways in which pharmacy benefit managers and health plans can negotiate costs, including the use of formulary inclusion or exclusion of certain medications. However, in the case of some drugs for which there are no other treatment alternatives, this negotiating power is diminished, although the therapeutic benefit of the drug is not. The Affordable Care Act instituted out-of-pocket maximums for insured and self-insured plans starting in January 2014. The out-of-pocket maximums ($6600 for an individual and $13 200 for a family plan) may alleviate some cost-sharing issues, but they may still be burdensome and prohibitive for some individuals and families. Rebates, coupons, and copayment assistance programs may also help reduce out-of-pocket costs but should not be considered a long-term solution.

The ACP has a comprehensive policy on formulary benefit design, including:

ACP opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs.

Decisions about which drugs are chosen for formulary inclusion should be based on the drug's effectiveness, safety, and ease of administration rather than solely based on cost.

ACP recommends that pharmacy and therapeutic committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

The full text of ACP's formulary and pharmacy benefit management policies can be found in **Appendix 2** (available at www.annals.org).

It has been suggested that in some cases, health plans place certain drugs in the higher classes of their formulary to deter patients from choosing those health plans and ending up with a sicker pool of patients, or to draw prospective consumers to their plan with low premiums only for those consumers to find that the drug formulary does not cover their drugs or places their drugs in higher-cost tiers. A survey showed that adults are willing to pay higher insurance premiums for better

coverage of specialty drugs; this would suggest that people assume their insurance plan will cover these drugs with less cost-sharing (132).

Not only do increased out-of-pocket costs for patients result in poorer medication adherence, but research also shows that increasing patients' share of out-of-pocket costs is ineffective for controlling costs. A study found that for each 10% increase in cost-sharing, prescription drug spending decreases by 2% to 6%, depending on the drug and the patient's condition (133). Patient cost-sharing incentives that work for traditional drugs typically only work for a small class of specialty drugs for which close substitutes exist; when there are no other alternatives and a specialty drug is placed in the highest formulary tier, patients have no other option but to pay the high cost for the drug (126). In this case, increases in cost-sharing would probably result in smaller decreases in drug spending. Traditional tiered programs are also less effective for specialty drugs, because manufacturer coupon programs pay the patient's share of the cost of the medication for a certain period, overcoming the copayment incentive to use cheaper drugs (123).

7. ACP believes that biosimilar drug policy should aim to limit patient confusion between originator and biosimilar products and ensure safe use of the biosimilar product in order to promote the integration of biosimilar use into clinical practice.

Now that the first biosimilar has been approved for marketing in the United States, unresolved policy issues need to be addressed to ensure safe use of approved biosimilars and maximum utilization of biosimilars by patients and physicians. The ACP encourages the use of lower-cost alternatives when available, and recently released clinical practice guidelines promoting the use of generic medications when appropriate. The guidelines acknowledged that perception regarding safety may affect the prescribing practices of the physician (134). The relatively new nature of biosimilar introduction into the U.S. market represents an opportunity for physicians to understand the relative safety and efficacy of biosimilars and establish reasoned prescribing practices for biosimilars.

One of main issues has to do with the substitution of biosimilars for originator biologic products. Not all biosimilars will be considered interchangeable, and the indications for a biosimilar may differ from those of an originator product. The only approved biosimilar, Zarxio (filgrastim-sndz), a bone marrow stimulant, was granted approval for all indications of the originator product Neupogen (filgrastim), although only 1 indication was studied before its approval.

There are conflicting issues regarding the naming and labeling of biosimilars. The BPCIA did not contain any provisions on the naming of biosimilar drugs, and some were concerned that too-similar naming may cause confusion, undermine the use of the reference or biosimilar product, and create issues between parent companies of reference products and the biosimilar manufacturers. In August 2015, the FDA issued the draft guidance "Nonproprietary Naming of Biological Products; Draft Guidance for Industry," which proposes that biosimilars use the nonproprietary substance name with an FDA-designated suffix (135). This hybrid approach aims to reduce medication errors and increase patient safety by preventing inadvertent substitutions on noninterchangeable products (136).

