Medication Safety Committee

Wednesday, July 5, 2017

California Hospital Association

1215 K Street, Suite 800

Sacramento, CA 95814

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

Medication Safety Committee - Meeting Book

AGENDA

Bartleson

11:00 USP 800 Impact on Physician Office Practice
Patricia Kienle, Director, Accreditation and Medication Safety,
Cardinal Health Innovative Delivery Solutions

MD Use of Sterile Hazardous Drugs Page 56
Hanni

Non Sterile Hazardous Compounding
Bartleson

Medication Shortage Page 60
Bartleson

Free Vaccination Programs and Barriers Page 64
Rogers/Cardone

Legislation
Bartleson

- Pharmacy Legislation Page 67
- AB40 Page 76
- AB1589 Page 82
- SB251 Page 86
- SB716 Page 95

12:00 LUNCH

12:30 STANDING REPORTS

Board of Pharmacy
Herald

CDPH
Lee/Woo

CSHP
DeMartini

CALNOC
Foley

ACNL

CHPSO
Jaffe

CAHF
Hall

HQI Update
Barlteson (for Munoz)

- Prevention and Monitoring of Respiratory Depression in

1:15 WORK GROUP REPORTS

1:45 INFORMATION
All

Drug Pricing Policy Options Page 98

NEXT MEETING

Next Meeting - Wednesday, October 11, 2017

2:00 ADJOURNMENT
Hanni

MEDICATION SAFETY COMMITTEE
2017

CO –CHAIRS

JEANNETTE HANNI, R.Ph, MPA, FCSHP
Bay Area Executive Director of Pharmacy Services
West and South Bay Region – Sutter Health
2350 W El Camino Real
Mountain View CA 94040
(650) 934-6967
hannij@sutterhealth.org

CANDACE FONG, PHARM.D
Director of Pharmacy and Medication Safety
Dignity Health
3400 Data Drive
Rancho Cordova, CA 95670
(916) 851-2678
candace.fong@dignityhealth.org

MEMBERS

EDDIE AVEDIKIAN, PHARM.D
Pharmacy Operations Manager
Providence Health & Services, Southern California
2727 Alameda Ave.
Burbank, CA 91505
(818) 847-6327
eddie.avedikian@providence.org

CAROLYN BROWN, RN, MS
Director, Quality and Safety
Santa Clara Valley Medical Center
777 Turner Drive, Suite 320
San Jose, CA 95128
(408) 885-2093
carolyn.brown@hhs.sccgov.org

KATIE CHOY, MS, RN, CNS, NEA-BC
Nursing Director, Education
Washington Hospital Healthcare System
2000 Mowry Avenue
Fremont, CA 94538
(510) 608-1366
choyka@whhs.com

JOHN CHRISTENSEN, PHARM.D.
Pharmaceutical Consultant II
California Department of Public Health
Licensing and Certification Program
MS3505
2170 Northpoint Parkway
Santa Rosa, CA 95407
(707) 576-2418
john.christensen@cdph.ca.gov

EDNA DELEON, RN, MSN
Executive Director
Long Beach Memorial Medical Center
Miller Children's & Women's Hospital Long Beach
Community Hospital Long Beach
2801 Atlantic Avenue
Long Beach, CA 90806
(562) 933-1910
Mdeleon2@memorialcare.org

LORIANN DEMARTINI, PHARM.D.
CEO
California Society of Health System Pharmacists
1314 H Street, Suite 200
Sacramento, CA 95814
(916) 447-1033
ldemartini@cshp.org

KEVIN DORSEY-TYLER, MD, PhD
Medical Director, Clinical Analytics
Enloe Medical Center
1531 Esplanade
Chico, CA 95969
(530) 891-5266
kevin.dorseytyler@enloe.org

VICKY FERRARESI, PHARMD, FASHP, FCSHP
President, California Society of Health-System Pharmacists
Director, Pharmacy Services
Pathways
585 North Mary Ave.
Sunnyvale, CA 94085
(408) 773-4247
VFERRARESI@PATHWAYSHEALTH.ORG

MARY FOLEY, RN, PhD
Director, Center for Nursing and Innovation
UCSF, School of Nursing
2 Koret Way, N631, Box 0610
San Francisco, CA 94143
(415) 514-3638
mary.foley@nursing.ucsf.edu

KATAYOON KATHY GHOMESHI, PHARM.D, MBA, BCPS, CPPS
Medication Safety Specialist, UCSF Medical Center
Assistant Clinical Professor, UCSF School of Pharmacy
533 Parnassus Ave., Rm 585-A, Box 0622
San Francisco, CA 94143
(415)851-5284
Kathy.ghomeshi@ucsf.edu

AMY GUTIERREZ, PHARM.D
Vice President, Chief Pharmacy Officer
Kaiser Permanente National Pharmacy Programs and Services
12254 Bellflower Blvd.
Downey, CA 90242
(562)658-3513
Amarylis.C.Gutierrez@kp.org

LISA HALL, RN
Director of Regulatory Affairs
California Association of Health Facilities
2201 K Street
Sacramento, CA 95816
(916) 432-5201
lhall@cahf.org

SUSAN HERMAN, DNP, RN, NEA-BC, CENP
Vice President Patient Care Services and CNO
San Joaquin Community Hospital/Adventist Health
418 Spirea St.
Bakersfield, CA 93314 (home address)
(650)575-0536
drsusanherman@gmail.com

VIRGINIA HEROLD
Executive Officer
California Board of Pharmacy
1625 N. Market Boulevard, Suite N-219
Sacramento, CA 95834
(916) 574-7911
virginia_Herold@dca.ca.gov

RORY JAFFE, MD, MBA
Executive Director, CHPSO
Special Advisor, AHRQ
1215 K Street, Suite 930
Sacramento, CA 95814
(916) 552-2600
rjaffe@chpso.org

RANDY KAJIOKA, PHARM.D
Chief of Pharmacy Services
California Correctional Health Care Services
P.O. Box 588500
Elk Grove, CA 95758
(916) 379-1677
randy.kajioka@cdcr.ca.gov

NASIM KARMALI, RPh
Clinical Director, Quality Services
Kaiser Foundation Hospital Redwood City
1150 Veterans Blvd.
Redwood City, CA 94063
(510) 659-8017
nasim.karmali@gmail.com

CARI LEE, PHARM.D
Pharmaceutical Consultant II
California Department of Public Health
Licensing and Certification Program
150 North Hill Drive, Suite 22
Brisbane, CA 94005
(415) 330-6779
cari.lee@cdph.ca.gov

CHRISTINE LOW, PHARM.D.
Manager Medication Safety & Pharmacy Compliance
Scripps System
10666 N Torrey Pines Rd – 303C
La Jolla, CA 92037
(858) 554-4331
low.Christine@scrippshealth.org

LORI NOLAN, MSN, RN, NE-BC, CEN
Director, Women & Children's Service Line
Providence Little Company of Mary Medical Center Torrance
4101 Torrance Boulevard
Torrance, CA 90503
(310) 303-6312
lorene.Mullenhour@providence.org

DOUG O'BRIEN, PHARM.D.
Regional Director for Inpatient Pharmacy Services
Kaiser Foundation Hospitals
Northern California
3240 Arden Way
Sacramento, CA 95825
(510) 301-3990
doug.C.O'brien@nsmtp.kp.org

CHRISTOPHER PATTY, DNP, RN, CPPS
Medication Safety Specialist
Kaweah Delta Health Care District
400 W. Mineral King
Visalia, CA 93291
(559) 624-2630
cpatty@kdhcd.org

RICHARD B. RABENS, MD, MPH, FAAP
Medical Director
The Permanente Medical Group, Inc/Kaiser Permanente
1800 Harrison Street, Ste. 410
Oakland, CA 94612
(510) 625-6881
richard.rabens@kp.org

DAN ROSS, PHARM.D
Representative
California Society of Health-System Pharmacists
1314 H Street, Suite 200
Sacramento, CA 95814
(818) 500-8262
dross@drossconsulting.com

DIANA SCHULTZ
Medication Safety Manager
Palomar Medical Center
2185 Citracado Parkway
Escondido, CA 92029
(442) 281-2564
diana.schultz@palomarhealth.org

RITA SHANE, PHARM.D, FASHP, FCSHP
Chief Pharmacy Officer
Cedars-Sinai Medical Center
Assistant Dean Clinical Pharmacy
UCSF School of Pharmacy
8700 Beverly Blvd., Room A903
Los Angeles, CA 90048
(310) 423-5611
rita.shane@cshs.org

SARAH STEPHENS, PHARM.D, BCPS
Medication Safety Coordinator
Kaweah Delta Health Care District
400 W. Mineral King
Visalia, CA 93291
Phone: (559) 624-5652
sastephe@kdhcd.org

TERRI VIDALS
Operations Manager and Medication Safety Officer
Tri-City Medical Center
4002 Vista Way
Oceanside, CA 92056
(760) 940-3061
vidalstc@tcmc.com

ART WOO, PHARM.D
Pharmaceutical Consultant II
California Department of Public Health
Center for Health Care Quality
Licensing and Certification Program
850 Marina Bay Parkway, Bldg P
Richmond, CA 94804-6403
(510) 620-3916
art.woo@cdph.ca.gov

REGIONAL ASSOCIATION REPRESENTATIVES

LISA BRUNDAGE O'CONNELL, MS
Education Manager
Hospital Council of Northern and Central California
3480 Buskirk Ave., Suite 205
Pleasant Hill, CA 94523
(925) 746-0728
loconnell@hospitalcouncil.net

CHA STAFF

BJ BARTLESON, RN, MS, NEA-BC
Vice President, Nursing & Clinical Services
California Hospital Association
1215 K Street, Ste. 800
Sacramento, CA 95814
(916) 552-7537
bjbartleson@calhospital.org

DAVID PERROTT, MD, DDS
Senior Vice President & Chief Medical Officer
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 552-7574
dperrott@calhospital.org

BARB ROTH
Administrative Assistant
California Hospital Association
1215 K Street, Suite 800
Sacramento, CA 95814
(916) 552-7616
broth@calhospital.org

Medication Safety Committee
Hospital Representation

BY COUNTY

As of March 21, 2017

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

Medication Safety Committee
Member Geographics - July 2017

HOSPITAL MEMBERS

Member Name	Organization Name	County
Amy Gutierrez	Kaiser Permanente National Pharmacy Programs and Services	Los Angeles
Candace Fong	Dignity Health	Sacramento
Carolyn Brown	Santa Clara Valley Medical Center	Santa Clara
Chris Patty	Kaweah Delta Health Care District	Tulare
Christine Low	Scripps System	San Diego
Diana Schultz	Palomar Medical Center	San Diego
Doug O'Brien	Kaiser Foundation Hospitals	Sacramento
Eddie Avedikian	Providence Health & Services	Santa Barbara
Edna DeLeon	Long Beach Memorial Medical Center	Los Angeles
Jeannette Hanni	Sutter Health - West and South Bay Region	Santa Clara
Kathy Ghomeshi	UCSF Medical Center	San Francisco
Katie Choy	Washington Hospital Health Care System	Alameda
Kevin Dorsey-Tyler	Enloe Medical Center	Butte
Lori Nolan	Providence Little Company of Mary Medical Center	Los Angeles
Nasim Karmali	Kaiser Foundation Hospital	Alameda
Richard Rabens	The Permanente Medical Group, Inc.	Alameda
Rita Shane	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens	Kaweah Delta Health Care District	Tulare
Susan Herman	San Joaquin Community Hospital/Adventist	Kern
Theresa Vidals	Tri-City Medical Center	San Diego

NON-HOSPITAL COMMITTEE MEMBER

Art Woo	California Department of Public Health	Contra Costa
Cari Lee	California Department of Public Health	San Mateo
Dan Ross	California Society of Health System Pharmacists	Sacramento
John Christensen	California Department of Public Health - Redwood	Sonoma
Lisa Brundage O'Connell	Hospital Council of Northern and Central	Contra Costa
Lisa Hall	California Association of Health Facilities	Sacramento
Loriann DeMartini	California Society of Health System Pharmacists	Sacramento
Mary Foley	UCSF, School of Nursing	San Francisco
Randy Kajioka	California Correctional Health Care	Sacramento
Rory Jaffe	California Hospital & Patient Safety Organization	Sacramento
Vicky Ferraresi	California Society of Health System Pharmacists	Santa Clara
Virginia Herold	California Board of Pharmacy	Sacramento

GUIDELINES FOR THE CALIFORNIA HOSPITAL ASSOCIATION MEDICATION SAFETY COMMITTEE

I. NAME

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

II. MISSION

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

III. PURPOSE

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

IV. COMMITTEE

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

California Department of Public Health
California Society of Health System
Pharmacists California Board of
PharmacyCenters for Medi-Care and Medi-Caid
Services
Collaborative Alliance for Nursing Outcomes
Association of California Nurse Leaders
California Medical Association
California HQI and CHPSO
Risk Management Association
Representatives from the following CHA committees/centers:

- Center for Behavioral Health
- Rural Health Center
- Quality Committee
- Joint Committee on Accreditation and Licensing
- Center for Hospital Medical Executives
- EMS/Trauma Committee
- Hospital Based Clinics Committee
- Center for Post Acute Care

Governance

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the Committee. CHA members will be hospital members. Non-hospital members are ex-officio members and can only be appointed to the Committee at the discretion of the CHA staff liaison

2. The CHA Committee members shall consist of various representatives from large hospital systems, public institutions, private facilities, free-standing facilities, small and rural facilities, university/teaching facilities and specialty facilities. A member may fulfill more than one required membership position

3. Hospital members are appointed by CHA Staff per recommendation of hospital committee members and per hospital and non-hospital membership requirements listed above.

4. Guidelines for membership – these guidelines should be used when selecting potential new members for the committee:

a) Demonstrated experience in medication safety and understanding of regulatory environment based on current or recent job responsibilities
b) Contributions to medication safety at the organizational and/or professional level
c) Practice experience related to medication safety and regulatory compliance: at least 3 years (preferred)

5 Term:

(a) Terms of office shall be based on member participation and desire to remain active on the committee. The CHA staff liaison will perform an annual review of member attendance, participation and desire to remain active on the committee.

(b) Chairs and Co-Chair positions will be filled by hospital members only and selected by the CHA staff liaison per recommendation of the present chair, co-chairs and by other members of the committee. They will be selected based on their leadership and desire to fill the position.

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee and CHA Board of Trustees

2. Identify issues and develop possible solutions and best practices to improve the safety of the medication use process.

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

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

5. Maintain/increased awareness of the legislative and regulatory environment with regard to medication safety issues.

C. COMMITTEE MEETINGS

1. Meetings of the Committee shall be held quarterly in person.

2. To maintain continuity, substitution of members should be discussed with the staff liaison and co-chairs on an individual basis.

3. Three consecutive unexcused absences by a ommittee member will initiate a review by the co-chairs and CHA staff liaison for determination of the ommittee member's continued service on the ommittee.

4. Special meetings may be scheduled by the co-chair, majority vote, or CHA staff liaison.

D. VOTING

1. Voting rights shall be limited to members of the committee, and each member present shall have one vote. Voting by proxy is not acceptable.

2. All matters requiring a vote of the committee must be passed by a majority of a quorum of the committee members present at a duly called meeting or telephone conference call.

E. QUORUM

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

F. MINUTES

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

V. OFFICERS

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

A. SUB-COMMITTEES

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

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

VI. GENERAL PROVISIONS

Goals, and objectives, shall be developed annually by the committee with approval by the CHA staff liaison. Quarterly updates and progress reports shall be completed by the ommittee 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 liaisonshall be an employeeof 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 ommittee who shall address the ommittee in other than a volunteer relationship excluding CHA staff and who shall engage with the ommittee 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 ommittee and shall further refrain, if a member of the ommittee, from any vote in which such issue is involved.

MEDICATION SAFETY COMMITTEE
MEETING MINUTES
April 5, 2017 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Candace Fong, Susan Herman, Virginia Herold, Amy Gutierrez, Loriann DeMartini, Vicky Ferraresi, Alicia Munoz, Rita Shane, Dan Ross, Sarah Stephens, Eddie Avedikian, Doug O'Brien, Art Woo, Randy Kajioka, John Christensen, Kathy Ghomeshi

Members on Call: Terri Vidals, Diane Schultz, Carolyn Brown

Members Absent: Jeannette Hanni, Katie Choy, Edna DeLeon, Kevin Dorsey-Tyler, Mary Foley, Lisa Hall, Nasim Karmali, Cari Lee, Christine Low, Robert Menet, Lori Nolan, Lynn Paulsen, Richard Rabens

CHA Staff: BJ Bartleson, Barb Roth, Debby Rogers

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Ms. Fong at 10:00 a.m.

Membership changes have been made regarding CHPSO. Ms. Bartleson suggested former presenter Chris Patty, RN, Medication Safety Specialist at Kaweah Delta be extended an invitation to be on the committee as he has extensive medication safety background and interest, as well as ACNL involvement. Members inquired on the status of Lynn Paulsen.

- *ACTION: Ms. Stevens will reach out to Mr. Patty regarding his potential interest and Ms. Bartleson will also email him with a request for CV and send out to committee members. Ms. Bartleson will also contact Lynn Paulsen to check on her status and continued interest in the committee. Mr. Rory Jaffe will replace Jennifer Boehne as CHPSO and HQI representative. Ms. Roth will resubmit the roster to committee members for updates.*

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the January 11, 2017, Medication Safety Committee meeting were reviewed as submitted.

IT WAS MOVED, SECONDED AND CARRIED: Ms. Susan Herman motioned to approve, seconded by Ms. Sarah Stephens.

- *ACTION: Minutes approved.*

III. OLD BUSINESS

A. Sterile Compounding Regulations Update

1. Webinar – Ms. BJ Bartleson reviewed the rationale for the upcoming webinar, "Planning, construction and Licensing Guidance Webinar". With member concerns voiced from hospital/health system facilities managers, Ms. Cheri Hummel, CHA VP for Facilities Management, worked with Ms. BJ Bartleson to plan a webinar that included OSHPD, BoP and CDPH so members could gain insight from the new process that has been designed for the state's sterile compounding construction waiver process.
   Ms. Ginny Herold asked if the webinar will be available for people to access after it is over. BoP would like it to be available after the session. Ms. BJ Bartleson stated the webinar will be available to registrants after the program via a web link. She will also check to see if the link can be made available to the BoP.