The issues of substitution and naming pose challenges to establishing a strong base for biosimilar use. When substituting a generic drug for a brand-name drug, the pharmacist and physician can be confident in the chemical composition of the drug; to gain FDA approval, the generic substitute must be chemically identical to the brand-name product. However, the sensitivity of biosimilars to minor differences in their composition, manufacturing, and handling can result in variability compared with the originator product, and patients cannot assume that they will have the same reaction to the biosimilar as to the originator product. Thus, it is imperative that policies are in place to ensure physicians are consulted and notified of any biosimilar substitution. Pharmaceutical substitution laws are passed on a state-by-state basis (137). Currently, only 16 states have passed biosimilar substitution laws, and 14 require pharmacies to notify the physician of substitution. Ten states require patient notification of pharmacist substitution (138).

Conclusion

Through development and evolution of prescription drugs, tremendous progress has been made in the treatment of disease. However, these therapies are only as effective as a patient's ability to access needed medications. Much has been said about the idea of getting the right drug to the right patient for the right indication at the right price. This philosophy highlights the need for comprehensive efforts to implement meaningful policies that link price, value, innovation, and access. We must start by identifying why drugs are priced the way they are, supporting extensive research efforts into innovative and value-based systems, and improving access to getting prescription drugs to the market and into the hands of the patients who need them most.

Appendix 2: ACP Policy on Formularies and Pharmacy Benefit Management

Formularies

1. ACP opposes any formulary that may operate to the detriment of patient care, such as those developed primarily to control costs.

2. Decisions about which drugs are chosen for formulary inclusion should be based upon the drug's effectiveness, safety, and ease of administration rather than solely based on cost.

3. Evaluation of physician prescribing patterns (i.e., drug utilization review) should give priority to the effectiveness, and safety and ease of administration of the drugs prescribed rather than solely based on costs.

4. ACP recommends that financial incentive arrangements should be linked to cost-effective practices rather than formulary compliance.

5. ACP opposes financial arrangements that place the physician's financial interest in conflict with his or her patient's well-being.

6. ACP recommends that formularies should be constructed so that physicians have the option of prescribing drugs that are not on the formulary (based on objective data to support a justifiable, medically indicated cause) without cumbersome prior authorization requirements.

7. ACP recommends that a patient information program be instituted by managed care plans to make patients aware of formulary utilization and any associated costs such as co-pays.

8. Patient formulary education should include how the formulary functions, and a discussion of how copayment and/or deductible requirements may affect their pharmacy benefit.

9. ACP supports prompt prior notification to patients and physicians when formularies are changed or discontinued.

10. ACP recommends such notification be given within a specified time period, not fewer than ninety (90) days prior to change implementation.

11. Formularies should be approved on a regional basis by a professionally qualified body which includes practicing physicians using that formulary.

12. ACP recommends that Pharmacy &Therapeutic (P&T) Committees be representative of, and have the support of, the medical staffs that will utilize the formulary.

13. ACP supports industry moves to develop technology to make formularies more accessible and easier to utilize. ACP recommends physician input in designing, and pre-testing of, these technologies.

14. ACP supports continued government and industry studies of the impact of formularies on patient care. ACP recommends that CMS and states develop annual report-cards on the impact of formularies on beneficiaries enrolled in Medicare managed care plans.

15. Prescribing patterns should be influenced primarily through educating physicians on safety and efficacy. Cost should be a determinant only when safety and efficacy are equal among specific drug choices.

Pharmacy Benefit Management

1. ACP supports government regulation and industry self-regulation of Pharmacy Benefit Managers (PBMs). ACP particularly supports close government oversight of mergers between PBMs and pharmaceutical manufacturers.

2. ACP supports the disclosure to patients, physicians, and insurers of the financial relationships between PBM companies, pharmacists, and pharmaceutical manufacturers.

3. ACP supports requiring that PBM organizations' requests to alter medication regimes should occur only when such requests are based on objective data supported by peer reviewed medical literature and which undergo review and approval of associated managed care plans'/MBHOs' P & T Committees.

4. ACP supports requiring that, with a patient's consent, PBM organizations be required to provide treating physicians with all available information about the patient's medication history. (BoR 00, reaffirmed BoR 11)

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DAILY NEWS

Burwell: Office-Use Compounding Can Occur In Absence Of Guidance

March 18, 2016

HHS Secretary Sylvia Burwell told House lawmakers Tuesday (March 15) that since neither a guidance nor a rule exists on office-use compounding, the practice should be able to occur, directly contradicting FDA's stance that traditional compounders must obtain patient-specific prescriptions.