   - *ACTION – CHA will host, " Sterile Compounding Pharmacies-Planning, Construction and Licensing Guidance Webinar" on Friday, April 21, 2017, from 10am-12pm with featured speakers, Christine Acosta, PharmD, Supervising Inspector, BoP, Paul Coleman, Deputy Director, Facilities Development Division, OSPHD, Diana Scaturro, Supervisor, Rapid Review Unit, Facilities Development Division, OSHPD, and Robert Menet, PharmD, Chief Pharmaceutical Consultant, CDPH. Ms. Bartleson will check to see if the webinar link can be made available to the BoP after the event.*

2. Ms. Ginny Herold reported that 509 BoP construction waivers have been received; 213 came from hospitals; 10% of 213 hospital waivers were denied; 9% withdrawn as not needed. BoP has approved 57% and 25% are still going their way through the approval process. Ms. Gutierrez requested that CHA let hospitals know there is an appeal process if a hospital waiver has been denied. Only 47 waivers have been denied, not all of which have been hospitals.
   Ms. Shane had a question regarding sterile compounding in physicians' offices. Per Ms. Herold, nobody is enforcing regulations there and the BoP has no authority in a physician's office.

   Ms. Gutierrez asked if CHA has received any questions or concerns from hospitals regarding waivers. Ms. Bartleson advised that the only questions thus far are from hospital/health system facilities staff to Ms. Cheri Hummel, CHA VP for Facilities Management, on sterile compounding construction issues.

   - *ACTION: CHA will advise members that an appeal process is available if a waiver has been denied by BoP. Hospitals should contact Christine Acosta @* compounding.waivers@dca.ca.gov *for the appeal process.*

3. Compounding Grids 2016
   Ms. Vicky Ferraresi stated that CSHP was reconvening the compounding grids task force to update the sterile compounding grids attached. Ms. Jeanette Hanni, CHA Medication Safety Co-Chair is the representative from CHA.

   - *ACTION: The CSHP Compounding workgroup will update grids and resend to*

CHA so the new grids can be incorporated in the Medication Safety Toolkit.

4. OSHPD Sterile Compounding Pharmacies Advisory Guide – draft 2-23-17
   Ms. Bartleson discussed the Advisory Guide that is the latest draft located on the OSHPD website. This guide will be the centerpiece of the April 21st webinar.

   - *ACTION: OSHPD Advisory Guide will be highlighted during the April 21st, Sterile Compounding Webinar.*

5. Article from TJC
   Ms. Shane advised that this Medication Compounding Certification Program is being mandated in the state of Michigan, as it is piloting the certification program. According to Ms. Shane, TJC certification standards appear similar to the California sterile compounding regulations and work we are currently doing in the state. The group discussed the potential to compare the standards to avoid additional resources needed for TJC certification. Ms. Fong asked if there is any way for the group to cross compare TJC and Ca BoP sterile compounding regulations. Ms. Vicky Ferraresi and Ms. Candace Fong agreed that the CHSP workgroup updating the sterile compounding work grids could also do a cross walk with TJC standards.

   - *ACTION: CHSP Sterile Compounding workgroup to do a crosswalk between TJC sterile compounding certification standards and our present state sterile compounding regulations, in addition to updating the sterile compounding tools (grids).*

6. Guidelines on Applying for Compliance Delays During Construction – Pharmacies

   - *ACTION: Information only*

7. Inquiry Regarding USP 797

   - *ACTION: Information only*

B. Medication Safety Toolkit

Ms. Bartleson reviewed the history of the tools and the goal to distribute to the membership. It will be updated annually. Discussion ensued regarding the viability of a toolkit that may not be absolutely complete vs. something that can be used as a starting point for hospitals that need an initial guideline and reference point.

1. Medication Safety Toolkit Tracking
   This document represents the tracking manual for each tool in production for the full toolkit. Each tool will also have a revision log to track updates and revisions.

   - *ACTION: Information only*

2. Anticoagulant Tool

Mr. Ross's comment on page 73 stimulated discussions within the group on whether to add additional information now within this tool or publish as is. Ms. Stevens reiterated an earlier addition and thought that we would provide a "part 2" at a later time and if it's worth the time and effort to do it now. Ms. Bartleson reminded the committee that we would like to provide these tools for all members as soon as possible and asked what time frame would be necessary to update the tool. Ms. Stevens stated it would take approximately three months and Ms. Ghomesi agreed to assist.

- *ACTION: Ms. Stephens and Ms. Ghomeshi will update this tool – to be ready in 3 months.(July)*
- *ACTION: Ms. Shane to send additional information (grids) to support the work.*

3. Reducing Controlled Substance Diversion Tool
   Ms. Gutierrez, Ms. Shane and Ms. Fong updated this tool.
   Ms. Vidals indicated that there is no mention of reporting to Board of Nursing or other provider boards. A discussion also ensued regarding DEA rules regarding patients bringing their own controlled substances to the hospital.

   - *ACTION: Ms. Herold will send correction to information on page 82 4a regarding number of days.*
   - *Mr. Adevekian will send correction/update regarding 4c – adding Board of Nursing.*
   - *Page 87 - take out last sentence reference to patient's own medication, remove, 'Patient's own medications and"*
   - *Ms. Bartleson set deadline of 3 months for finalization of tool.*

4. Insulin Recommended Safe Practice Tool

   - *ACTION: Add information in the Nursing Administration section on barcoding – barcoding when available. Sentence on page 96 should read, "Barcode scanning of all insulin doses is required when available"*

5. ED Medication Management Safety Tool
   Ms. Shane had question about the ED pharmacist role to prioritize work. Offered to assist with tools she has developed.

   - *ACTION: Ms. Shane to send tool they use at her hospital; Ms. Hanni to review and possibly integrate. CHA will set up call between Ms. Shane and Ms. Hanni to discuss.*

6. Recommendations for Improving Safety of Opioid Use Tool
   Ms. Ferraresi initiated discussion regarding over-sedation.
   Ms. Munoz advised that HQI will have their Respiratory Monitoring toolkit done by 8/23/17. They will be asking for review by this committee.

   - *ACTION: Mr. Ross and Ms. Ferraresi to review and enhance this tool within 3 month deadline.*

7. SB 1039 Implementation
   Ms. Bartleson initiated discussion regarding the Advanced Pharmacist role. CHSP

had something on their website on this. Ms. Herold advised that this supersedes Title 22, but not many people know about it. Consensus from the committee is to keep this in the toolkit.

- *ACTION: Confirmation to include.*

8. Track and Trace Law FAQs
   Ms. Bartleson advised that Mr. O'Brien had provided this information. Do we want to add this to the toolkit?

   - *ACTION: Mr. O'Brien will review this item to make sure it is up to date for 3 month deadline.*

C. CURES

1. AB 40

   - *ACTION: Information Only*

2. SB 641

   - *ACTION: Information Only*

D. Regulations

- *ACTION: Information Only*

IV. NEWBUSINESS

A. Legislation

1. 2017 Legislation

2. AB 401 - Telepharmacy – Cardinal Health and CPHA (sponsors) – allows for patient consultation via Skype. It would allow a ratio of 1 pharmacist: to 6 pharmacy technicians, with 4 not within line of sight. Techs would be dispensing medications with telephonic supervision. North Dakota was the first state to do this and codified it. Discussion with regard to what problem this bill is trying to fix as there is no shortage of pharmacists. Concern was expressed regarding the ratio. Bill has made it out of committee, 14-0

3. AB 602 - Diabetic devices – no thoughts expressed on this bill.

4. AB1048 – Ms. Rogers discussed the one component of the bill, partial refill and how it would affect pharmacists and the operational issues surrounding partial refills with payment and insurance.

5. AB1589 - Pharm techs – this bill would allow the BoP to review the ratio on biennial basis. Ms. DeMartini reported that her group is keeping their eye on this

bill.

6. SB 315 - This was a spot bill which has now changed. It currently does not have anything to do with pharmacy.

7. SB 351 – see BoP report below.

8. SB 443

9. SB 510

10. SB 528

11. SB 716 - CSHP is asking CHA support on this bill.

12. SB 790 – Ms. Rogers reported that this bill will regulate sponsors for conferences, etc. – for example manufacturers of medical devices. Ms. Roth to send copy of this bill out to committee members after the meeting.

    - *ACTION: Ms. Roth to send out copy of bill to committee members for their review.*

B. HQI Update

- *ACTION: no update*

V. STANDING REPORTS

A. Board of Pharmacy (BoP)

Ms. Herold reported they are sponsoring 4 bills this year. They are listed below.

SB 443 – This ambulance bill would allow public fire departments to establish a location for a Pyxis station with inventory of drugs for restocking ambulances. A pharmacist or physician would oversee the dispensing.

SB 351 – This bill allows hospitals to have an additional hospital pharmacy permit outside of the main building facility, as long as it is under the hospital license and is treating hospital patients.

SB 510 – This bill would repeal 4127.7 BoP regulation mandating specific environmental components.

SB 752 - Allows additional licensure category of reverse distributors for waste management and disposal of drugs.

ACTION: Information only

B. CDPH

Mr. Woo/Mr. Christensen reported that they will be covering the waiver process in the upcoming webinar.

- *ACTION: information only*

C. CSHP

Ms. DeMartini – SB716 – This bill would add a Pharmacy Tech to the BoP as a board member. There has been no change in Pharm Tech specifications since 2002. This is a growing area and they want to add legitimacy and education. They are seeking to increase programs for Pharm Techs. Ms. DeMartini requested CHA support on the bill.

- *ACTION: Information only*

D. CALNOC – no report

Ms. Foley –

E. ACNL – no report

F. CHPSO - no report

G. CAHF - no report

VIII. WORKGROUP REPORTS –

A. Nursing Sterile Compounding

Bartleson/Herman/Nolan: This workgroup is seeking more clarification and will work with Janette Wackerly of the BRN. The purpose at this point is to cross reference present regulations.

- *ACTION: Discuss with Janette at BRN. Continue to research and report back to the committee.*

B. Medication Reconciliation

Ms. Shane kicked off the discussion and stated problems occur when the medication history being entered into the record by a medical assistant. The information may not be accurate, primarily due to lack of knowledge. Incorrect or incomplete medication history results in higher rates of readmission. There is a significant increase in accuracy if a pharm tech takes the medication history. High risk patients are most vulnerable to this. It is vitally important to have an accurate medication list.

Ms. Shane reported that the goal is for pharmacists to own this process as they are the best profession to ensure safety and accuracy. Ideally this needs to be in the regulations. There is also a need for a discharge pharmacist to reevaluate medications for continuity of care when the patient leaves.

Ms. Munoz reported that Mr. Jaffe just had study done regarding medication

reporting problems. Information is available on the CHPSO data base.

Ms. Bartleson asked that the committee work on what regulations would be changed. After identification there should be discussion with various groups such as CDPH and CMS, etc. Internal discussions as to how this would affect everybody.

- *ACTION: Task force created: Fong, DeMartini, Shane and Herold. Research and report back to the committee. CHA will set up the meeting.*

IX. NEXT MEETING

Wednesday, July 5, 2017

XI. ADJOURNMENT

Having no further business, the committee adjourned at 1:34 PM

CHA Medication Safety Committee Action List – 4/5/17 meeting

A lot of information was covered during the Medication Safety Committee last week. I thought it would be a good idea to send this update so that everyone is aware of the various **ACTION** items between now and our next meeting on July 6. Please review and contact us if you have any questions.

CHA:

- Advise members of appeal process available from BoP if a waiver has been denied;
- Highlight OSHPD Advisory Guide during the upcoming Sterile Compounding Webinar

CSHP:

- Compounding workgroup to update grids and resend to CHA to be incorporated into the Medication Safety Toolkit
- Sterile Compounding workgroup to do a crosswalk between TJC sterile compounding certification standards and our present state sterile compounding regulations, in addition to updating the grids.

Sarah Stephens and Kathy Ghomeshi:

- Update the Anticoagulant Tool for the toolkit (to be ready in 3 months) - Rita Shane to send additional information (grids) to support the work. DONE

Virginia Herold:

- Send correction to information on page 82 4a regarding number of days in the Reducing Controlled Substances Diversion Tool - DONE
- See task force info below

Eddie Avedikian:

- Send correction/update regarding 4c – adding Board of Nursing to the Reducing Controlled Substances Diversion Tool - DONE
- Take out last sentence referencing a patient's own medication, remove "patient's own medications and" DONE

Rita Shane:

- Send additional information (grids) to support work for the Anticoagulant Tool - DONE
- Send tool used at her hospital for the ED Medication Management Safety Tool to Jeannette Hanni - DONE
- See task force info below

Jeannette Hanni:

- Review and possibly integrate the information from Rita Shane to the ED Medication Management Safety Tool

Dan Ross and Vicky Ferraresi:

- Review and enhance the Recommendations for Improving Safety of Opioid Use Tool

Doug O'Brien:

- Review the Track and Trace Law FAQs to make sure it is up to date - DONE

BJ Bartleson:

- Contact Chris Patty for possible addition to committee; - DONE

- Discuss Nursing Sterile Compounding with Janette Wackerly of BRN. Continue to research and report back to committee.

Candace Fong, Loriann DeMartini, Rita Shane and Virginia Herold:

- Task Force created for Medication Reconciliation created. Research and report back to committee. – Started

Barb Roth:

- Send copy of roster to committee members for updates; DONE
- Send copy of SB 790 for review DONE
- Set up meeting/call for the Medication Reconciliation Task Force DONE
- Set up call for BJ Bartleson, Rita Shane and Jeannette Hanni to discuss possible updates to the ED Medication Management Safety Tool

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Sterile Compounding Regulations Update

DISCUSSION

Waiver and waiver renewals.

ACTION REQUESTED

- Discussion

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 5, 2017

TO: CHA Medication Safety Committee

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

SUBJECT: CHA MEDICATION SAFETY TOOLKIT MANUAL

CHA's Medication Safety Committee has produced outstanding medication safety tools that now include the six original tools, and the four sterile compounding grids. In order to produce the manual, the tools should be painstakingly accurate. We also need to determine if anything else needs to be added at this time.

ACTION REQUESTED

- *Review and discuss outstanding tools to be finalized.*
- *Add updated tools (ie: Track and Trace)*

DISCUSSION QUESTIONS:

1. Are there any other tools that need to be added, such as FAQ's for Track and Trace, and or Sterile Compounding?
2. How will annual updates be distributed for review amongst members?

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	
12	Track and Trace Law FAQs	MS Cmte		6/28					

Section	Chapter Title	Author	Due Date	Rcv Docs	Review thru BJ	Review thru Pubs	Comments	Status	Final thru Pubs
13	Nursing Sterile Compounding	BJ							

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Tool

Anticoagulation Guidelines for Direct Oral Anticoagulants (DOACs) - Part 2

Anticoagulation Guidelines for Commonly Used Anticoagulants in the Inpatient Setting - Part 1 (Under Separate Cover)

1215 K Street, Suite 800, Sacramento, CA 95814 • *Telephone:* 916.443.7401 • *Facsimile:* 916.552.7596 • www.calhospital.org

Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

TABLE OF CONTENTS

REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
1.0	7/2017	Sarah Stephens, Kathy Ghomeshi provide rough draft for Committee Review
2.0		
3.0		
4.0		
5.0		

CHA Medication Safety Committee and Medication Safety Tool

INTRODUCTION

The tools contained herein have been reviewed by the California Hospital Association's Medication Safety Committee, and are intended for hospital and health care providers for consideration as they evaluate current practices and develop specific programs**. These tools are not fixed protocols that must be followed, nor are they entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results.** The CHA Medication Safety Committee is a voluntary collaborative supported by the California Hospital Association, and is comprised of CHA member hospitals and non-hospital representatives, which include the Association of California Nurse Leaders, California Association of Health Facilities, California Board of Pharmacy, California Correctional Health Care Services, California Department of Public Health, California Hospital Patient Safety Organization, California Society of Health System Pharmacists, and the Collaborative Alliance for Nursing Outcomes.

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel.

COMMITTEE REPRESENTATION

The committee includes nurse, physician, and pharmacist representatives from:

- Association of California Nurse Leaders (ACNL)
- California Association of Health Facilities (CAHF)
- California Board of Pharmacy
- California Correctional Health Care Services (CDCR)
- California Department of Public Health (CDPH)
- California Hospital Patient Safety Organization (CHPSO)
- California Society of Health-System Pharmacists (CSHP)
- Collaborative Alliance for Nursing Outcomes (CALNOC)

This document is a continuation of Part 1 published under a separate cover. This tool is intended to guide acute care facilities in the safe use of DOACs in the inpatient setting. The DOACs included in this guideline are apixaban, dabigatran, edoxaban, and rivaroxaban. The tool is set up with the standard steps in the medication use process, as medication safety includes all aspects of medication use from the acquisition stage to ongoing monitoring. The standard steps in the medication process are outlined on the left side of the page and the DOACs listed horizontally with each standard step in the medication process along with corresponding actions to consider under each drug, and common considerations listed for all drugs in the specific section. A "Resource Tools" section is listed at the end of the document to assist with an organizational self-assessment of practices relating to DOAC use.

Step	Actions to Consider To Increase Medication Safety			
Pharmacy Purchasing, Storage and Product Labeling	**Apixaban**	**Dabigatran**	**Edoxaban**	**Rivaroxaban**
	• Consider addition to Look-Alike/Sound-Alike list (apixaban and axitinib)	• Consider addition to Look-Alike/Sound-Alike list (Pradaxa and Plavix) • Dispense and store in original blister package or manufacturer's bottle to protect from moisture. o Discard bottle 4 months after opening original container		
	Common considerations • Limit inpatient formulary where possible • Consider high alert medication labeling to distinguish products and/or segregate products where feasible • Separate product from look-alike/sound-alike medications			
Patient Care Unit Storage	**Apixaban**	**Dabigatran**	**Edoxaban**	**Rivaroxaban**
	Common considerations • If providing unit stock, do so in automated dispensing cabinets (ADCs) • Stock in automated dispensing cabinets that are interfaced with the pharmacy system to enable pharmacy review prior to removal (not available via override feature). • Employ additional verification measures in procedure areas if ADCs are not interfaced with the pharmacy system			

	Apixaban	Dabigatran	Edoxaban	Rivaroxaban
Prescribing	• Identify and include indication for use and duration at that dose (some indications require dose change during use) • Review clinical indication, patient age, weight, and renal function to determine if renal dosage adjustment is necessary • Drug interactions: Consider dosage adjustment for drug-drug interactions with strong CYP3A4 inhibitors and P-glycoproteins • Not recommended for use in severe hepatic impairment (Child-Pugh class C) • Not recommended for use in patients with body mass index (BMI) greater than 40 kg/m^2 or weight greater than 120 kg due to lack of clinical data. If used, consider monitoring peak and trough anti-factor Xa levels. • Body weight less than 50 kg may warrant dose reduction due to increased systemic exposure	• Consider age as a factor; Beers Criteria potentially inappropriate in patients age 75 and older • Review clinical indication, patient age, weight, concomitant therapy, and renal function to determine if renal dosage adjustment is necessary • Drug interactions: avoid use with P-glycoprotein inducers (eg, rifampin); avoid use with P-glycoprotein inhibitors based on indication for use and CrCl	• Review clinical indication and renal function to determine appropriate dose • *Do NOT use in patients with CrCl GREATER THAN 95 mL/min due to reduced efficacy* • Not recommended in moderate to severe hepatic impairment (Child-Pugh B or C) • Not recommended in patients with mechanical heart valves or moderate to severe mitral stenosis • Drug interactions: Avoid use with P-glycoprotein inducers (eg, rifampin)	• Identify and include indication for use and duration at that dose (some indications require dose change during use) • Consider age as a factor; Beers Criteria potentially inappropriate in older adults • Review clinical indication and renal function to determine appropriate dose • Avoid use in older adults with CrCl less than 30 mL/min • Not recommended in patients with prosthetic heart valves • Drug interactions: avoid use with P-glycoprotein and strong CYP3A4 inducers or HIV protease inhibitors • Not recommended in moderate to severe hepatic impairment (Child-Pugh B or C) or hepatic coagulopathy

Common considerations:

- Avoid duplicate therapy with other anticoagulants (eg, deep vein thrombosis prophylaxis or therapeutic anticoagulation) utilizing system hard stops or warnings that require an override reason
- Consider a thrombosis service or pharmacy consult and/or review for all patients prescribed a DOAC. Indications, drug interactions, dosing considerations for renal and hepatic dysfunction, and special population considerations are required and different for all agents.
- Require indications for all DOAC prescriptions
- Have standardized protocols and/or coupled order sets in place that permit the emergency administration of all appropriate antidotes, reversal agents, and rescue agents for emergency bleeding caused by DOACs
- Create institutional guidelines to support transitioning between agents, heparin products, and perioperative management of anticoagulation
- US Boxed Warning for spinal/epidural hematoma: Use with caution in patients receiving neuraxial anesthesia or undergoing spinal puncture due to increased risk of spinal or epidural hematoma; do not remove indwelling catheters sooner than 12 hours after the last dose and wait 2 hours after catheter removal before administering. Implement system warnings where possible to alert prescribers of this risk in applicable patients
- US Boxed Warning for discontinuation: Premature discontinuation of any oral anticoagulant increases the risk of thrombotic events. If anticoagulation is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- Update guidelines/order sets to reflect current evidence based practice e.g. CHEST, ACC, AHA, etc.
- Implement a standardized assessment of bleeding risk (eg, HAS-BLED score) to help ensure minimization of risk
- Obtain a baseline serum creatinine and a complete blood count prior to initiating therapy
- Include ongoing lab monitoring in order sets and policies/protocols
- Include reminders on protocols, order forms and CPOE system to avoid concomitant use of anticoagulants, or to discontinue other anticoagulants, as appropriate
- Maintain a list of error-prone abbreviations that are not permitted.
- Establish a procedure for 'hold' orders
- Verify a patient's home medication regimen utilizing at least two sources and reconcile anticoagulants upon admission, transfer and discharge

Pharmacist Order Entry Process

Apixaban	Dabigatran	Edoxaban	Rivaroxaban

Common considerations:

- Use height and weight in metric units in pharmacy computer systems
- Create pharmacy system alerts for therapy with other anticoagulants (eg, deep vein thrombosis prophylaxis or therapeutic anticoagulation) utilizing system hard stops or warnings that require an override reason. Provide dose range alerts for over/under dosing as applicable.
- One time doses administered in the ED or procedure settings should be entered in the pharmacy system to prevent dose duplication

	• Pharmacist should validate baseline labs and medication histories for patients taking DOACs prior to admission • Employ a pharmacist-led anticoagulation dosing service for all anticoagulants

Pharmacy Dispensing	Apixaban	Dabigatran	Edoxaban	Rivaroxaban
	Common considerations • Use machine readable bar coding for verification prior to dispensing from the pharmacy for refill of automated dispensing cabinets or for single patient use • Consider high alert medication labeling to distinguish products			

Administration	Apixaban	Dabigatran	Edoxaban	Rivaroxaban
	• Consider timing of initial dose after hip/knee replacement or other surgery/procedure • Use caution in patients who consume grapefruit juice during therapy due to potential increase in levels/effects	• Administer with full glass of water. Do not break, chew, or open capsules, as this will lead to 75% increase in absorption. • Consider ADC and/or BCMA warning to avoid crushing or opening capsules	• May be administered with or without food	• 10 mg dose may be taken with our without food • 15 mg and 20 mg tablets should be taken with food at approximately the same time each day • Product may be crushed; intragastric administration instructions are available
	Common considerations • Have standardized protocols and/or coupled order sets in place that permit the emergency administration of all appropriate antidotes, reversal agents, and rescue agents for emergency bleeding caused by DOACs • List specific interventions or treatments that are to be avoided (e.g. neuraxial anesthesia) on pharmacy and medication administration records			

d c a t	Apixaban	Dabigatran	Edoxaban	Rivaroxaban

Common considerations

- Consider initial training and baseline competency evaluation for all practitioners who prescribe, dispense and/or monitor therapy (including physicians, nursing, and pharmacy)
- Include anticoagulants as part of the institutional high alert medication policy and educate staff on risk reduction strategies that are employed to improve safety
- Share information about error-prone situations and errors within and outside the facility with practitioners on an ongoing basis
- For inpatients, provide education about antithrombotics at initiation of therapy; aim to provide most of the information about after discharge therapy well before discharge
- Provide pharmacist-delivered patient education prior to discharge

Monitoring

Apixaban	Dabigatran	Edoxaban	Rivaroxaban
• Routine monitoring of coagulation tests is not required • Anti-Ca level may be helpful in guiding clinical decisions	• Routine monitoring of coagulation tests is not required • Reversal agent available: idarucizumab (Praxbind) • Routine monitoring of coagulation tests not required • Activated partial thromboplasting time (aPTT), escarin clotting test (ECT), or thrombin time (TT) bay be useful for presence of dabigatran and level of coagulopathy • CBC with differential	• Routine monitoring of coagulation tests is not required • No antidote available to reverse agent • Anti-Xa activity reliable for assessing below and on-therapy drug levels, but not for excess drug levels • Normal prothrombin time may rule out excess drug levels	• No antidote available to reverse agent • No therapeutic lab monitoring is established • Prothrombin complex concentrates may cause partial reversal of prolonged prothrombin time

Common Considerations

- Primary monitoring criteria for all DOACs are improvement in symptoms or a reduction in recurrence of thrombosis and signs/symptoms of bleeding. Renal function is also monitored closely to ensure appropriate dosing.
- Implement a protocol or guideline for monitoring and/or discontinuing therapy prior to invasive procedures
- Implement order sets to guide reversal agent dosing and administration and supportive care
- Include alerts on pharmacy order entry screens, automated dispensing cabinets, protocols/pathways to review medications the patient has received in the last 24hrs (including in ED) to ensure that an adequate time has lapsed between doses
- Report critical values to the responsible caregiver within the facility identified time frame
- Enhance detection of potential adverse events by interfacing pharmacy and lab systems and incorporating alerts to the pharmacy system for selected values of lab tests (e.g. percentage reduction in hemoglobin/hematocrit, changes in renal function requiring dose adjustment)

<table>
<tr><td></td><td>

- Monitor patients for fall risk and notify physician immediately post fall

</td></tr>
<tr><td>Other</td><td>

Apixaban	Dabigatran	Edoxaban	Rivaroxaban

Common considerations:

- Avoid use of the term NOAC (novel oral anticoagulants) to refer to these agents; this abbreviation has been misinterpreted as “no anticoagulation” resulting in omission of therapy.

</td></tr>
<tr><td>Transitions of Care</td><td>

Apixaban	Dabigatran	Edoxaban	Rivaroxaban

Common Considerations

- Provide education on the importance of vigilant adherence with anticoagulation therapy
- Utilize a concierge medication service to ensure a new prescription is filled and provided to the patient at the time of discharge if possible
- Facilitate a confirmed appointment for follow-up prior to discharge from the hospital. Stress the importance of making and keeping follow up appointments.
- Prior to discharge, collaborate with case managers and social workers to identify and address barriers for adherence to medication therapy e.g. insurance coverage, prescription affordability, access and transportation for physician appointments, support in post discharge setting
- For dispensing of discharge prescriptions, provide patient FDA Medication Guide, available at https://www.fda.gov/Drugs/DrugSafety/ucm085729.htm
- Collaborate with long term care providers and community based organizations who can provide follow up visits or phone calls to encourage medication adherence

</td></tr>
<tr><td>Resource tools</td><td>

- 2017 ISMP Medication Safety Self Assessment for Antithrombotic Therapy http://www.ismp.org/selfassessments/Antithrombotic/2017/Default.aspx
- Direct Oral Anticoagulants Resources for Managing and Reversing Therapy http://www.doacresources.org/resources
- ASHP Anticoagulation Resource Center http://www.ashp.org/anticoagulation
- ISMP - Sample Failure Mode and Effects Analysis for Anticoagulants http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf
- The Joint Commission Sentinel Event Alert, Issue 41: Preventing errors relating to commonly used anticoagulants https://www.jointcommission.org/assets/1/18/SEA_41.PDF

</td></tr>
</table>

TRACK & TRACE

June 1st, 2017

DOCUMENT GUIDELINES:	
PURPOSE:	PROVIDING "FREQUENTLY ASKED QUESTIONS" (FAQ) AND ANSWERS REGARDING NEW FEDERAL TRACK & TRACE LAW.
ATTENTION:	THIS DOCUMENT SHOULD BE DISTRIBUTED TO ALL EMPLOYEES WHO PROCURE, RECEIVE & HANDLE PHARMACEUTICAL PRODUCTS.
TABLE OF CONTENTS:	

Section 1: Brief History & Overview

A. What is Track and Trace?

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

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

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

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

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

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

D. When does Track and Trace law take effect?

DSCSA law also went into effect for all Dispensers (aka - Pharmacies) on July 1st, 2015.

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

Please populate with your facility/organization-specific information

Section 2: Policies and Procedures

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

Please populate with your facility/organization-specific information

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

Section 3: Training Requirements

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

Please populate with your facility/organization-specific information

Section 4: Track and Trace Support

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

Please populate with your facility/organization-specific information

Section 5: Long-Term Solutioning

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

Please populate with your facility/organization-specific information

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

Section 6: More Frequently Asked Questions:

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

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

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

Secondly, Track and Trace is Federal law.

Q2: What is an "authorized trading partner?"

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

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

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

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

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

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

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

Q5: Do all drugs require 3T information?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Medication Reconciliation

SUMMARY

Information provided by: Robert Menet, Pharm.D.
Chief Pharmaceutical Consultant, CDPH

In response to your request, "The group would like to explore regulatory changes and want to have all the present state regulations and JC standards to begin the process. Would you be able to identify those for us?" I've not been engaged in any of these medication reconciliation discussions you've been having so I'm not exactly sure what is being championed here.

I know the Joint Commission (JC) has recognized the importance of medication reconciliation for some time (2005) through several iterations of its National Patient Safety Goals (NPSGs) – there is one . However, since we do not survey to or enforce the JC standards we do not have access to any of their materials. Candace Fong or Rita Shane are best positioned to help you in this regard.

The American Society of Health-System Pharmacists (ASHP) issued a statement on the pharmacists' role in medication reconciliation in 2012 – it addresses such a role across the health care continuum. I'm not aware of any other "Position Statement" by this organization. Loriann De Martini should be able to point you in the right direction.

As to L&C, CCR, Title 22 is silent wherein medication reconciliation is concerned. Broadly speaking, however, potential regulations which may be applicable could include (highlighting for emphasis added):

70263 Pharmaceutical Services

(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or his or her representative and the administrator or his or her representative.
(1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures.

Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate.

70701. Governing Body
a) The governing body shall:
(1) Adopt written bylaws in accordance with legal requirements and its community responsibility which shall include but not be limited to provision for:
(G) Preparation and maintenance of a complete and accurate medical record for each patient.

For comparison, federally (42 CFR Appendix A) we have (highlighting added):

A-0489
§482.25 Condition of Participation: Pharmaceutical Services.
The hospital must have pharmaceutical services that meet the needs of the patients. The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

A-0837
§482.43(d) Standard: Transfer or Referral
The hospital must transfer or refer patients, along with necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care.

Interpretive Guidelines §482.43(d)
The hospital must take steps to ensure that patients receive appropriate post-hospital care by arranging, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services.

"Appropriate facilities, agencies, or outpatient services" refers to entities such as skilled nursing facilities, nursing facilities, home health agencies, hospice agencies, mental health agencies, dialysis centers, suppliers of durable medical equipment, suppliers of physical and occupational therapy, physician offices, etc. which offer post-acute care services that address the patient's post-hospital needs identified in the patient's discharge planning evaluation. The term does not refer to non-healthcare entities,

Necessary medical information must be provided not only for patients being transferred, but also for those being discharged home, to make the patient's physician aware of the outcome of hospital treatment or follow-up care needs.

The "medical information" that is necessary for the transfer or referral includes, but is not limited to:

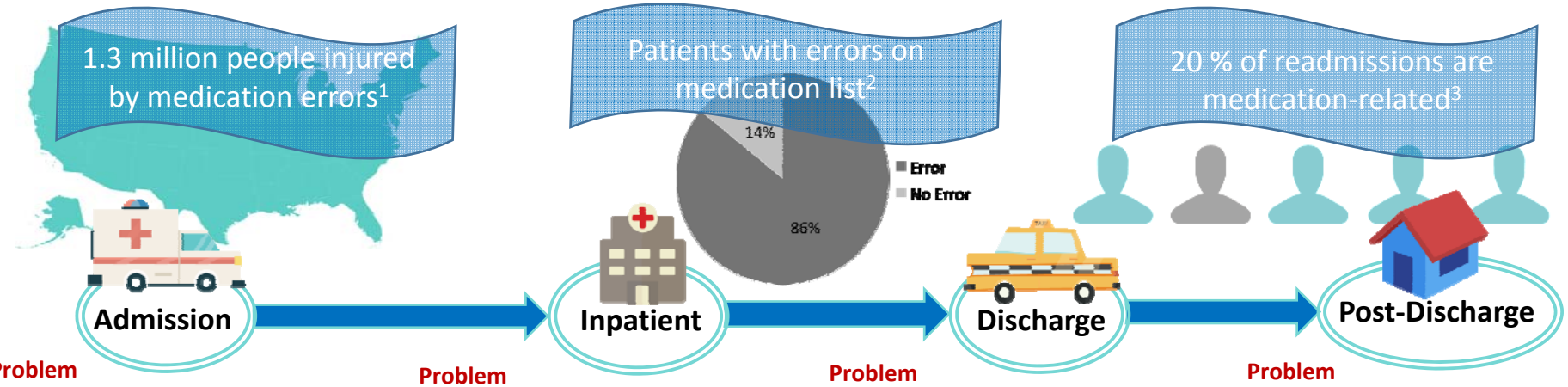
Medication list (reconciled to identify changes made during the patient's hospitalization) including prescription and over-the-counter medications and herbal [supplements]. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available somewhere else in the medical record.)

ACTION REQUESTED

-

Safe Medication Transitions:

Evidence-Based Solutions



Problem

- 1 in 5 Hospitalizations are the result of treatment complications, of which, 1/2 are medication related[4]
- 7.4 errors per medication list[5]

Evidence

- 20.3% of pharmacist medication histories had at least 1 postoperative medication discrepancy related to home medications compared to 40.2% of the nurse-conducted medication histories[9]
- Pharmacist-conducted medication reconciliations resulted in 16% reduction in all visits to the hospital and a 47% reduction in visits to the emergency department. Drug–related readmissions were reduced by 80%[14]

Problem

- During hospitalization, medication errors occur in up to 75% of patients[6]
- Over 1/3 of hospitalized patients had medication order errors - 85% originated with the medication history[7]

Evidence

- Geriatric patients who had a pharmacist involved in patient care rounds saw a reduction in number of medications by day 3. [15]
- Pharmacists reduced dosing times for 89% of patients, number of medications for 17%, and made additional recommendations for 33% of patients throughout the course of the admission.[25]

Problem

- More medications at discharge results in a higher rate of readmission[8]
- 14% - 80% of patients have at least one medication list discrepancy upon leaving the hospital[9]

Evidence

- Pharmacists identified preventable ADEs in 1% of patients who received discharge education and follow up compared with 11% of patients who did not receive these benefits.[16]
- Discharge medication lists completed by pharmacists resulted in an absolute risk reduction of 46.5% when compared to usual care.[17]

Problem

- Post-discharge adverse drug events occur in up to 19% of patients, of which one-third are preventable[10]
- Up to 90% of hospital-to-SNF discharge summaries contained one or more DRPs[11,12,13]

Evidence

- Post-discharge pharmacist follow up with discharge education reduced readmissions and ED visits vs usual care (39% to 24.8%).[18]
- Post-discharge pharmacist reconciliation and education reduced readmissions and ED visits vs usual care (0% vs 40.5%).[19]
- Post-discharge pharmacist follow up can reduce readmission from skilled nursing facility by 25%. [20]

Safe Medication Transitions:Evidence-Based Solutions

A significant number of errors are found on medication lists which results in errors during hospital admissions and adverse outcomes post-discharge including ED visits and readmissions. Evidence supports that pharmacists and trained technicians reduce these errors and adverse outcomes.