FDA started a firestorm in 2014 when it laid out its stance in response to a bipartisan House inquiry on whether the agency would allow anticipatory compounding for physicians to use in their practice without having patient-specific prescriptions. Industry sources had seen signals from agency inspection trends on how FDA would treat office-use compounding, but were surprised when FDA's letter to lawmakers drew what some viewed as “a line in the sand."

Burwell sent a different signal this week. When Rep. Buddy Carter (R-GA) raised his concerns about FDA restrictions on compounding for office-use at a hearing held by the House Committee on Education and the Workforce, Burwell told him there is no guidance or rule preventing the practice. Carter said he is looking for guidance from FDA on the topic.

“We don’t have any guidance out preventing that, maybe I can follow up with your staff to understand…Right now compounding should be occurring and that there is not a problem in terms of any guidance or any rules about it right now,” said Burwell.

The International Academy of Compounding Pharmacists found the HHS secretary's remarks encouraging. Dagmar Anderson, vice president of communications for IACP, said the group has been arguing that office-use compounding is allowed by the Drug Quality and Security Act. In IACP’s white paper on the topic, the group says that “[b]ecause Congress only reinstated Section 503A, and did nothing to change any office-use provisions within 503A, FDA has recognized in the past that Section 503A allowed office-use. Thus, FDA’s prohibition of office-use has left a widely accepted industry practice encompassed in a cloud of uncertainty."

Meanwhile, key brand and generic industry groups are urging House and Senate appropriators to keep language out of the 2017 appropriations bill that “impedes FDA’s ability to enforce compounding law, including prescription and quality standard requirements.” Signers of the March 7 letter include the Biotechnology Innovation Organization, Generic Pharmaceutical Association, Pharmaceutical Research and Manufacturers of America, Pew Charitable Trusts, Trust for America’s Health and American Public Health Association.

The groups wrote: “Traditional pharmacies, primarily regulated by the states, should not produce supplies of compounded drugs without prescriptions, also known as “office stock” compounding. The quality standards applied to pharmacies are appropriate for traditional practice, but not for operations at a larger scale where more patients are exposed. These compounded office stock supplies may also sit on clinic shelves for an extended period of time, allowing any microbial contaminants to proliferate to harmful levels.”

The letter notes that appropriators included language in the report accompanying the FDA funding bill that directed FDA to issue a guidance document how compounding pharmacists can continue to engage in office-use compounding before the receipt of a patient-specific prescription.

FDA's interpretation of the Drug Quality and Security Act in restricting office-use compounding sparked a backlash from pharmacy and healthcare provider organizations, who pushed congressional health care committees at the end of 2014 to take legislative steps to stop FDA from requiring patient-specific prescriptions for office-use compounding, complaining the agency's approach is barring patient access to urgently-needed antibiotics and goes against congressional intent.

The agency's move also triggered Sen. David Vitter (R-LA) to introduce legislation last year that would put the practice of office-use compounding clearly under state regulation by exempting compounding pharmacies from new drug, current good manufacturing and adequate directions-for-use requirements if the drug is compounded and distributed to a practitioner as permitted by state law for use in the treatment of or administered to a patient of the practitioner.

Some stakeholders have also pushed broader use of compounding as a way to temporarily resolve drug pricing issues. Hospital and pharmacy stakeholders told the Senate Special Committee on Aging in December that Congress should make it easier for pharmacies to compound drugs subject to price gouging while FDA reviews generic applications for those drugs. However, Pew cautioned against the move, noting that compounded products do not meet the same approval standards as commercially available products. -- *Erin Durkin*(*edurkin@iwpnews.com*)

The obscurity of drug spending in Medi-Cal

What do you want to know about State spending on high-cost drugs?

California will be a flashpoint in the policy debate this year around reining in the cost of high-priced prescription drugs.

A measure expected to be before voters this November would restrict the state's drug payment to no more than the lowest price paid for the same drug by the U.S. Department of Veterans Affairs.

And an unlikely coalition of health insurers, labor and consumer advocates promises to keep pushing for controls on high-cost drugs, after a state Assembly bill that would have forced pharmaceutical manufacturers to disclose their costs stalled in committee last week.