Pharmacist

- A study comparing medication reconciliation performed by pharmacists to ED providers found that pharmacists identified 1096 home medications compared with 817 home medications identified by ED providers. 78% of medications documented by ED providers were incomplete and were supplemented with information by the pharmacists.[21]
- Patients who received pharmacist medication reconciliation and counseling had a readmission rate of 16.8% vs the usual care arm of 26% (p=0.006).[24]
- In a randomized trial, pharmacists provided medication counseling, reconciliation at admission and discharge, and a follow up phone call after discharge as part of a care coordination bundle. Patients in the intervention arm had a reduction in 30 day readmissions (10% vs 38.1%, p=0.04) and time to first readmission or ED visit (36.2 days vs 15.7 days, p=0.05).[27]
- Another study found that patients who received discharge medications and follow up phone calls by pharmacists had nearly half the risk of readmission as those who did not receive a pharmacist phone call (5.0% vs 9.5%, p<0.05).[25]

Pharmacy Technician

- In the ED, a pre-post study found that pharmacy technicians created an accurate medication history 88% of the time compared to 57% of the time when nurses completed the history (p<0.0001).[22] Nurses were 7.5 times as likely to make an error than pharmacy technicians (p<0.0001).
- Another study found that nurses created an accurate medication list only 14% of the time compared to pharmacy technicians who created an accurate list 94.4% of the time (p<0.0001).[23]
- A randomized controlled study to evaluate the accuracy of admitting medication histories performed by pharmacists, pharmacist-supervised pharmacy technicians (PSPTs) and usual care (nurses, physicians) demonstrated a statistically significant reduction in admitting medication history errors performed by pharmacists and PSPTs vs usual care(p<0.0001). There was also a significant reduction in the severity of errors intercepted (p<0.0001).[5]

Recommendation: For high risk patients, pharmacy staff will ensure the accuracy of the medication list at admission and discharge

References

1.Center for Drug Evaluation and Research. (2016, October 10). Medication Errors - Medication Error Reports. Retrieved April 18, 2017, from https://www.fda.gov/Drugs/DrugSafety/MedicationErrors/ucm080629.htm

2.Tam VC, Knowles SR, Cornish PL, et al. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. *Canadian Medical Association Journal.* 2005; 173(5):510-5.

3.Angamo MT, Leanne C, Curtain CM, et al. Adverse-Drug-Reaction-Related Hospitalisations in Developed and Developing Countries: A Review of Prevalence and Contributing Factors. *Drug Safety*. 2016;39(9): 847-57.

4.Magdelijns FJH, Pijpers E, Rouhl RPW, et al. Acute Hospital Admissions Because of Health Care-Related Adverse Events: A Retrospective Study of 5 Specialist Departments. *J Am Med Dir Assoc*. 2015;16(12):1055-1061. doi:10.1016/j.jamda.2015.06.019.

5.Pevnick JM, Nguyen CB, Jackevicius CA, Palmer KA, Shane R, Bresee C, Bear ME, Zaitseva O, Seki D, Desai A, Doyle B, Bell DS. Minimizing Medication Histories Errors for Patients Admitted to the Hospital Through the Emergency Department: A Three-Arm Pragmatic Randomized Controlled Trial of Adding Admission Medication History Interviews by Pharmacists or Pharmacist-Supervised Pharmacy Technicians to Usual Care. J Patient-Centered Res Rev.2015;2:93

6.Lewis PJ, Dornan T, Taylor D, Tully MP, Wass V, Ashcroft DM. Prevalence, incidence and nature of prescribing errors in hospital inpatients: a systematic review. Drug Saf. 2009;32(5):379-389. http://www.ncbi.nlm.nih.gov/pubmed/19419233. Accessed January 17, 2017.

7.Gleason KM, McDaniel MR, Feinglass J, et al. Results of the medications at transitions and clinical handoffs (MATCH) study: an analysis of medication reconciliation errors and risk factors at hospital admission. J Gen Intern Med 2010;25:441–7.

8.Salvi F, Marchetti A, D'Angelo F, Boemi M, Lattanzio F, Cherubini A. Adverse Drug Events as a Cause of Hospitalization in Older Adults. Drug Saf. 2012;35(S1):29-45. doi:10.1007/BF03319101.

9.Kwan JL, Lo L, Sampson M, Shojania KG. Medication Reconciliation During Transitions of Care as a Patient Safety Strategy. *Ann Intern Med*. 2013;158(5_Part_2):397. doi:10.7326/0003-4819-158-5-201303051-00006.

10.Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. Adverse drug events occurring following hospital discharge. J Gen Intern Med. 2005;20(4):317-323. doi:10.1111/j.1525-1497.2005.30390.x

11.. Tjia J, Bonner A, Briesacher BA, McGee S, Terrill E, Miller K. Medication discrepancies upon hospital to skilled nursing facility transitions. J Gen Intern Med. 2009;24(5):630e635

12. Kerstenetsky L, Birschbach MJ, Beach KF, Hager DR, Kennelty KA. Improving medication information transfer between hospitals, skilled-nursing facilities, and long-term-care pharmacies for hospital discharge transitions of care: A targeted needs assessment using the Intervention Mapping framework. Res Social Adm Pharm. 2017 Apr 7. pii: S1551-7411(16)30374-6. doi: 10.1016/j.sapharm.2016.12.013.

13.McGaw J, Conner DA, Delate TM, Chester EA, Barnes CA. A multidisciplinary approach to transition care: a patient safety innovation study. Perm J. 2007 Fall;11(4):4-9.

14.Gillespie U, Alassaad A, Henrohn D, et al. A comprehensive pharmacist intervention to reduce morbidity in patients 80 years or older: a randomized controlled trial. *Arch Intern Med.* 2009;169(9):894-900.

15.Kaboli PJ, Hoth AB, McClimon BJ, Schnipper JL. Clinical Pharmacists and Inpatient Medical CareA Systematic Review. *Arch Intern Med.* 2006;166(9):955-964. doi:10.1001/archinte.166.9.955

16.Schnipper JL, Kirwin JL, Cotugno MC, Wahlstrom SA, Brown BA, Tarvin E, Kachalia A, Horng M, Roy CL, McKean SC, Bates DW. Role of Pharmacist Counseling in Preventing Adverse Drug Events After Hospitalization. *Arch Intern Med.* 2006;166(5):565-571. doi:10.1001/archinte.166.5.565

17.Tong, E. Y., Roman, C. P., Mitra, B., Yip, G. S., Gibbs, H., Newnham, H. H., … Dooley, M. J. (2017). Reducing medication errors in hospital discharge summaries: a randomised controlled trial. *The Medical Journal of Australia*, *206*(1), 36–39. http://doi.org/10.5694/mja16.00628

18.Phatak A, Prusi R, Ward B, Hansen LO, Williams MV, Vetter E, Chapman N, Postelnick M, Pharmacist Impact on Transitional Care. *J. Hosp. Med* 2016;1;39-44. doi:10.1002/jhm.2493

19.Hawes, E. M., Maxwell, W. D., White, S. F., Mangun, J., & Lin, F. C. (2014). Impact of an outpatient pharmacist intervention on medication discrepancies and health care resource utilization in posthospitalization care transitions. *Journal of primary care & community health*, *5*(1), 14-18. DOI: 10.1177/2150131913502489

20.Rosen B, Nguyen C, Hart K, Shane R. Mitigating the Risks of Adverse Medication Events During Care Transitions from Hospital to Skilled Nursing Facilities [abstract]. Journal of Hospital Medicine. 2014; 9 (suppl 2). http://www.shmabstracts.com/abstract/mitigating-the-risks-of-adverse-medication-events-during-care-transitions-from-hospital-to-skilled-nursing-facilities/. Accessed May 9, 2017.

21.Carter MK, Allin DM, Scott LA, Grauer D. Pharmacist-acquired medication histories in a university hospital emergency department. *Am J Health-Syst Pharm*. 2006; 63:2500-2503.

22.Hart C, Price C, Grazioe G, Grey J. A program using pharmacy technicians to collect medication histories in the emergency department. P T. 2015; 40(1): 56-61.

23.Markovic M, Mathis AS, Ghin HL, Gardiner M, Fahim G. A Comparison of Medication Histories Obtained by a Pharmacy Technician Versus Nurses in the Emergency Department. P T. 2017; 42(1):41-46.

24.Pal A, Babbott S, Wilkinson ST. Can the targeted use of a discharge pharmacist significantly decrease 30-day readmissions? Hosp Pharm 2013;48:380–8

25.Kirkham, H. S., Clark, B. L., Paynter, J., Lewis, G. H., & Duncan, I. (2014). The effect of a collaborative pharmacist–hospital care transition program on the likelihood of 30-day readmission. American Journal of Health-System Pharmacy, 71(9). Retrieved from http://www.ajhp.org/content/71/9/739.long

26.Calabrese, A. T., Cholka, K., Lenhart, S. E., McCarty, B., Zewe, G., Sunseri, D., … Kapoor, W. (2003). Pharmacist involvement in a multidisciplinary inpatient medication education program. *Am J Health-Syst Pharm—Vol*, *60*, 1012–1018. Retrieved from http://www.ajhp.org/content/ajhp/60/10/1012.full.pdf

27.Koehler BE, Richter KM, Youngblood L et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4:211–18.

VIEWPOINT

Beyond Medication Reconciliation
The Correct Medication List

Adam J. Rose, MD, MSc
RAND Corporation, Boston, Massachusetts; and Section of General Internal Medicine, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

Shira H. Fischer, MD, PhD
RAND Corporation, Boston, Massachusetts.

Michael K. Paasche-Orlow, MD, MPH
Section of General Internal Medicine, Department of Medicine, Boston University School of Medicine, Boston, Massachusetts.

Medication reconciliation is a major focus of quality measurement activities, and according to The Joint Commission, primary care clinicians are expected to reconcile a patient's medications at every visit.[1] In principle, medication reconciliation is quite important; in practice, however, it has failed to have a demonstrable effect on patient outcomes. This may partly be because the lack of agreement about what constitutes medication reconciliation makes it difficult to decide when it has occurred and therefore difficult to study its effect.

Medication reconciliation is sometimes defined as the comparison of medication lists at admission or discharge, and is sometimes defined more broadly to include information from the patient. However, these concepts set the bar too low: What is needed is not merely a reconciled list, but the correct medication list. Achieving this list would involve multiple levels of reconciliation.

Levels of Medication Reconciliation

Clinician Agreement. All of the clinicians who provide care for the patient need to agree which medications should be on the list. It is often necessary to compare multiple lists, none of which may be completely correct or up-to-date. Due to gaps in electronic medical record (EMR) interoperability, this can be a challenging, laborious, and error-prone task.

> Creating and maintaining a correct medication list for every patient will not be a trivial task, but it represents a fulfillment of the responsibility of physicians.

Patient Agreement. Incorporating the patient's perspective is fundamental. Keeping medications on the list that patients cannot obtain or do not want to take is misleading. If the patient purposefully stops a medication, the clinician must decide whether the medication is still warranted (and persuade the patient) or remove it from the list.

Deprescribe. Some of the medications on the patient's various medication lists may no longer be appropriate or may never have been ideal. Carrying these suboptimal choices forward does not serve the patient's interests. Prescribing should be paired with deprescribing: Inappropriate and unnecessary medications should be removed from the list.

Decrease Patient Burden. The burden of adherence can be minimized by choosing medications given fewer times per day and aligning dosing intervals to reduce the frequency that medications should be taken. Similarly, the burden of adverse effects can be minimized by choosing the lowest effective dose. This is a particularly difficult task because it may involve talking with various clinicians and the patient, as well as understanding the patient's insurance plan, which may not cover all drugs.

Minimize Out-of-Pocket Expenses. Unnecessarily expensive medications do not belong on the list; a medication the patient cannot afford will not help. Physicians may be hampered by a lack of information about out-of-pocket costs. Electronic medical records could be improved to help play this role.

Inform Outside Entities. The correct medication list will not be effective unless all entities interacting with the patient also have the list. Other clinicians need to know about prescription changes or problems may be perpetuated. This concern extends to pharmacies because automatic refill programs prompt patients to keep taking previously prescribed medications. Even though The Joint Commission requires communication with the pharmacy, it likely occurs only rarely. The SCRIPT standard for e-prescribing, Version 10.6 (available since 2014) would accomplish much of this task. However, because many pharmacies and EMRs have not fully enabled all SCRIPT functionalities, this communication is not a reality for most clinicians.[2]

Reasons for Medication Reconciliation

It will likely be time-consuming to develop and maintain the correct medication list. In medicine, and especially in primary care, there is no shortage of worthwhile activities. In current clinical settings in which most practitioners already have too much to do,[3] why should the correct medication list receive priority? There are several reasons.

1. Substantial potential to improve patient outcomes. Establishing the correct medication list has demonstrated effect on outcomes. One study, Project RED[4] (an intervention that included most of the steps suggested above), included 749 patients and demonstrated a decrease of approximately 30% in patients returning to the hospital within 30 days, from 0.45 to 0.31 hospitalization or emergency department visits per month. Other studies have linked similar approaches with improved medication adherence.[5] The effort invested in achieving the correct medication list could potentially improve outcomes more than other competing priorities.

Corresponding Author: Adam J. Rose, MD, MSc, RAND Corporation, 20 Park Plaza, Ste 920, Boston, MA 02116 (arose@rand.org).

2. Having the correct medication list will prevent problems that would have taken even more effort to solve. Creating a correct list will take time, but having the list could help avert crises and readmissions. For example, duplicate or interacting medications could be discovered and rectified before they lead to an adverse event. Also, having a correct list could simplify the workflow for many stakeholders.
3. Strategies are available to facilitate developing and maintaining the correct medication list. The primary clinician should ultimately be responsible for these strategies, although some of this work can be delegated. Technology can also help. Full implementation of standards, as previously mentioned, will make communication with pharmacies more reliable—and information will flow in both directions. Indication-based prescribing could prevent errors, whereas availability of cost information in the EMR could decrease cost. A system to allow patients or caregivers to offer amendments between visits will improve accuracy.
4. Establishing a correct medication list will often involve removing medications. The rate of polypharmacy (defined as taking ≥5 medications) for US individuals older than 65 years is close to 40%.[6] The correct medication list will help to address polypharmacy by ensuring that medications are appropriately stopped, reducing the potential for medication error, adverse effects, interactions, and excessive costs.
5. The correct medication list, instead of a more limited conception of medication reconciliation, is what most patients would likely want.

Questions Involving Medication Reconciliation

However, creating and maintaining a correct medication list also creates some questions:

1. *Who will pay for this?* Some programs already pay for an enhanced version of medication reconciliation. One example is the Centers for Medicare & Medicaid Services (CMS) Enhanced Medication Therapy Management pilot, that pays Medicare Part D plans to conduct or arrange for activities similar to those described herein.[7] The results of that pilot could support the idea of paying for the activity of maintaining a correct medication list.
2. *How can the task of creating and maintaining the correct medication list be measured?* Primary care clinicians and hospitalists currently must attest that medication reconciliation has been completed, but this does not measure accuracy. Currently, no validated measures are available to assess the quality of medication reconciliation. More meaningful measures are needed, and studies can be built upon these measures to assess the value of medication reconciliation across a gradient of how comprehensively it was performed.
3. *Who should be responsible for this task?* While delegating some of the responsibility is possible, systems made up of care teams, engaged patients, and helpful technology need to be developed to achieve and maintain the correct medication list with a minimum of human effort and maximum effectiveness. Developing such systems is where the ultimate responsibility should lie.
4. *When should this be done and for whom?* Although current practice is based on assumptions about which patients need medication reconciliation and when, additional research is needed to identify patients who would benefit most from this activity. For example, in the CMS pilot, Part D plans are encouraged to find creative ways to identify patients at the highest risk of adverse events and focus efforts on them.[7]

Conclusions

Creating and maintaining a correct medication list for every patient will not be a trivial task, but it represents a fulfillment of the responsibility of physicians. Properly developing and maintaining a correct medication list for all patients will require appropriate delegation, implementation of relevant information technology, creating systems to support the work to maintain a list, and developing payment mechanisms and performance measures. It is time to look beyond basic medication reconciliation. All patients should have confidence that their medication list is the correct list.

ARTICLE INFORMATION

Published Online: April 20, 2017. doi:10.1001/jama.2017.4628

Conflict of Interest Disclosures: All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest and no disclosures were reported.

REFERENCES

1. Agency for Healthcare Research and Quality. Patient safety primer: medication reconciliation. https://psnet.ahrq.gov/primers/primer/1/medication-reconciliation. Accessed March 15, 2017.
2. Fischer S, Rose A. Responsible e-prescribing needs e-discontinuation. *JAMA*. 2017;317(5):469-470.
3. Yarnall KS, Pollak KI, Østbye T, Krause KM, Michener JL. Primary care: is there enough time for prevention? *Am J Public Health*. 2003;93(4):635-641.
4. Jack BW, Chetty VK, Anthony D, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med*. 2009;150(3):178-187.
5. Wolf MS, Davis TC, Curtis LM, et al. A patient-centered prescription drug label to promote appropriate medication use and adherence. *J Gen Intern Med*. 2016;31(12):1482-1489.
6. Kantor ED, Rehm CD, Haas JS, Chan AT, Giovannucci EL. Trends in prescription drug use among adults in the United States from 1999-2012. *JAMA*. 2015;314(17):1818-1831.
7. Centers for Medicare & Medicaid Services. Part D enhanced medication therapy management model. https://innovation.cms.gov/initiatives/enhancedmtm/. Accessed March 15, 2017.

Study: 75% of hospital executives concerned patient medication data is incomplete, inaccurate

Written by Tamara Rosin (Twitter | Google+) | June 22, 2017 | Print | Email

Although approximately 83 percent of hospital executives say medication reconciliation is a multidisciplinary effort across the organization, 74.8 percent say incomplete and inaccurate medication data remains a top concern, according to a recent study.

The study, conducted in February by the College of Healthcare Information Management Executives Foundation on behalf of DrFirst, an e-prescribing and medication management solutions provider, included responses from 120 hospital CIOs, CMIOs, directors of informatics and other hospital administrators.

Various issues challenge hospitals' medication reconciliation efforts, according to the study. The most commonly cited concerns include:

- Inconsistent practices across departments, disciplines and shifts (59.7 percent)
- Patients being discharged with an incorrect medication list (47.9 percent)
- Difficulty importing external medication history, including home medications (46.2 percent)
- Lengthy patient interviews that required calls to families, pharmacies and providers (42.9 percent)
- Outdated workflows that drive bad medication reconciliation practices (30.3 percent)

The Agency for Healthcare Research and Quality estimates that anywhere from 28 percent to 95 percent of all adverse drug events — which can cost individual hospitals up to $5.6 million annually — can be prevented by reducing medication errors through computerized monitoring systems. In total, inpatient medication errors cost hospitals $16.4 billion each year.

When asked about the most important aspects of a medication reconciliation process, more than half of all respondents named each of these components among the top three, according to the study:

- Technology to enhance drug data stewardship
- Technology for patient engagement and accountability
- Additional data feeds to mitigate medication history gaps

More articles on health IT:
New module helps healthcare organizations mitigate emerging infection risks in their communities
Viewpoint: How email archiving supports HIPAA compliance
Only 18% of rural patients use a patient portal, athenahealth finds

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: AHA Quality Advisory Regarding Codein and Tramadol Warning

SUMMARY

The FDA has issued new warnings regarding the use of Tramadol and Codeine in Pediatric patients and women who are breastfeeding.

Appropriate protocol should be implemented to physicians from ordering either drug on breast feeding women or children under the age of 12.

ACTION REQUESTED

- Information and discussion

American Hospital Association

Quality Advisory

Thursday, April 20, 2017

FDA RESTRICTS USE OF CODEINE AND TRAMADOL MEDICINES IN CHILDREN, RECOMMENDS AGAINST USE IN BREASTFEEDING MOTHERS

The Issue:

The Food and Drug Administration (FDA) today announced that it is restricting the use of codeine and tramadol medicines in children, as well as recommending against using codeine and tramadol medicines in breastfeeding mothers due to possible harm to their infants.

Codeine is approved to treat pain and cough, and tramadol is approved to treat pain. These medicines carry serious risks, including slowed or difficult breathing and death, which appear to be a greater risk in children younger than 12 years, and should not be used in these children. These medicines also should be limited in some older children.

The FDA is requiring several changes to the labels of all prescription medicines containing these drugs. These new actions further limit the use of these medicines beyond FDA's 2013 restriction of codeine use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids. The agency is now adding:

- FDA's strongest warning, called a *Contraindication*, to the drug labels of codeine and tramadol alerting that codeine should not be used to treat pain or cough and tramadol should not be used to treat pain in children younger than 12 years.
- A new *Contraindication* to the tramadol label warning against its use in children younger than 18 years to treat pain after surgery to remove the tonsils and/or adenoids.
- A new *Warning* to the drug labels of codeine and tramadol to recommend against their use in adolescents between 12 and 18 years who are obese or have conditions such as obstructive sleep apnea or severe lung disease, which may increase the risk of serious breathing problems.
- A strengthened *Warning* to mothers that breastfeeding is not recommended when taking codeine or tramadol medicines due to the risk of serious adverse reactions in breastfed infants. These can include excess sleepiness, difficulty breastfeeding or serious breathing problems that could result in death.

The FDA is urging health care professionals and patients to report side effects involving codeine-and tramadol-containing medicines to the FDA MedWatch program, through its online form.

What You Can Do:

Please share this advisory with medical and nursing staff leadership, pediatrics, obstetrics, emergency department, family medicine, surgery, pharmacy and risk management.

Further Questions:

Please contact Roslyne Schulman, AHA director of policy, at rschulman@aha.org.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: MD Office Use of Sterile Hazardous Drugs

ACTION REQUESTED

- For discussion

6/13/2017

Attention Turns to Nonpharmacy Sterile Compounding Activities

Cheryl A. Thompson
Director
News Center

In the year since investigators entered a New York City oncology clinic in search of the source of an outbreak of fungal bloodstream infections involving 17 patients, information has emerged suggesting that healthcare facilities without a pharmacy professional go unmonitored for adherence to sterile compounding standards.

Three of the 17 patients, all with cancer, died less than 90 days after diagnosis with *Exophiala dermatitidis* or *Rhodotorula mucilaginosa* bloodstream infection, said investigator Amber M. Vasquez of the Centers for Disease Control and Prevention (CDC).

Whether the infections contributed to the patients' demise may never be known, she said.

What is known, Vasquez said during a CDC-hosted webinar, is that all 17 patients had a central venous catheter that had been flushed at least once with fluid from a 1-L bag of heparin-vancomycin-ceftazidime lock solution compounded at the clinic on February 7, 2016.

Inspections of nonpharmacy settings. FDA has "recently done a couple of inspections" at physician offices in response to complaints about compounding activities, the agency's Sarah Rothman told the Pharmacy Compounding Advisory Committee on May 8.

One of those inspections occurred because of an outbreak of infections at a physician office in New York, she said.

"We haven't been focusing on physicians," Rothman said of the more than 350 inspections conducted since enactment of the Drug Quality and Security Act through November 27, 2016.

But because FDA knows there are concerns about compounding in physician offices, she said, the agency has been considering how best to focus its resources and has been speaking with state medical boards, the National Association of Boards of Pharmacy, and CDC.

"Egregious" practice conditions. Vasquez said investigators learned that the single-physician oncology clinic had the following routine for preparing syringes of heparin-antimicrobial lock solution: Compound the 1-L bag. Store it in a refrigerator. Use 10-mL syringes to access the bag multiple times each morning to prepare a batch for use throughout the day. Continue accessing the bag until empty, which could be up to 8 weeks after the day on which the solution was compounded.

Unfortunately for the investigators, she said, nothing remained of the bag involved in the February 7, 2016, compounding incident when they arrived on the scene in late May. Their initial clue came on May 24 from an infectious diseases physician who notified the New York City Department of Health and Mental Hygiene that 2 patients with *E. dermatitidis* bloodstream infection admitted to the same hospital had received care at the same oncology clinic.

Through whole genome sequencing, Vasquez said, the team identified a single source of the outbreak: the compounded lock solution.

"So we performed an infection-control assessment to determine what might have gone wrong with the i.v. flush solution," she said.

Joel Ackelsberg, with the New York City health department, said he had "never [before] heard the word egregious used so many times by so many people to describe" conditions in a healthcare provider's office.

"An i.v. flush solution that was stored in the refrigerator for up to 2 months was improperly prepared in a biological safety cabinet that was last tested and failed inspection in 2014 and which was situated next to a refrigerator and in which improper technique was used to prepare parenteral medications," he said during the webinar.

Problems aplenty. Among the slides of the clinic shown by Vasquez was a photo of the biological safety cabinet. It had a sticker stating "REJECTED" in red and a date roughly 2 years before the outbreak.

Another photo showed the interior of the refrigerator used to store the 1-L bag and flush syringes. There was grime on the floor of the refrigerator. A self-sealing bag held moldy-looking materials. The same refrigerator, Vasquez said, had reportedly also been used to store the staff's food items.

"Not good at all," declared Nitika Agarwal, director of specialty, oncology, and infusion pharmacy for DuPage Medical Group in Illinois, in assessing the clinic's sterile compounding practices after viewing the slides.

Agarwal, who was not part of the investigation and was not speaking on behalf of her employer, said the slides showed the clinic had obvious problems.

"No wonder things didn't work out," she said.

Among the problems mentioned by Agarwal was the lack of any onsite pharmacy professional —"critical pieces of the sterile compounding [operation]."

Vasquez had reported that sterile compounding activities at the clinic were performed by a nurse who had no pharmaceutical training and whose performance had not been assessed before the investigators' arrival.

Agarwal said any pharmacy technician trained in sterile compounding who walked into a work area like the one shown in the photos would sense that the conditions were inappropriate.

"Even at home, you would not leave anything [in the refrigerator] with the moldy stuff around it"—let alone store i.v. medications alongside food rather than in a refrigerator dedicated to drug storage, she said. "You can't even fathom that anybody would practice in that situation."

DuPage Medical Group, she said, has a pharmacy technician working at every infusion site where sterile compounding activities occur and separates each site's sterile compounding area from the other work areas in accordance with *United States Pharmacopeia* chapter 797.

"It's very, very important—no matter what the setting is—that patient safety comes first," Agarwal said.

Changes needed. Willis Triplett, a principal with the group known as Comply 797 and a consultant with ASHP's consulting services unit, said many of the nation's oncologists do not believe they need to handle sterile products in the same way that hospital pharmacies do.

“I’ve been at many, many oncology practices in the last year,” Triplett said. “And every one of them has had a biological safety cabinet, but they don’t know how to use it. I’ll walk into an oncology practice and the rear air return [grill] on the biological safety cabinet will have vials sitting on it,” disrupting the unidirectional airflow.

But his concern is not restricted to oncology practices.

“There’s infusion clinics everywhere,” Triplett said, noting the ones operated by allergists and immunologists to administer i.v. immune globulin and others operated by rheumatologists and gastroenterologists to infuse tumor necrosis factor inhibitors.

Nine states have laws, regulations, or policies that specifically apply to compounding activities by healthcare practitioners who are not pharmacists, according to the results of a 2015 survey by the Government Accountability Office (https://www.gao.gov/assets/690/681096.pdf); 23 states had no such law, regulation, or policy, and representatives of the remaining states either did not know the answer (17) or did not respond (1).

New York, where the outbreak occurred, lacks laws specific to compounding, the survey report states.

That lack of specificity frustrates Ackelsberg.

“After speaking with the New York State Department of Health, which has an office that addresses clinical misconduct, it became clear that there was a considerable regulatory gap in regard to pharmacy-related and infection-prevention practices by outpatient physicians, specifically oncologists,” Ackelsberg said during the webinar. “They could rescind the provider’s license if an investigation uncovered maleficence, but there was no ongoing oversight of outpatient provider settings other than a requirement for them to take an online infection-control course every 4 years.”

The city’s health department commissioner on May 31 issued a cease-and-desist order to the oncology clinic, relying on the department's authority to abate public nuisances, Ackelsberg said.

On October 5, the department lifted the order, Vasquez said. The clinic had completed remediation efforts under the guidance of an infection control practitioner and pharmacist, demonstrated workers’ ability to safely prepare and deliver medications, and stopped compounding.

A recording of CDC’s April 18 webinar, with slides, is available online (http://www.youtube.com/watch?v=dtM1lQYCdZ8).

[This news story appears in the July 1, 2017, issue of *AJHP*.]

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Medication Shortage

SUMMARY

Medication shortage has been reported statewide. Attached is an article that appeard in the June 13, 2017 issue of CHA News. Also attached is a copy of a customer letter received by one of our committee members from Pfizer regarding their shortage.

ACTION REQUESTED

- Discussion

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Pfizer Reports Shortage of Key Injectable Medications

JUNE 13, 2017 | BJ BARTLESON, RN, MS, NEA-BC

Recently, member hospitals have notified CHA of shortages of key emergency medications, particularly injectable drugs manufactured by Pfizer. Pfizer has issued the attached letter updating providers on the shortages as well as the steps the company is taking to meet demand expeditiously, including:

- Prioritizing the manufacture and delivery of medically necessary drugs
- Allocating certain medicines to minimize stock outs
- Increasing production at key injectable manufacturing plants
- Adding resources to address distribution delays
- Increasing inventory levels for key manufacturing materials

CHA will continue to monitor the situation and encourages members to direct questions to BJ Bartleson, vice president, nursing and clinical services, at bjbartleson@calhospital.org or (916) 552-7537. Providers should note that, overall, drug shortages have decreased in recent years; for more information, visit the American Society of Health-System Pharmacists website.

Pfizer Inc.
275 North Field Drive
Lake Forest, IL 60045

May 16, 2017

Notification On Pfizer Injectables Supply Recovery Update

Dear Valued Customer,

The Pfizer Injectables business is currently experiencing shortages on several injectable drugs used in hospitals and other clinical settings. We understand and regret the challenges these shortages pose to clinicians and patients. We are expediting our recovery activities, and are sharing details and timing so you can plan accordingly.

While the causes of individual shortages vary, the majority are due to three main factors – manufacturing, distribution, and third-party supplier delays.

Pfizer has a dedicated team focused on addressing these delays, and has already taken the following steps to expedite supply recovery of these drugs, including:

- prioritizing the manufacture and delivery of medically necessary drugs;
- allocating certain medicines to minimize stock outs;
- increasing production at our key injectable manufacturing plants;
- adding resources to address distribution delays;
- prioritizing wholesaler and distribution channel delivery to reach a broad customer segment more quickly;
- qualifying alternative third-party suppliers who meet Pfizer quality standards; and
- increasing inventory levels for key manufacturing materials.

At the end of this letter, we've included a list that details the anticipated recovery timeframe for select products. Knowing how important this is for you, you can contact us via

- Our website at https://www.PfizerInjectables.com/Injectables_Availability_Report to receive the most up-to-date information on Pfizer Injectables product availability.
- Our Supply Continuity Team is also available between 7:00am – 6pm CT to discuss any product availability questions that you may have. They can be reached at 844-646-4398 (Select Option 3) or at PISupplyContinuity@Pfizer.com.

We will continue to communicate with you on important updates to help you make arrangements to address your patient needs.

We are highly focused on alleviating the shortages, while ensuring the highest quality and safety standards. We recognize the impact on patient care and the challenges that this situation is creating for you. We are available to speak with you to discuss this in more detail, and answer any questions that you may have. Please email us at PfizerInjectables@Pfizer.com and we will respond to you as quickly as possible.

Kind regards,

Ellen Wetterling
US Portfolio Lead
Drug Delivery Systems, Brand Marketing,
Anti-Infectives, Opioids & Oncology

Dave Engels
US Portfolio Lead
Surgical & Specialty Brand Marketing,
Anesthesia & Injectables

NDC Number	Product Description	Is Inventory Depleted ?	Next delivery	Full recovery expected with consistent supply
60793-700-10	Bicillin™ L-A (penicillin G benzathine injectable suspension) Pediatric 600,000 Units/mL PFS	No-Allocating	Late August	October - December
60793-701-10	Bicillin™ L-A (penicillin G benzathine injectable suspension) 1.2 million units/2 mL (600,000 units/mL) PFS	No-Allocating	Early June	October - December
60793-702-10	Bicillin™ L-A (penicillin G benzathine injectable suspension) 2.4 million units/4 mL (600,000 units/mL) PFS	No-Allocating	Late June	October - December
00409-2267-20	Labetalol Hydrochloride Injection, USP 100 mg/20 mL (5 mg/mL) Multiple Dose Glass Fliptop Vial	YES	Late July	July
00409-2339-34	Labetalol Hydrochloride Injection, USP 20 mg/4 mL (5 mg/mL) CARPUJECT™ Luer Lock Glass Syringe (no needle)	YES	Late May	June
00409-2267-54	Labetalol Hydrochloride Injection, USP 200 mg/40 mL (5 mg/mL) Multiple Dose Glass Fliptop Vial	YES	Late July	July
00409-3299-05	Sodium Acetate Injection, USP 100 mEq/50 mL (2 mEq/mL) Pharmacy Bulk Package Glass Fliptop Vial	YES	Late July	December
00409-3299-06	Sodium Acetate Injection, USP 200 mEq/100 mL (2 mEq/mL) Pharmacy Bulk Package Glass Fliptop Vial	YES	Early June	December
00409-7299-73	Sodium Acetate Injection, USP 40 mEq/20 mL (2 mEq/mL) Single Dose Plastic Fliptop Vial	No-Allocating	Early October	December
00409-6625-02	Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) Single Dose Glass Fliptop Vial (8.4% concentration)	YES	Late August	November
Emergency Syringes				
00409-4928-34	Calcium Chloride Injection, USP 1 g/10 mL (100 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1½")	YES	Early July	September
00409-1775-10	25% Dextrose Injection, USP (For Infant Use) 2.5 g/10 mL (250 mg/mL) ANSYR™ Plastic Syringe	NO	May	August
00409-7517-16	50% Dextrose Injection, USP 25 g/50 mL (500 mg/mL) ANSYR™ II Plastic Syringe (side/side)	NO	May	August
00409-4911-34	Atropine Sulfate Injection, USP (Adult) 1 mg/10 mL (0.1 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1 1/2")	YES	Early August	October
00409-4910-34	Atropine Sulfate Injection, USP (Adult) 0.5 mg/5 mL (0.1 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1 1/2")	YES	Mid August	October
00409-1630-10	Atropine Sulfate Injection, USP (Adult) 1 mg/10 mL (0.1 mg/mL) ANSYR™ Plastic Syringe	YES	June	October
00409-9630-05	Atropine Sulfate Injection, USP (Pediatric) 0.25 mg/5 mL (0.05 mg/mL) ANSYR™ Plastic Syringe	YES	June	October
00409-1631-10	Calcium Chloride Injection, USP 1 g/10 mL (100 mg/mL) ANSYR™ Plastic Syringe	YES	May	September
00409-4902-34	50% Dextrose Injection, USP 25 g/50 mL (500 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (18 G x 1 1/2")	YES	Mid July	August
00409-4921-34	Epinephrine Injection, USP 1 mg/10 mL (0.1 mg/mL) LifeShield™ ABBOJECT™ Glass Syringe (20 G x 1 1/2")	YES	Mid July	August
00409-5534-34	Sodium Bicarbonate Injection, USP (Infant) 5 mEq/10 mL (0.5 mEq/mL) LifeShield™ ABBOJECT™ Glass Syringe with Male Luer Lock Adapter and 20-Gauge protected needle (4.2% concentration)	YES	Mid August	August
00409-4916-34	Sodium Bicarbonate Injection, USP 44.6 mEq/50 mL (0.9 mEq/mL) LifeShield™ ABBOJECT™ Glass Syringe with Male Luer Lock Adapter and 18-Gauge protected needle (7.5% concentration)	YES	2018	2018
00409-6637-34	Sodium Bicarbonate Injection, USP 50 mEq/50 mL (1 mEq/mL) LifeShield™ ABBOJECT™ Glass Syringe (18 G x 1 1/2") (8.4% concentration)	YES	Late June	August
00409-4900-34	Sodium Bicarbonate Injection, USP (Pediatric) 10 mEq/10 mL (1 mEq/mL) LifeShield™ ABBOJECT™ Glass Syringe with Male Luer Lock Adapter and 20-Gauge protected needle (8.4% concentration)	YES	Mid August	November

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: July 5, 2017

TO: Medication Safety Committee Members

FROM: Debby Rogers, RN, MS, FAEN, VP Clinical Performance and Transformation
Sarah Cardone, RN, BSN, Policy Analyst

SUBJECT: Free Vaccination Programs and Barriers

SUMMARY

The Centers for Disease Control and the California Department of Public health both offer programs to provide free vaccines for health care providers. The Vaccines For Children (VFC) program is a federally funded program that provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. CDC buys vaccines at a discount and distributes them to grantees—i.e., state health departments and certain local and territorial public health agencies—which in turn distribute them at no charge to hospitals, providers and clinics registered as VFC providers (e.g. hepatitis B vaccinations for newborns who are Medi-Cal beneficiaries). In addition, hospitals can receive Hepatitis A vaccinations to combat the Hepatitis A outbreak in the San Diego area.