"California is truly ground zero for this fight," says Mike Roth, spokesperson for the campaign to pass the California Drug Price Relief Act, about efforts to lower prescription drug costs. The ballot initiative's campaign is funded by the AIDS Healthcare Foundation. "It is clear Congress as a whole is not going to take meaningful action."

Over the coming months, CALmatters will investigate how specialty and other high-cost drugs are affecting the state budget, particularly Medi-Cal, which covers almost one in three Californians.

But as we've learned so far, just as there may be a lack of transparency about how drug makers price drugs, what is actually spent on a particular drug is also obscured—by confidentiality laws.

Sources with the California Department of Health Care Services told us that both federal and state laws prevent the public from knowing the ultimate price the state pays for a particular drug. Drug price negotiations contain proprietary information, trade secrets.

"There's a lack of transparency all through this," says Joel Hay, professor of pharmaceutical economics and policy at the University of Southern California.

"You don't know anything about these confidential price rebates, and you never will."

Hay said researchers only have "vague ideas" of the drug price discounts given to health care programs like Medi-Cal, but there is a public benefit to keeping them confidential: It helps ensure that health programs that cover the poor keep receiving discounts.

If, for example, California's discounted drug prices were public, Hay said, insurance companies and other health care payers would demand the same price. In that scenario, manufacturers may decide to sell the drug at the same amount to everyone. Without a discount, the price may be too high for Medicaid, and California might be forced to limit access to brand-name drugs.

"The State of California, to protect the taxpayers, and to protect the funding for its Medi-Cal recipients, is not going to reveal the confidential rebates it gets," Hay said.

There are other challenges to identifying overall state drug spending trends in Medi-Cal. The program has two payment systems for its 12.8 million members. Roughly 80 percent of recipients have coverage through health plans, and services for the rest are reimbursed directly by the state.

- 10.1 million Medi-Cal members get care from 22 managed-care organizations, and their spending on prescription drugs—on a "granular" level—is neither aggregated nor public.
- The state Department of Health Care Services puts the fee-for-service population's prescription usage data online, but it doesn't disclose the final price it pays for drugs.

There's reason to believe the state is feeling the cost pressure of new Hepatitis C drugs like Sovaldi, drugs which California says cost $85,000 per course of treatment.

"It's a very serious problem," said California Health and Human Services Secretary Diana Dooley about the high cost of prescription drugs.

Dooley says drug prices are a problem for many health care payers; CalPERS, Medi-Cal and private insurers, too. The state is addressing the issue "in every way (it) can."

"There are very few tools in our toolbox," Dooley said.

Over the next few months, CALmatters will find out more about measures the state is taking to manage high-cost drugs. We'll blog pieces of the drug spending picture along the way on Medium and CALmatters.org; on how per-member prescription drug spending has changed over time, which drugs account for the most spending, who they benefit, and how patient access is affected by a drug's cost. Our blog posts will culminate in a story we'll distribute to CALmatters' print, online and radio news partners throughout California.

Tell us what you think. Feel free to post a comment at the bottom of this story.

- Suggest ways to examine the impact of high-cost drugs on California's budget
- Share opinions about bringing transparency to drug pricing, and what is ultimately spent on drugs.
- Suggest another drug price question you'd like us to explore.

Or, you can Tweet or email us.

CALmatters is a nonprofit journalism venture dedicated to explaining state policies and politics.

PHARMACISTS to the fore

Dispensing with old limits, they're playing crucial roles in patients' education and care

BY GERI ASTON

Even as rising drug prices intensify cost pressures, hospital pharmacies are striving to improve care and expand services without breaking the bank.

The biggest change motivator is health reform, with its push toward value-based payment, accountable care and Medicare payment penalties for readmissions. Its emphasis on care throughout a patient's disease state is spurring hospital pharmacists to extend their reach, says Mark Eastham, senior vice president and general manager of McKesson Pharmacy Optimization.

"They want to follow the patients and make sure they're taking their medication, they're taking it the right way, and they don't have any side effects," he says. "What that does for them and the patient is it really creates more continuity of care versus how the model was before, where it gets handed off to a retail pharmacy and then, all of the sudden, you have this big disconnect."

That interest in ensuring care continuity has prompted many hospitals to involve pharmacists in patients' transitions out of the hospital.