- The attached document summarizes 317 vaccine requirements of registered providers to obtain and use free vaccinations (317 Vaccine Use During Outbreak Response)

CHA has heard that the requirements for the free vaccinations are robust and some hospitals choose not to participate. CDPH and CHA are interested in understanding vaccine management, temperature-monitoring practices, and reporting protocols currently in place, which would assist in the identification and elimination of barriers for this program.

There has been raised concern regarding hospitals' compliance with the required temperature monitoring practices and other barriers. The following questions to be addressed include:

- Does the system have a temperature sensor in a buffered solution?
- Current Hi and Lo alarm parameters
  - Set low temperatures triggering an alarm, after how many minutes?
  - Set high temp triggering an alarm after how many minutes?
- Does the system have the ability to display current, MIN and MAX temperatures either via digital display or monitor in close proximity with the vaccine storage unit?

  - Some systems only display current temperatures, but fail to provide the coldest temperature vaccines have been exposed to (MIN) or the warmest temperature vaccines have been exposed to (MAX)
- Who responds to an alarm?
  - If the refrigerator is outside the manufacturer's recommended temperature range, are temperatures adjusted and clinical staff notified so that vaccines are quarantined until viability is determined (based on time and exposure temperatures)?
  - If temperatures are outside the recommended ranges, does the pharmacist contact vaccine manufacturers to determine vaccine viability?
- Temperature reports
  - Does the system have the ability to generate a daily report of current MIN and MAX temperatures?
- Are there other barriers hospitals face in managing and administering 317 vaccines?

ACTION REQUESTED

- Discuss barriers to using the free immunization program and the responses to the questions raised above.

317 Vaccine Use During Outbreak Response
PROVIDER AGREEMENT

I agree to the following conditions, on behalf of myself and all the practitioners, nurses, and others associated with the health care facility of which I am the medical director or equivalent, regarding the use of Section 317 funded vaccines, at no cost, for the purpose of responding to a vaccine preventable disease outbreak:

1.	Federally-funded Section 317 vaccine doses will be administered to any individual, regardless of insurance coverage status, only during the prevention and control of a vaccine preventable disease outbreak effort approved by the California Department of Public Health.
2.	Each patient receiving a 317 vaccine dose will be documented in the provided Outbreak Response Vaccine Usage Log, similar paper log, or electronic information system containing the required documentation elements included in CDPH's Outbreak Response Vaccine Usage Log. The total number of patients immunized with 317 doses will be promptly reported to the local health department upon the conclusion of the response effort (or as agreed upon receipt of doses).
3.	Vaccine doses will be administered in compliance with immunization schedules, dosages, and contraindications that are established by the Advisory Committee on Immunization Practices (ACIP), and in accordance with any special CDPH approved outbreak control guidelines, unless: a) In the provider's medical judgment, and in accordance with accepted medical practice, the provider deems such compliance to be medically inappropriate for the patient; b) The particular requirements contradict state law, including laws pertaining to religious and other exemptions.
4.	All records related to the administration and management of 317 vaccine doses will be maintained for a minimum of three years. Upon request by CDPH or DHHS representatives, these records will be made available for review. Records include, but are not limited to, vaccine administration documentation, billing records, medical records that verify receipt of vaccine, and vaccine temperature log records.
5.	Patients will be immunized with 317-supplied vaccine at no charge. Patients will not be billed for the cost of the vaccine.
6.	A vaccine administration fee of up to $26.03 per vaccine dose may be charged to patients. Administration of a federally-supplied 317 vaccine dose cannot be denied because the individual is unable to pay the administration fee.
7.	Current Vaccine Information Statements (VIS) will be offered prior to each vaccination. Vaccine administration records will be maintained in accordance with the National Childhood Vaccine Injury Act (NCVIA), which includes reporting clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) (www.vaers.hhs.gov).
8.	I will comply with the standards for vaccine management including: a) Following proper vaccine transport guidelines b) Not storing vaccine in dormitory-style units at any time c) Storing vaccine under proper storage conditions at all times d) Monitoring and documenting vaccine storage unit temperatures on a temperature log
9.	Upon conclusion of outbreak response efforts, unused doses will be returned to the local health department. I agree to operate within the 317 Program in a manner intended to avoid fraud and abuse.
10.	I agree to replace vaccine purchased with federal funds (317) that are deemed non-viable due to provider negligence on a dose-for-dose basis.

By signing this form, I certify on behalf of myself and all immunization providers in this facility, I have read and agree to the requirements listed above and understand I am accountable (and each listed provider is individually accountable) for compliance with these requirements.

Medical Director or Equivalent who is authorized to prescribe vaccines under California State Law (Print Name):	Medical License #:
Signature:	Date:

CA AB 29

AUTHOR: Nazarian [D]
TITLE: Pharmacy Benefit Managers
INTRODUCED: 12/05/2016
LAST AMEND: 05/11/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Requires a pharmacy benefit manager to disclose certain information to a purchaser, including the aggregate amount of rebates, retrospective utilization discounts, and other income that the pharmacy benefit manager would receive from a pharmaceutical manufacturer or labeler in connection with drug benefits related to the purchaser. Excuses a pharmacy benefit manager from making these disclosures unless the purchaser agrees to keep any proprietary information disclosed confidential.

STATUS:

05/26/2017 In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.

INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 40

AUTHOR: Santiago [D]
TITLE: CURES Database: Health Information System
INTRODUCED: 12/05/2016
LAST AMEND: 05/26/2017
DISPOSITION: Pending
COMMITTEE: Senate Business, Professions & Economic Development Committee
HEARING: 07/03/2017 10:00 am
SUMMARY:

Requires the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the Controlled Substance Utilization Review and Evaluation System, available to the practitioner through either an online Internet Web portal or an authorized health information technology system. Authorizes an entity that operates a health information technology system to integrate with the CURES database.

STATUS:

06/14/2017 To SENATE Committees on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT and JUDICIARY.

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F, X

CA AB 265

AUTHOR: Wood [D]
TITLE: Prescription Drugs: Prohibition on Price Discount
INTRODUCED: 01/31/2017
LAST AMEND: 06/22/2017
DISPOSITION: Pending
COMMITTEE: Senate Health Committee

HEARING: 07/05/2017 1:30 pm

SUMMARY:

Prohibits a person who manufactures a prescription drug from offering any discount, repayment, product voucher, or other reduction in an individual's out-of-pocket expenses, including a copayment, coinsurance, or deductible, for any prescription drug if a lower cost generic drug is covered under the individual's health plan on a lower cost-sharing tier. Requires a violation of prohibitions against offering a discount to be treated as a public offense with specified sentencing and penalties.

STATUS:

06/22/2017 From SENATE Committee on HEALTH with author's amendments.

06/22/2017 In SENATE. Read second time and amended. Re-referred to Committee on HEALTH.

INDEX: 89

ISSUES: DG

LOBBYIST: AH

POSITION: F

CA AB 315

AUTHOR: Wood [D]

TITLE: Pharmacy Benefit Management

INTRODUCED: 02/06/2017

LAST AMEND: 05/30/2017

DISPOSITION: Pending

COMMITTEE: Senate Health Committee

HEARING: 07/05/2017 1:30 pm

SUMMARY:

Requires pharmacy benefit managers to be licensed by the Department of Managed Health Care. Requires the department to develop an application for new and renewed licenses, and specifies certain information to be provided in those applications. Requires a pharmacy benefit manager to exercise a duty of good faith and fair dealing in the performance of its contractual duties to a purchaser.

STATUS:

06/14/2017 To SENATE Committee on HEALTH.

INDEX: 39, 89

ISSUES: DG

LOBBYIST: AH

POSITION: F

CA AB 401

AUTHOR: Aguiar-Curry [D]

TITLE: Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy

INTRODUCED: 02/09/2017

LAST AMEND: 05/10/2017

DISPOSITION: Pending

COMMITTEE: Senate Business, Professions & Economic Development Committee

HEARING: 07/10/2017

SUMMARY:

Requires the State Board of Pharmacy to issue certain remote dispensing site pharmacy licenses. Requires such pharmacies to be located in a medically underserved area unless approved by the Board. Authorizes a pharmacy located

in the State to serve as a supervising pharmacy to provide telepharmacy services for up to a certain number of remote dispensing sites. Authorizes a licensed remote dispensing site pharmacy, as defined, to order dangerous drugs and devices and controlled substances.

STATUS:

06/19/2017 In SENATE Committee on BUSINESS, PROFESSIONS AND ECONOMIC DEVELOPMENT: Not heard.

INDEX: 89
ISSUES: BJ*, PW
LOBBYIST: AH
POSITION: F

CA AB 532

AUTHOR: Waldron [R]
TITLE: Drug Courts: Drug and Alcohol Assistance
INTRODUCED: 02/13/2017
LAST AMEND: 05/26/2017
DISPOSITION: Pending
COMMITTEE: Senate Health Committee
HEARING: 06/28/2017 1:30 pm
SUMMARY:

Authorizes a court to develop a program to offer mental health and addiction treatment services to women who are charged in a complaint that consists only of misdemeanor offenses or who are on probation for one or more misdemeanor offenses. Excludes from these provisions a woman who is charged with a felony or who is under supervision for a felony conviction.

STATUS:

06/14/2017 To SENATE Committees on HEALTH and PUBLIC SAFETY.

INDEX: 89
ISSUES: SL
LOBBYIST: AH
POSITION: F

CA AB 587

AUTHOR: Chiu [D]
TITLE: State Government: Pharmaceuticals: Procurement
INTRODUCED: 02/14/2017
LAST AMEND: 05/30/2017
DISPOSITION: Pending
COMMITTEE: Senate Health Committee
HEARING: 07/05/2017 1:30 pm
SUMMARY:

Requires the Department of General Services to convene the state Pharmaceutical Collaborative to address the rising cost of pharmaceuticals, coordinate best value clinical treatment protocols, leverage governmental efficiencies to achieve best value procurement, and negotiate with manufacturers for discounts on pharmaceuticals. Requires the participation of various agencies in the collaborative.

STATUS:

06/14/2017 To SENATE Committee on HEALTH.

INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 904

AUTHOR: Gallagher [R]
TITLE: Prescription Drugs
INTRODUCED: 02/16/2017
DISPOSITION: Pending
LOCATION: ASSEMBLY
SUMMARY:

Declares the intent of the Legislature to enact legislation that would address high prescription drug costs.

STATUS:

02/16/2017 INTRODUCED.
INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 937

AUTHOR: Eggman [D]
TITLE: Health Care Decisions: Order Of Priority
INTRODUCED: 02/16/2017
LAST AMEND: 05/03/2017
DISPOSITION: Pending
LOCATION: Senate Health Committee
SUMMARY:

Provides that to the extent of a conflict between resuscitative measures and a patient's individual health care instruction, the most recent of the documents is effective. Deems a request regarding resuscitative measure signed by specified persons on behalf of the individual to be signed by the individual. Makes conforming changes.

STATUS:

06/01/2017 To SENATE Committees on HEALTH and JUDICIARY.
INDEX: 89, 9
ISSUES: DG, JG, LR*
LOBBYIST: BG
POSITION: F, X

CA AB 966

AUTHOR: Chau [D]
TITLE: Pupil Health: Medication Assistance
INTRODUCED: 02/16/2017
DISPOSITION: Pending
LOCATION: ASSEMBLY
SUMMARY:

Makes nonsubstantive changes to the provision that authorizes a school nurse or other designated school personnel to assist any pupil who is required to take, during the regular schoolday, medication prescribed for him or her by a physician and surgeon.

STATUS:

02/16/2017 INTRODUCED.
INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA AB 1589

AUTHOR: Bocanegra [D]
TITLE: Pharmacy: Pharmacist Supervision: Technicians

	INTRODUCED:	02/17/2017
	LAST AMEND:	05/09/2017
	DISPOSITION:	Pending
	LOCATION:	Assembly Appropriations Committee
	SUMMARY:	

Raises the limit on the number of pharmacy technicians a pharmacy with one pharmacist may have. Raises the limit on the ratio of pharmacy technicians to any additional pharmacists.

	STATUS:	
	05/24/2017	In ASSEMBLY Committee on APPROPRIATIONS: Not heard.
	INDEX:	89
	ISSUES:	BJ
	LOBBYIST:	AH
	POSITION:	F

CA SB 17

	AUTHOR:	Hernandez [D]
	TITLE:	Health Care: Prescription Drug Costs
	INTRODUCED:	12/05/2016
	LAST AMEND:	04/25/2017
	DISPOSITION:	Pending
	COMMITTEE:	Assembly Health Committee
	HEARING:	06/27/2017 1:30 pm
	SUMMARY:	

Requires health care service plans or health insurers that file certain rate information to report specified cost information regarding covered prescription drugs, including generic drugs, brand name drugs, and specialty drugs. Requires the publication of a certain report. Establishes notification requirements for manufacturer of a prescription drug that is purchased or reimbursed by specified purchasers, including state agencies, health care service plans, health insurers, and pharmacy benefit managers.

	STATUS:	
	06/08/2017	To ASSEMBLY Committee on HEALTH.
	INDEX:	65, 89
	ISSUES:	AO, DG*
	LOBBYIST:	AH*, BG
	POSITION:	S, X

CA SB 351

	AUTHOR:	Roth [D]
	TITLE:	Hospital Satellite Compounding Pharmacy: Licensing
	INTRODUCED:	02/14/2017
	LAST AMEND:	04/04/2017
	DISPOSITION:	Pending
	LOCATION:	Assembly Business and Professions Committee
	SUMMARY:	

Authorizes the State Board of Pharmacy to issue a license to a hospital satellite compounding pharmacy meeting specified requirements. Defines a hospital satellite compounding pharmacy as an area licensed by the board to perform sterile compounding that is separately licensed by the board to perform that compounding and located outside of the hospital in another physical plant regulated as a general acute care hospital. Sets forth requirements for such pharmacies.

	STATUS:	
	06/12/2017	To ASSEMBLY Committee on BUSINESS AND PROFESSIONS.

	INDEX:	89
	ISSUES:	BJ*, PW
	LOBBYIST:	AH
	POSITION:	S, X

CA SB 443

AUTHOR:	Hernandez [D]
TITLE:	Pharmacy: Emergency Medical Services Drug Delivery
INTRODUCED:	02/15/2017
DISPOSITION:	Pending
LOCATION:	Assembly Business and Professions Committee

SUMMARY:

Authorizes a pharmacy or wholesaler to furnish dangerous drugs or dangerous devices into an emergency medical services automated drug delivery system, as defined.

STATUS:

06/01/2017	To ASSEMBLY Committee on BUSINESS AND PROFESSIONS.
INDEX:	89
ISSUES:	BJ
LOBBYIST:	AH
POSITION:	S, X

CA SB 476

AUTHOR:	Nguyen [R]
TITLE:	Discount Prescription Drug Program
INTRODUCED:	02/16/2017
DISPOSITION:	Pending
LOCATION:	Senate Rules Committee

SUMMARY:

Makes a technical, nonsubstantive change to the Discount Prescription Drug Program, which requires the State Department of Health Care Services to negotiate drug discount agreements with drug manufacturers and which authorizes any licensed pharmacy and any drug manufacturer to participate in the program.

STATUS:

03/02/2017	To SENATE Committee on RULES.
INDEX:	89
ISSUES:	AK, AO, DG*
LOBBYIST:	AH
POSITION:	F

CA SB 510

AUTHOR:	Stone [R]
TITLE:	Pharmacies: Compounding
INTRODUCED:	02/16/2017
DISPOSITION:	Pending
FILE:	33
LOCATION:	Assembly Third Reading File

SUMMARY:

Repeals a provision under the Pharmacy Law which requires a pharmacy to compound sterile products from one or more nonsterile ingredients in prescribed environments.

STATUS:

06/26/2017	In ASSEMBLY. Read second time. To third reading.
INDEX:	89
ISSUES:	BJ

LOBBYIST: AH
POSITION: F

CA SB 528

AUTHOR: Stone [R]
TITLE: Pharmacy: Automated Drug Delivery Systems
INTRODUCED: 02/16/2017
LAST AMEND: 06/12/2017
DISPOSITION: Pending
LOCATION: Assembly Appropriations Committee
SUMMARY:

Provides an alternative program to authorize a pharmacy to provide pharmacy services to covered entities that are eligible for discount drug programs under federal law, as specified, through the use of an automated drug delivery system.

STATUS:

06/20/2017 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS: Do pass to Committee on APPROPRIATIONS. (15-0)

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA SB 641

AUTHOR: Lara [D]
TITLE: Controlled Substance Utilization
INTRODUCED: 02/17/2017
LAST AMEND: 04/20/2017
DISPOSITION: Pending
COMMITTEE: Assembly Public Safety Committee
HEARING: 07/11/2017 9:00 am
SUMMARY:

Amends existing law which requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances. Prohibits the release of data obtained from CURES to a law enforcement agency except pursuant to a valid court order.

STATUS:

06/15/2017 To ASSEMBLY Committee on PUBLIC SAFETY.

INDEX: 89
ISSUES: BJ
LOBBYIST: AH
POSITION: F

CA SB 716

AUTHOR: Hernandez [D]
TITLE: California State Board of Pharmacy: Pharmacy Technician
INTRODUCED: 02/17/2017
LAST AMEND: 04/26/2017
DISPOSITION: Pending
LOCATION: Assembly Business and Professions Committee
SUMMARY:

Increases the number of members of the Board of Pharmacy by adding one pharmacy technician appointed by the Governor.

STATUS:

06/01/2017 To ASSEMBLY Committee on BUSINESS AND PROFESSIONS.

INDEX: 89

ISSUES: BJ*, DP

LOBBYIST: AH

POSITION: S, X

CA SB 752

AUTHOR: Stone [R]

TITLE: Pharmacy: Designated Representative-reverse Distributor

INTRODUCED: 02/17/2017

LAST AMEND: 03/28/2017

DISPOSITION: Pending

LOCATION: Assembly Appropriations Committee

SUMMARY:

authorizes a wholesaler that only acts as a reverse distributor to operate under the supervision of a designated representative-reverse distributor, as an alternative to operating under the supervision of a designated representative or pharmacist, and would provide for the separate licensure of individuals as designated representative-reverse distributors upon application, payment of an application fee, and completion of certain requirements.

STATUS:

06/20/2017 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS: Do pass to Committee on APPROPRIATIONS. (15-0)

INDEX: 89

ISSUES: BJ*, DBR, DP

LOBBYIST: AH

POSITION: F

CA SB 800

AUTHOR: Bus, Prof and Econ Dev Cmt

TITLE: Professions and Vocations

INTRODUCED: 02/17/2017

LAST AMEND: 06/05/2017

DISPOSITION: Pending

LOCATION: Assembly Business and Professions Committee

SUMMARY:

Amends the Pharmacy Law which provides for the licensure and regulation of pharmacies, pharmacists, and other associated persons and entities by the State Board of Pharmacy. Requires each pharmacist, intern, pharmacy technician, and designated representative 3rd-party logistics provider licensed in this state to join the board's email notification list within sixty days of obtaining a license. Relates to Licensed and Family Therapist Act.

STATUS:

06/05/2017 From ASSEMBLY Committee on BUSINESS AND PROFESSIONS with author's amendments.

06/05/2017 In ASSEMBLY. Read second time and amended. Re-referred to Committee on BUSINESS AND PROFESSIONS.

INDEX: 89

ISSUES: BJ, DP, LR*

LOBBYIST: AH

POSITION: F

AMENDED IN ASSEMBLY MAY 26, 2017

AMENDED IN ASSEMBLY APRIL 19, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 40

Introduced by Assembly Member Santiago

December 5, 2016

An act to amend Section 11165.1 of the Health and Safety Code, relating to controlled substances, and declaring the urgency thereof, to take effect immediately.

LEGISLATIVE COUNSEL'S DIGEST

AB 40, as amended, Santiago. CURES database: health information technology system.

Existing law classifies certain controlled substances into designated schedules. Existing law requires the Department of Justice to maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by a health care practitioner authorized to prescribe, order, administer, furnish, or dispense a Schedule II, Schedule III, or Schedule IV controlled substance.

This bill would require the Department of Justice to make the electronic history of controlled substances dispensed to an individual under a health care practitioner's care, based on data contained in the CURES database, available to the practitioner through either an online Internet Web portal or an authorized health information technology system, as defined. The bill would authorize *an entity that operates* a health information technology system to establish an integration with

and submit queries to the CURES database if the ~~system~~ *entity* can certify, among other requirements, that the data received from the CURES database will not be used for any purpose other than delivering the data to an authorized health care practitioner or performing data processing activities necessary to enable delivery, and that the system meets applicable patient privacy and information security requirements of state and federal law. The bill would also authorize the Department of Justice to require an entity operating a health information technology system *that is requesting to establish an integration with the CURES database* to enter into a memorandum of understanding or other agreement setting forth terms and conditions with which the entity must comply.

This bill would declare that it is to take effect immediately as an urgency statute.

Vote: ⅔. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 11165.1 of the Health and Safety Code, as amended by Section 2 of Chapter 708 of the Statutes of 2016, is amended to read:

11165.1. (a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to access information regarding the controlled substance history of a patient through an online Internet Web portal that is maintained by the department, or through an authorized health information technology system, and, upon approval, the department shall release to that practitioner, through an online Internet Web portal or an authorized health information technology system, the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the

department to obtain approval to access information online regarding the controlled substance history of a patient that is stored on the Internet and maintained within the department, and, upon approval, the department shall release to that pharmacist the electronic history of controlled substances dispensed to an individual under his or her care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons which include, but are not limited to, the following:

(i) Materially falsifying an application for a subscriber.

(ii) Failure to maintain effective controls for access to the patient activity report.

(iii) Suspended or revoked federal DEA registration.

(iv) Any subscriber who is arrested for a violation of law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Any subscriber accessing information for any other reason than caring for his or her patients.

(C) Any authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.

(D) ~~A~~ *An entity that operates a* health information technology system may establish an integration with and submit queries to the CURES database on either a user-initiated basis or an automated basis if the ~~system~~ *entity* can certify all of the following:

(i) The health information technology system ~~can establish it has been~~ *is* authorized to query the CURES database on behalf of an authorized health care practitioner on either a user-initiated basis, an automated basis, or both, for purposes of delivering patient data from the CURES database to assist an authorized health care practitioner with evaluating the need for medical or pharmaceutical treatment or providing medical or pharmaceutical treatment to a patient for whom a health care practitioner is providing or has provided care.

(ii) The ~~health information technology system~~ *entity* will not use or disclose data received from the CURES database for any purpose other than delivering the data to an authorized health care practitioner or performing data processing activities that may be necessary to enable this delivery.

(iii) The health information technology system ~~authenticates~~ *will authenticate* the identity of any authorized health care practitioner initiating queries to the CURES database on either a user-initiated basis or an automated basis and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iv) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(E) The department may, in its discretion, determine whether to establish a direct system integration between one or more health information technology systems and the CURES database, or whether to develop a gateway system to which multiple health information technology systems can establish an integration for purposes of accessing the CURES database.

(F) The department may require an entity that operates a health information technology system *that is requesting to establish an integration with the CURES database* to enter into a memorandum of understanding or other agreement that sets forth terms and conditions with which the entity shall comply, including, but not limited to, all of the following:

(i) Paying a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(ii) Enforcement mechanisms for failure to comply with oversight or audit activities by the department, up to and including termination of access to the CURES database.

(iii) Any other term or condition that the department may determine in its reasonable discretion is necessary to carry out the intent of this section.

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been

approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) Any request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual. An authorized health care practitioner may use a health information technology system, either on a user-initiated basis or an automated basis, to initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to other licensed health care practitioners, pharmacists, or both.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a prescriber or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) "Automated basis" means using predefined criteria established or approved by a health care practitioner to trigger an

automated query to the CURES database, which can be attributed to a specific health care practitioner by an audit trail in the health information technology system.

(2) "Department" means the Department of Justice.

(3) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(4) "User-initiated basis" means an authorized health care practitioner has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner by an audit trail in the health information technology system.

SEC. 2. This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to ensure that information in the CURES database is available to prescribing physicians so they may prevent the dangerous abuse of prescription drugs and to safeguard the health and safety of the people of this state, it is necessary that this act take effect immediately.

O

AMENDED IN ASSEMBLY MAY 9, 2017

CALIFORNIA LEGISLATURE—2017–18 REGULAR SESSION

ASSEMBLY BILL No. 1589

Introduced by Assembly Member ~~Salas~~ *Bocanegra*

February 17, 2017

An act to ~~an act~~ amend Section 4115 of the Business and Professions ~~Code~~ *Code*, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1589, as amended, ~~Salas~~ *Bocanegra*. Pharmacy: pharmacist supervision: technicians.

The Pharmacy Law provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy, which is within the Department of Consumer Affairs. Existing law authorizes a pharmacy technician to perform certain tasks under the direct supervision and control of a pharmacist. Existing law prohibits a pharmacy with one pharmacist from having more than one pharmacy technician and prohibits the ratio of pharmacy technicians to any additional pharmacists from exceeding ~~2:1,~~ *2 to 1,* except as specified.

This bill ~~would require the board to review that ratio on a biennial basis and would require the board to provide a report to the Legislature with legislative recommendations if the board decides a change is necessary.~~ *would raise the limit on the number of pharmacy technicians a pharmacy with one pharmacist may have to 4 and would raise the limit on the ratio of pharmacy technicians to any additional pharmacists to 4 to 1.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 4115 of the Business and Professions Code is amended to read:

4115. (a) A pharmacy technician may perform packaging, manipulative, repetitive, or other nondiscretionary tasks only while assisting, and while under the direct supervision and control of, a pharmacist. The pharmacist shall be responsible for the duties performed under his or her supervision by a technician.

(b) This section does not authorize the performance of any tasks specified in subdivision (a) by a pharmacy technician without a pharmacist on duty.

(c) This section does not authorize a pharmacy technician to perform any act requiring the exercise of professional judgment by a pharmacist.

(d) The board shall adopt regulations to specify tasks pursuant to subdivision (a) that a pharmacy technician may perform under the supervision of a pharmacist. Any pharmacy that employs a pharmacy technician shall do so in conformity with the regulations adopted by the board.

(e) A person shall not act as a pharmacy technician without first being licensed by the board as a pharmacy technician.

(f) (1) A pharmacy with only one pharmacist shall have no more than ~~one~~ *four* pharmacy ~~technician~~ *technicians* performing the tasks specified in subdivision (a). The ratio of pharmacy technicians performing the tasks specified in subdivision (a) to any additional pharmacist shall not exceed ~~2:1,~~ *4 to 1,* except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117. This ratio is applicable to all practice settings, except for an inpatient of a licensed health facility, a patient of a licensed home health agency, as specified in paragraph (2), an inmate of a correctional facility of the Department of Corrections and Rehabilitation, and for a person receiving treatment in a facility operated by the State Department of State Hospitals, the State Department of Developmental Services, or the Department of Veterans Affairs.

(2) The board may adopt regulations establishing the ratio of pharmacy technicians performing the tasks specified in subdivision (a) to pharmacists applicable to the filling of prescriptions of an inpatient of a licensed health facility and for a patient of a licensed

home health agency. Any ratio established by the board pursuant to this subdivision shall allow, at a minimum, at least one pharmacy technician for a single pharmacist in a pharmacy and two pharmacy technicians for each additional pharmacist, except that this ratio shall not apply to personnel performing clerical functions pursuant to Section 4116 or 4117.

(3) A pharmacist scheduled to supervise a second pharmacy technician may refuse to supervise a second pharmacy technician if the pharmacist determines, in the exercise of his or her professional judgment, that permitting the second pharmacy technician to be on duty would interfere with the effective performance of the pharmacist's responsibilities under this chapter. A pharmacist assigned to supervise a second pharmacy technician shall notify the pharmacist in charge in writing of his or her determination, specifying the circumstances of concern with respect to the pharmacy or the pharmacy technician that have led to the determination, within a reasonable period, but not to exceed 24 hours, after the posting of the relevant schedule. An entity employing a pharmacist shall not discharge, discipline, or otherwise discriminate against any pharmacist in the terms and conditions of employment for exercising or attempting to exercise in good faith the right established pursuant to this paragraph.

(g) Notwithstanding subdivisions (a) and (b), the board shall by regulation establish conditions to permit the temporary absence of a pharmacist for breaks and lunch periods pursuant to Section 512 of the Labor Code and the orders of the Industrial Welfare Commission without closing the pharmacy. During these temporary absences, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. The pharmacist shall be responsible for a pharmacy technician and shall review any task performed by a pharmacy technician during the pharmacist's temporary absence. This subdivision shall not be construed to authorize a pharmacist to supervise pharmacy technicians in greater ratios than those described in subdivision (f).

~~(h) Notwithstanding Section 10231.5 of the Government Code, the board shall review the ratio of pharmacy technicians described in subdivision (f) on a biennial basis and provide a report to the Legislature, as set forth in Section 9795 of the Government Code,~~

~~with legislative recommendations if the board decides a change in the ratio is necessary.~~

~~(i)~~

(h) The pharmacist on duty shall be directly responsible for the conduct of a pharmacy technician supervised by that pharmacist.

~~(j)~~

(i) In a health care facility licensed under subdivision (a) of Section 1250 of the Health and Safety Code, a pharmacy technician's duties may include any of the following:

(1) Packaging emergency supplies for use in the health care facility and the hospital's emergency medical system or as authorized under Section 4119.

(2) Sealing emergency containers for use in the health care facility.

(3) Performing monthly checks of the drug supplies stored throughout the health care facility. Irregularities shall be reported within 24 hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with the health care facility's policies and procedures.

O

AMENDED IN SENATE APRIL 4, 2017

AMENDED IN SENATE MARCH 20, 2017

SENATE BILL No. 351

Introduced by Senator Roth
(Principal coauthor: Senator Stone)

February 14, 2017

An act to amend ~~Section~~ *Sections* 4029 *and 4400* of, and to add Section 4127.15 to, the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

SB 351, as amended, Roth. Hospital satellite compounding pharmacy: license: requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists and pharmacies by the California State Board of Pharmacy. A knowing violation of the Pharmacy Law is a crime. Existing law prohibits the operation of a pharmacy without a license and a separate license is required for each pharmacy location.

Under existing law, a hospital pharmacy means and includes a pharmacy, licensed by the board, located within any licensed hospital that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets specified requirements. A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated under a hospital's consolidated license as a general acute care hospital that includes more than one physical plant maintained and operated on separate premises or that has multiple licenses for a single health facility on the same premises. As a condition of licensure by the board, the pharmacy in

another physical plant is required to provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as specified. Existing law requires a pharmacy compounding sterile drug products to possess a sterile compounding pharmacy license.

With respect to a hospital pharmacy located outside of the hospital in another physical plant, this bill would redefine a "hospital pharmacy" as regulated as a general acute care hospital, as defined.

This bill would authorize the board to issue a license to a hospital satellite compounding pharmacy meeting specified ~~requirements and~~ *requirements. The bill* would make ~~the license~~ *a license* subject to *a fee and an* annual ~~renewal.~~ *renewal fee, as specified.* The bill would define a hospital satellite compounding pharmacy as an area licensed by the board to perform sterile compounding that is separately licensed by the board to perform that compounding and located outside of the hospital in another physical plant that is regulated as a general acute care hospital. The bill would require a hospital satellite compounding pharmacy to compound sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located. The bill would also require the services to be directly related to the services or treatment plan administered in the physical plant. The bill would require a hospital satellite compounding pharmacy to comply with specified requirements relating to, among other things, purchasing, supervision, and recall and adverse effect notices.

By imposing new requirements on these pharmacies, the knowing violation of which would be a crime, the bill would impose a state-mandated local program.

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

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

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

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

SECTION 1. Section 4029 of the Business and Professions Code is amended to read:

4029. (a) "Hospital pharmacy" means and includes a pharmacy, licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of this chapter and the rules and regulations of the board.

(b) A hospital pharmacy also includes a pharmacy that may be located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located, except as provided in Article 7.6 (commencing with Section 4128). The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant. Nothing in this subdivision shall be construed to restrict or expand the services that a hospital pharmacy may provide.

(c) "Hospital satellite compounding pharmacy" means an area licensed by the board to perform sterile compounding that is separately licensed by the board pursuant to Section 4127.15 to perform that compounding and is located outside of the hospital in another physical plant that is regulated as a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code.

SEC. 2. Section 4127.15 is added to the Business and Professions Code, to read:

4127.15. Subject to the requirements of this section, the board may issue a license to a hospital satellite compounding pharmacy. *The license fee and annual renewal fee shall be in an amount established by the board in subdivision (u) of Section 4400.* The license ~~shall be renewed annually and~~ shall not be transferable.

(a) A hospital satellite compounding pharmacy license shall not be issued or renewed until the location is inspected by the board and found to be in compliance with this article and regulations adopted by the board.

(1) A hospital satellite compounding pharmacy shall compound sterile drug products for administration only to registered hospital

patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

(2) The services provided shall be directly related to the services or treatment plan administered in the physical plant.

(b) A hospital satellite compounding pharmacy license shall not be issued or renewed until the board does all of the following:

(1) Reviews a current copy of the hospital satellite compounding pharmacy's policies and procedures for sterile compounding.

(2) Reviews the hospital satellite compounding pharmacy's completed self-assessment form as described in Section 1735.2 of Title 16 of the California Code of Regulations.

(3) Receives a list of all products compounded by the hospital satellite compounding pharmacy since the last license renewal.

(c) A hospital satellite compounding pharmacy shall do all of the following:

(1) Purchase, procure, or otherwise obtain all components through the license of the hospital pharmacy as defined in subdivision (a) of Section 4029.

(2) Satisfy the ratio of not less than one pharmacist on duty for a total of two pharmacy technicians on duty.

(3) Ensure immediate supervision, as defined in Section 70065 of Title 22 of the California Code of Regulations, by a pharmacist of licensed ancillary staff involved in sterile compounding.

(4) Provide to the board, within 12 hours, any recall notice issued by the hospital satellite compounding pharmacy for sterile drug products it has compounded.

(5) Report to the board, within 12 hours, adverse effects reported or potentially attributable to the sterile drug products compounded by the hospital satellite compounding pharmacy. Unexpected adverse effects shall also be, within 12 hours, reported to the MedWatch program of the federal Food and Drug Administration.