At Lifespan, a Rhode Island health system, pharmacists visit patients at risk of readmission while they're in the hospital. They go over medications with them and describe how the drugs work in the body, says Christine Berard-Collins, director of pharmacy. The pharmacists ask patients to repeat what they've heard to make sure they understand their medications before they leave the hospital.

"It's not just saying, 'Do you have any questions?'" says Berard-Collins, "It's explaining to them the whole connection of the medication and what it means to them."

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Christine Berard-Collins

A clinical pharmacist oversees the transitions-of-care program, offered at Lifespan's Rhode Island Hospital and The Miriam Hospital. Three pharmacists make the patient visits. After discharge, case-management nurses call patients to follow up on a number of issues, including medication.

Comprehensive Pharmacy Services, which serves more than 550 hospitals and health care facilities, launched a transitions-of-care program in 2014. Under RxTransitions, pharmacists conduct patient discharge teaching, and admission and discharge reconciliation. They follow up with patients 24 and then 48 hours after they've been discharged from the hospital to talk through their medications and answer any questions.

Patients can be so overwhelmed at discharge that they don't absorb medication instructions, says Rod Recor, CPS chief strategy officer. "When we get in touch with that patient a couple of days later, they're much more receptive to hearing things, and they're more intently listening."

The six participating clients, with more than 10,000 patients, have seen readmissions for the conditions they've targeted fall between 30 and 50 percent, Recor says.

Instead of sending patients home with a prescription, many hospitals are sending them on their way with their outpatient medicines in hand. These meds-to-beds programs are a way to prevent that patient-provider disconnect that exists in the traditional model of hospital pharmacy services, Berard-Collins says. "We [used to give] them very important, and often lifesaving, prescriptions and hoped

FRAMING THE ISSUE:

- U.S. spending on prescription drugs jumped 12.6 percent in 2014 to $305 billion, compared with 2.5 percent in 2013, largely because of increased spending on new hepatitis C treatments and drugs for cancer and multiple sclerosis, according to the CMS.
- Prescription drug prices increased 4.1 percent overall in 2014, up from 2.3 percent in 2013, CMS reports.
- Annual price increases for prescription drugs are expected to average 3 percent through 2024, CMS states.
- 700 specialty drugs are in the drug development pipeline, according to PricewaterhouseCoopers LLP.
- The average price of cancer drugs for about a year of therapy increased from $5,000 to $10,000 before 2000 to more than $100,000 by 2012, according to an April 2015 article in *Mayo Clinic Proceedings*.

Illustration by Shutterstock

they got them filled, hoped they had a ride to the pharmacy, hoped they didn't run into a co pay issue, hoped it was covered by their insurance, hoped that they could find a pharmacy that stocked it," she says. "That did not seem to us to be in the spirit of accountable care."

Besides meds-to-beds, Lifespans offers free home delivery for patients who might not need their medications at discharge or when drugs need to be specially ordered. While the service has a cost, the patient value is more important, Berard-Collins says.

"Making sure our patients take their medications is the No. 1 priority," she says. "We're prescribing them for a reason, and that reason is to keep them healthy."

Growing appeal of retail pharmacy

Interest in maintaining continuity of care into the outpatient setting also is prompting an increasing number of hospitals to create their own retail pharmacies, Eastham says.

Access to patients' electronic health records means hospital retail pharmacists can check physicians' notes, what drugs a patient was on in the hospital, lab values, and the last time a patient visited a hospital clinic. "This gives them more data to take care of that patient in a way that a retail pharmacy would not have," Eastham says.

Care has to be taken in deciding where to locate a retail pharmacy on a hospital campus. Places with high foot traffic or near outpatient clinics often work well.

Hospital-owned retail pharmacies also allow hospitals to capture revenue that otherwise would be lost to pharmacy chains. Careful analysis needs to be made to determine whether a hospital-owned retail pharmacy is financially viable.

Lifespan hired a consultant to conduct a business analysis before entering into the retail pharmacy business. The goal was to make sure the endeavor would at least cover its expenses within five years and not become a drain on the organization, says Berard-Collins, who is director of Lifespan Pharmacy LLC.

Retail pharmacy has many fixed costs, including space, phones, computers, pharmacists and technicians, so the organization had to determine the baseline number of discharges and specialty services necessary to cover those expenses. The business analysis showed that the threshold was achievable at Lifespan's two largest hospitals. The organization opened its first retail pharmacy in May 2013 at Rhode Island Hospital and its second in October 2014 at The Miriam Hospital.