SEC. 3. Section 4400 of the Business and Professions Code, as added by Section 26 of Chapter 799 of the Statutes of 2016, is amended to read:

4400. The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a

temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, or as a designated representative-3PL pursuant to Section 4053.1, shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative or designated representative-3PL shall be two

hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(*l*) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license *or a hospital satellite compounding pharmacy* shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall

be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to

cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) This section shall become operative on July 1, 2017.

~~SEC. 3.~~

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

O

AMENDED IN SENATE APRIL 26, 2017

AMENDED IN SENATE MARCH 23, 2017

SENATE BILL No. 716

Introduced by Senator Hernandez

February 17, 2017

An act to amend Section 4001 of the Business and Professions Code, relating to professions and vocations.

LEGISLATIVE COUNSEL'S DIGEST

SB 716, as amended, Hernandez. California State Board of Pharmacy: pharmacy technician member.

The Pharmacy Law establishes the California State Board of Pharmacy within the Department of Consumer Affairs for the licensure and regulation of pharmacists and pharmacies. Under that law, the board is comprised of 13 members, including 7 competent pharmacists appointed by the Governor and 6 public members appointed as specified.

This bill would increase the number of members of the board to ~~14~~ *15* by adding one pharmacy technician *appointed by the Governor and one additional public member* appointed by the Governor. The bill would require ~~this~~ *the* pharmacy technician board member to have at least 5 years of experience and to continue to work in California as a pharmacy technician. The bill would require the pharmacy technician board member to have specified work experience as a pharmacy technician and to have documented work experience in a variety of pharmacy procedures and practices, as specified.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

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

SECTION 1. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of ~~14~~ *15* members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint one pharmacy technician as a member of the board. The Governor shall appoint ~~four~~ *five* public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) (1) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(2) (A) The pharmacy technician board member shall have at least five years of experience and shall continue to work in California as a pharmacy technician.

(B) The pharmacy technician board member shall have work experience as a pharmacy technician in at least two of the following health care settings:

(i) Acute care hospital.

(ii) Outpatient ~~care clinic.~~ *pharmacy.*

(iii) Long-term care ~~facility.~~ *pharmacy.*

~~(iv) Primary care clinic.~~

(iv) Community pharmacy.

(C) The pharmacy technician board member shall have documented work experience in a variety of pharmacy procedures and practices, including, but not limited to, procedures and practices related to sterile compounding, medication reconciliation, medication history, and automated drug delivery devices.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of his or her successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2021, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

O

TO: Paige Heckathorn
FROM: Robert Choy
RE: State Policy Options to Tackle Drug Pricing

May 26, 2017

Background

In 2014, prescription drugs accounted for $97 billion in Medicare spending (Kaiser Family Foundation, 2016) and $22 billion in Medicaid spending (Medicaid and CHIP Payment and Access Commission, 2016). States – who pay for the cost of prescription drugs through their Medicaid programs, Medicare Part D contributions, and by managing the health benefits of state employees – have an interest in controlling drug spending. They also have an interest in controlling drug spending as a service to residents.

This memo briefly describes common and feasible policy proposals that attempt to systematically reduce the price of – or restrain the growth in cost of – prescription drugs in states sold to government programs or consumers. It then surveys 2017 legislative attempts to implement the proposals and, where applicable, reviews relevant action taken by the Hawaii State Legislature. Finally, the memo reviews potential ways to implement the policy proposals during the next legislative session and the history of similar proposals from previous years.

Options

Regulation of Pharmacy Benefit Managers

A pharmacy benefit manager (PBM) is a third party responsible for administering an insurance plan's drug benefits. PBMs contract with pharmacies, develop formularies, negotiate discounts from manufacturers, and process drug claims. PBMs provide prescription drug benefits for more than 260 million Americans (Winegarden, 2017). By using purchasing power aggregated from contracts with multiple insurers, PBMs can negotiate better discounts from manufacturers. PBMs can also steer patients to cheaper generics. PBMs should pass on some of those negotiated savings to consumers as well as encourage the use of lower-priced generics, theoretically reducing system costs. However, as a third party, PBMs may have incentives that increase the cost of prescription drugs.

For example, many PBMs charge fees to pharmacies based on a percentage of a drug's initial purchase price. This means that they get more money from rebates (where they receive a discount after purchase) rather than discounts (where they receive a discount before purchase). To maximize money made from fees, PBMs may steer patients towards brand-name drugs with higher prices rather than cheaper generics. Manufacturers – in anticipation of having to offer large discounts – may raise their prices to maintain revenue. The price that PBMs pay to manufacturers may be significantly different from what it bills insurers, but PBMs do not disclose these amounts to either party (Ramsey & Gould, 2017). The inability of manufacturers or insurers to see prices hinders their ability to negotiate and allows PBMs to maintain high charges.

On May 3, 2017, the Hawaii State Legislature passed HB 1444. This bill prohibits PBMs from operating in the state unless they register with the insurance commissioner.[1] As part of their registration, PBMs must provide the commissioner information about the company's governing board and the information of anyone else who "exercises control or influence over the affairs of" the PBM.[1] Individual pharmacists and

[1] Relating to Pharmacy Benefit Managers, HB 1444, 29th Hawaii Legislature (2017)

disease advocacy organizations supported the bill. Although the industry opposed the measure, no elected official throughout the legislative process voted against the bill. In the committee report for the final version of the measure, the Hawaii State Legislature stated that the bill would be, "… a first step toward regulating the pharmacy benefit management industry" (Committee on Conference, 2017).

It is not clear how Hawaii will regulate PBMs in the future, but one proposal in California would require PBMs to "exercise a duty of good faith and fair dealing" to a purchaser and to provide information about drug acquisition costs, received rebates, and rates negotiated with pharmacies.[2] A previous version of the same measure required PBMs to act as fiduciaries to purchasers.[2] Nebraska took a more limited approach to PBMs and introduced a bill to require PBMs to disclose pricing information to parties they contract with.[3]

Coupon Prohibitions

In 2017, two states introduced legislation to prohibit manufacturers from offering consumers coupons for brand-name drugs when generic versions are available (National Academy for State Health Policy, 2017). Although coupons reduce the out-of-pocket cost of prescriptions to consumers, they may increase costs to insurers and governments because patients tend to choose the more expensive name-brand drug over the clinically equivalent and cheaper generic. These increased costs to the system result in higher premiums.

Massachusetts was the last state to have a total ban on coupons for prescription drugs sold in the state, but it lifted this restriction in 2012 (Goldberg, 2012) and has repeatedly extended the repeal date (O'Donnell, 2016). Despite this, increasing awareness of how coupons may contribute to increased prices has policymakers rethinking their legality (O'Donnell, 2016). Though no state introduced a bill to make them illegal in all circumstances, California[4] and New Jersey[5] introduced bills that would make them illegal to use when a generic is available. Only the California proposal, however, has progressed through its lawmaking body. It is unclear how much further California's bill will go. Many organizations that supported and opposed the bills – mostly insurers and manufacturers, respectively – in the first committee hearing (Assembly Committee on Health, 2017) did not show up to a subsequent hearing (Assembly Committee on Appropriations, 2017).

Price Transparency and Regulation

In 2017, twenty-eight states introduced legislation to create greater price transparency (National Academy for State Health Policy, 2017). Price transparency is when payers have accurate information as to an item's cost and – in the pharmaceutical context, most commonly – the factors contributing to that cost. The goal of such disclosure is to increase the amount of information available to payers to enable them to negotiate better prices, help consumers better evaluate a product or service's value, or to embarrass drug companies that unreasonably inflate drug prices.

Although proposals differed, bills typically targeted drugs that were clinically important, cost more than a specified amount per unit, or whose prices increased beyond certain thresholds. For example, one bill introduced in Maine would have empowered the attorney general to identify prescription drugs with a

[2] An act to add Division 121 (commencing with Section 152000) to the Health and Safety Code, relating to pharmacy benefits, AB 315, 2017 Regular Session of the California State Legislature (2017)
[3] Adopt the Pharmacy Benefit Fairness and Transparency Act, LB 324, 105th Legislature of Nebraska (2017)
[4] An act to add Article 7 (commencing with Section 111647) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to public health, AB 265, 2017 Regular Session of the California State Legislature (2017)
[5] An Act concerning prescription medications and supplementing Title 24 of the Revised Statutes, S. 2769, 217th New Jersey Legislature (2017)

"substantial public interest" and allowed him or her to require manufacturers to release information about the drug's research and development costs, marketing costs, and the drug's retail price domestically and abroad.[6] Nevada had a similar proposal that would require manufacturers of diabetes medications whose wholesale price exceeded the highest price paid in a foreign country or whose price increased more than a certain amount to report cost information to the state.[7]

New York state, in the budget bill for its health and mental health programs, included a new section establishing a total limit on Medicaid drug expenditures.[8] If the state projects that drug-related expenses will exceed this cap, the law authorizes the commissioner to refer drugs to the Drug Utilization Review Board (DURB) who may then recommend that the manufacturer provide a rebate to the Medicaid program.[8] The DURB may consider the drug's impact on exceeding the cap, whether the drug's price has increased unjustifiably, and whether it is priced proportionately to its benefits.[8] If there is no agreement between the DURB and the manufacturer, the DURB can require the manufacturer to disclose development costs, advertising costs, prices charged for the drug abroad, and average or anticipated profit margins.[8]

In 2017, ten states introduced legislation to regulate the price of pharmaceuticals (National Academy for State Health Policy, 2017). Price regulation attempts to limit the amount of money payers spend by setting price ceilings based on a formula or on what other entities pay.

States took very different approaches to regulating prices. For example, one proposal in Maine would have forbade the state from purchasing any drugs – after taking into consideration all available discounts – whose price was greater than what the Department of Veterans Affairs paid.[9] The New York State Senate introduced a bill prohibiting "price gouging", defined as a "gross disparity" between the price of a pharmaceutical as compared to its price six months ago or a price that "grossly [exceeds]" the price readily obtainable by other payers, to set a price ceiling on drug cost increases.[10]

Legislative Action in 2018

Further Regulate PBMs

Given the ease with which HB 1444 passed and the language contained in its committee reports, the Hawaii State Legislature seems ready to further regulate PBMs. However, the best approach to regulating PBMs is unclear. One option would be to mandate the standard of care PBMs owe to purchasers, as California is attempting to do. Whether this is a fiduciary duty (as Maine required in 2003[11], but repealed in 2011[12]), a duty of "good faith and fair dealing" (as California proposes[2]), or something else entirely remains to be discussed. More narrowly, it is also possible to require PBMs to disclose their business dealings either to the state or purchasers rather than mandate the standard of care, as Nebraska's proposal does.

The most recent previous proposal to regulate PBMs in Hawaii was SB 2900, introduced in 2010, which would have required PBMs contracted with the Employer-Union Health Benefits Trust Fund to pass on

[6] An Act To Promote Prescription Drug Price Transparency, LD 1406, 128th Maine Legislature (2017)
[7] SB 265, 79th Session of the Nevada State Legislature (2017)
[8] S 2007, 2011th New York Legislature (2017)
[9] An Act To Provide Drug Price Relief, LD 652, 128th Maine Legislature (2017)
[10] Relates to the price gouging of pharmaceuticals, SB 2402, 211th New York Legislature (2017)
[11] Pharmaceutical Care Management Ass'n v. Rowe 429 F. 3d 294 - Court of Appeals, 1st Circuit 2005
[12] An Act To Restore Market-based Competition for Pharmacy Benefits Management Services, LD 1116, 125th Maine Legislature (2011)

any savings they received because of their negotiations.[13] There have been other proposals to regulate PBMs in earlier years, but limitations of the Capitol website necessitate a visit to the State Archives to obtain more information. Without more data and investigation to examine the benefits, drawbacks, and legality of PBM regulatory proposals, an interim solution might be to convene a working group through a concurrent resolution.

Prohibit Coupons

Federal law already prohibits the use of coupons in federal healthcare programs like Medicare and Medicaid because they constitute kickbacks under the False Claims Act (Department of Health and Human Services, 2014). However, their use in commercial health plans still creates incentives that increase the cost of care. To my knowledge, nobody has ever introduced a bill to prohibit the use of drug coupons in Hawaii. Legislation – if introduced – should be based on California's bill, which seems to be the most developed and contains important exemptions for state programs, charities, and drugs related to the prevention or treatment of HIV.[4]

Price Transparency and Regulation

Creating drug pricing transparency and implementing processes to identify and contain overpriced drugs is also an option. During the 2017 session, the only bills tackling prescription drug prices related to the workers' compensation system – a perennial topic since Hawaii has the highest reimbursement rates in the nation. Bills proposed reducing the reimbursements from 140% of the average wholesale price to 90%[14] or -10%[15].

However, the most recent bill relating to price transparency was introduced in 2008. The bill would have required manufacturers to give the state quarterly reports about their average wholesale price, wholesale acquisition cost, average manufacturer price, and Medicaid best price.[16] The most recent bill to attempt to regulate the price of drugs sold in the state was also introduced in 2008. The bill would have made it illegal to charge "excessive prices" – defined as being more than 30% higher than the price in the United Kingdom, Germany, Canada, or Australia – and created a civil judicial remedy.[17] To defend against such an accusation, the manufacturer would have to disclose its development and production costs.[17]

Considering that it has been almost a decade since the Hawaii State Legislature looked at systematic prescription drug transparency or price regulation bills, it may be an opportune time to do so. However, choosing among proposals is a difficult task. New York's creation of the DURB seems to be a reasonable, compromise-focused way to control prescription drugs costs in the Medicaid program and create transparency, but it is not clear whether the benefit of cost control is enough to outweigh the difficulty of added administrative complexity. A more limited proposal to require confidential disclosure of pricing information to the state as a condition of participation in the state's Medicaid formulary might also be an option. In any case, if introducing a bill would be premature, establishing a working group through a concurrent resolution would be one way to further explore the issue and generate information that could inform action in 2019.

[13] Relating to the Employer-Union Health Benefits Trust Fund, SB 2900, 25th Hawaii State Legislature (2010)
[14] Relating to Workers' Compensation, HB 705, 29th Hawaii Legislature (2017)
[15] Relating to Workers' Compensation, HB 706, 29th Hawaii Legislature (2017)
[16] Relating to Prescription Drugs, HB 6, 24th Hawaii State Legislature (2007)
[17] Relating to Prescription Drugs, HB 8, 24th Hawaii State Legislature (2007)

Works Cited

Assembly Committee on Appropriations. (2017). *Assembly Committee on Appropriations.* Sacramento: California State Assembly. Retrieved May 24, 2017, from http://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180AB265

Assembly Committee on Health. (2017). *Assembly Committee on Health.* Sacramento: California State Assembly. Retrieved May 24, 2017, from http://leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180AB265

Committee on Conference. (2017). *Conference Committee Report for HB 1444.* Honolulu: Hawaii State Legislature. Retrieved May 24, 2017, from http://www.capitol.hawaii.gov/session2017/CommReports/HB1444_CD1_CCR38_.htm

Department of Health and Human Services. (2014, September). *Pharmaceutical Manufacturer Copayment Coupons*. Retrieved May 25, 2017, from Office of the Inspector General: https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/SAB_Copayment_Coupons.pdf

Goldberg, C. (2012, July 16). *Mass., 50th State, Now Allows Drug Coupons: What You Need To Know*. Retrieved May 26, 2017, from WBUR: http://commonhealth.legacy.wbur.org/2012/07/drug-coupons-massachusetts

Hawaii State Department of Human Services. (2011). *Department of Human Services Annual Report on 2011*. Honolulu: Hawaii State Department of Human Services. Retrieved May 25, 2017, from http://files.hawaii.gov/dhs/main/reports/AnnualReports/DHS%20Annual%20Report%20FY%202011.pdf

Kaiser Family Foundation. (2016, July 7). *10 Essential Facts About Medicare and Prescription Drug Spending*. Retrieved May 22, 2017, from The Henry J. Kaiser Family Foundation: http://kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/

Medicaid and CHIP Payment and Access Commission. (2016). *Medicaid Spending for Prescription Drugs.* Washington, DC: Medicaid Spending for Prescription Drugs. Retrieved May 22, 2017, from https://www.macpac.gov/wp-content/uploads/2016/01/Medicaid-Spending-for-Prescription-Drugs.pdf

National Academy for State Health Policy. (2017, April 27). *NASHP's Prescription Drug Cost Workgroup.* Retrieved May 22, 2017, from National Academy for State Health Policy: http://nashp.org/wp-content/uploads/2016/09/2017-Rx-Legislation-Tracker-4.27.pdf

National Academy for State Health Policy. (2017, April 27). *State Legislative Action on Pharmaceutical Prices*. Retrieved May 22, 2017, from National Academy for State Health Policy: http://nashp.org/state-legislative-action-on-pharmaceutical-prices/

National Conference of State Legislatures. (2016, November 4). *Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans*. Retrieved May 24, 2017, from National Conference of State Legislatures: http://www.ncsl.org/research/health/bulk-purchasing-of-prescription-drugs.aspx#NMPI

O'Donnell, J. (2016, June 8). *Drug co-pay assistance programs facing increasing state, federal scrutiny*. Retrieved May 26, 2017, from USA Today:

https://www.usatoday.com/story/news/politics/2016/06/08/drug-co-pay-assistance-programs-facing-increasing-state-federal-scrutiny/85547788/

Ramsey, L., & Gould, S. (2017, April 25). *A huge pharma middleman just lost its biggest customer — and it shows how drug pricing really works*. Retrieved May 24, 2017, from Business Insider: http://www.businessinsider.com/express-scripts-esrx-anthem-not-renewing-pbm-2017-4

Winegarden, W. (2017, March 7). *Reform Pharmacy Benefit Managers (PBMs) To Improve Pharmaceutical Affordability*. Retrieved May 24, 2017, from Forbes Magazine: https://www.forbes.com/sites/econostats/2017/03/07/reform-pharmacy-benefit-managers-pbms-to-improve-pharmaceutical-affordability/#334543ff7635