Business know-how has to be taken into account when opening a hospital retail pharmacy. "We called it the pharmacy that it took a village to build," jokes Berard-Collins about Lifespan's first foray into retail. "It was not a pharmacy project; it was an organization project. It involved marketing, security, information systems, contracting, accounts payable, finance. All the different elements of the organization really came together."

Lifespan was able to open its pharmacies with existing pharmacists, many of whom had previous retail experience. Each facility has a pharmacist in charge who works only in that location, but other pharmacists alternate between retail and inpatient pharmacy. "We love the fact that we are an integrated service, so our pharmacists in the retail pharmacy are comfortable going into a patient's room to counsel them," Berard-Collins says.

Care has to be taken in deciding where to locate a retail pharmacy on a hospital campus, Eastham notes. Places with high foot traffic or near outpatient clinics often work well. "It can't be your typical hospital pharmacy where it's in the basement," Eastham says. "People aren't going to go down there."

Some hospitals want to offer patients the convenience and access of on-site retail pharmacy without entering the business themselves. Advocate Health Care in the Chicago area has partnered with Walgreens to provide retail pharmacy in three of its 12 hospitals, with plans to open three more, likely in 2017. "Retail pharmacy is not our core competency, so partnering with someone with expertise makes a lot more sense," says Rishi Sikka, M.D., Advocate's senior vice president of clinical operations.

Advocate doesn't share more patient information with the in-house Walgreens than it would with any other retail pharmacy, says Bill Forslev, Advocate's vice president of pharmacy. But because the pharmacists are on-site, they have built relationships with physicians and nurses that allow for easy communication.

Specialty pharmacy pros and cons

The explosion of specialty drugs is prompting some hospital systems to create their own specialty pharmacies. Again, the philosophy behind offering the service is to improve care continuity while potentially generating revenue, Eastham says.

In general, specialty drugs are expensive medications that require special handling or careful patient monitoring — traditional cancer chemotherapies are an example. These days, offerings have expanded way beyond infused chemotherapies. In recent years, patient-administered specialty drugs have hit the market, including oral chemotherapies, medications for rheumatoid arthritis and drugs that cure hepatitis C. A prom-

Illustration by Thinkstock

ising class of specialty cholesterol-lowering drugs, called PCSK9 inhibitors, are in the drug-development pipeline and could be approved in the next couple of years.

In 2013, Lifespan launched a specialty drug service at its Rhode Island Hospital retail pharmacy after concluding that it made no sense for patients or the organization to passing hand off those patients to outside pharmacies, Berard-Collins says. "The clinical pharmacists in my clinics are seeing the patients, teaching them about their medications, following up with them to see if they're having any side effects, checking their lab values," she says. "They were doing all this work and then sending the prescription out to be filled by some out-of-state pharmacy."

Complex, sometimes toxic, specialty medications can be managed better by the clinical pharmacists working with the rest of the patient's care team using a shared EHR, Berard-Collins says. "Their patients are our patients, so we have a personal and vested interest in them," she says. Pharmacists serve in the oncology, renal transplant and hepatitis C clinics.

Lifespan's retail pharmacy enterprise, including the specialty drug service, is nonprofit. Any revenue gained goes back into the system to pay for new programs, Berard-Collins says. Both retail pharmacy locations are significantly exceeding their revenue targets, and their combined revenues have surpassed the break-even point, she says. As a result, this year they were able to add pharmacist positions in the rheumatology, GI, dermatology and neurology clinics.

Insurance coverage for specialty drugs is tricky, however. Some specialty medicines are covered under the patients' medical benefits and others under the pharmacy benefit, Eastham says. Pharmacy benefit managers want insurers to move specialty drugs into the pharmacy benefit because that allows them to run them through the PBM's specialty pharmacies, he says. "But right now, it just depends on how the payer has decided what health benefit to put that in."

In Rhode Island, the two largest private health insurers have exclusive relationships with outside pharmacies, so patients with their insurance can't fill their specialty drug prescriptions at Lifespan's pharmacy. The situation is frustrating because it means Lifespan's specialty clinic pharmacists can't keep tabs on those patients as thoroughly, Berard-Collins says.

However, Medicare patients have access to the Lifespan specialty pharmacy through Medicare Part D, Berard-Collins notes. Lifespan is self-insured, and its plan members can fill specialty drug prescriptions at the organization's retail pharmacy.

Another barrier for hospitals is that some specialty drug manufacturers have established limited distribution networks so only certain pharmacy chains can supply their drugs. Lifespan has had some success in working around those deals. "We say, 'we're not looking to take over the market for this drug. When it's our own patient, we're responsible for them anyway, so can we just fill the drug?' Some of them have been very open to that," Berard-Collins says. — *Geri Aston is a contributing writer for* H&HN ●

EXECUTIVE CORNER

A number of major trends, from rising drug prices to value-based payment, will affect hospital pharmacy departments in the coming years. "Pharmacy Forecast 2016—2020," published in December 2015 by the ASHP Foundation, lays out forces impacting pharmacy departments and recommendations for coping with them, including:

TREND | STANDARDIZATION/BEST PRACTICES
The pharmacy enterprise can help their organizations to succeed by standardizing processes, implementing best practices that improve patient health, managing the formulary properly and applying business acumen throughout the medication-use process.

TREND | SPECIALTY DRUGS
Because of growth in the use of expensive specialty drugs, health systems should conduct an assessment to determine the best approach to these medications. Options include creating a hospital-owned specialty pharmacy service, establishing such a service with a business partner, completely outsourcing the service, or not providing a specialty drug service while ensuring safe and appropriate care of patients on specialty drugs.

TREND | QUALITY AND VALUE
The push for quality improvement and payment for value will extend into pharmacy departments. They should design and implement medication therapy-related quality measures and performance metrics that focus on enhancing quality, efficiency and cost management.

TREND | GENERICS
Consolidation of generic drug manufacturers is posing challenges. The switch from multisource to single-source generics will lead to at least a 25 percent increase in health system expenditures for generics by 2020.

TREND | PATIENT FIRST
In the face of pressure to deal with continual escalation of drug prices, pharmacy should ensure that the driving force behind its work is patients' best interests complemented by compliance with evidence-based medication use and waste minimization. — GERI ASTON ●

Health and Human Services Department
Sherri Z. Heller, Ed.D., Director

County of Sacramento

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Behavioral Health Services
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Primary Health Services
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Senior and Adult Services

DRUG OVERDOSE HEALTH ALERT: Counterfeit Norco Containing Fentanyl April 1, 2016

Situational Update

The Sacramento County Division of Public Health has received reports of 36 opioid-related overdoses since March 23 associated with ingestion of counterfeit Norco prescription pain pills being sold on the streets. Nine (25%) of the 36 overdose patients have died. These counterfeit pills contain the synthetic opioid fentanyl instead of the active ingredients of Norco (acetaminophen and hydrocodone). Please see actions requested of clinicians and emergency responders below:

Actions Requested of All Clinicians and Emergency Responders:

1. **Report all deaths** from suspected or confirmed opioid overdose to the Sacramento County Coroner by phone (916) 874-9320 and fax (916) 874-9257.

2. **Report** to Sacramento County Division of Public Health (SCDPH) electronically via CalREDIE or via confidential fax (916) 854-9709 the following suspected and confirmed drug poisoning cases:
   - *Emergency department visits* due to opioid overdose
   - *All deaths* due to opioid overdose

   Medical records should be sent via confidential fax (916) 854-9709.

3. **Exercise increased vigilance** in promptly identifying suspected overdose patients and taking appropriate action. Signs and symptoms of opioid overdose include unconsciousness or unresponsiveness, respiratory depression or arrest, cyanosis, vomiting and pinpoint pupils.

4. **Warn patients** against taking prescription-type pills that are not prescribed by and obtained from one's own physician and/or pharmacy. Counterfeit Norco containing fentanyl may not be easily distinguished from non-counterfeit Norco. Fentanyl is estimated to be 80 times as potent as morphine and hundreds of times more potent than heroin.

5. **Consider toxicology screening** specific for fentanyl when ordering drug panels for overdose patients.

If you need more information about reporting suspected cases of drug poisoning overdoses, call Sacramento County Public Health at (919) 875-5881 Monday-Friday between 8:00 am – 5:00 pm.

Sincerely,

Olivia Kasirye MD

Olivia Kasirye, MD, MS
Public Health Officer