Medication Safety Committee Meeting

October 11, 2017

California Hospital Association - Boardroom

1215 K Street, Suite 800

Sacramento, CA, 95814

Conference Call Option:

800-882-3610 passcode: 4206832#

Meeting Book - Medication Safety Committee Meeting

AGENDA

10:00 I. CALL TO ORDER/INTRODUCTIONS
Hanni

A. Roster/Member Map/Member Breakdown — Page 5

B. 2018 Meeting Schedule — Page 11

C. Membership Updates

D. Committee Guidelines — Page 12

10:15 II. MINUTES
Hanni/Fong — Recommend: Approval

A. Meeting Minutes - July 5, 2017 — Page 17

10:20 III. OLD BUSINESS

A. Sterile Compounding Update
Hanni/Fong

1. USP 800

a. Extension Date — Page 23

b. Staff Medical Surveillance & Monitoring

c. Environmental Monitoring

2. BoP Waiver Process
Herold

a. Present and Continuation Status

b. CDPH Approval Issue and Intersection with CAU Process

3. Nursing Sterile Compounding
Bartleson

a. BRN

4. Education/Resources
All

a. FAQ's

b. Other Suggestions

c. TJC - Learn Ways to Reduce Sterile Medication Compounding Risks — Page 29

B. Medication Safety Toolkit
Bartleson

1. Toolkit Location on CHA Website — Page 35

2. Outstanding Tools

C. Medication Reconciliation/Safe Medication Transitions
Forsey/Shane

1. HQI - ADE Work Related to Medication Lists — Page 45
Forsey - HQI

2. Medication List Infographic — Page 46
Shane

3. Improving Admission Medication Reconciliation - Study — Page 49

4. Skilled Nursing Facility Transitions and Reduction in Readmissions — Page 58

5. Next Steps
All

11:30 D. Reducing Harm from Respiratory Depression in Non-ICU Patients through Risk Mitigation and Respiratory Monitoring
Munoz

12:00 IV. LUNCH

12:30 V. NEW BUSINESS

A. Hospice Facility and Use of ADD — Page 65
Bartleson

B. Issues Facing the Pharmacy Workforce — Page 69

C. IV Solutions — Page 79
Bartleson

D. Hep A Vaccine — Page 82
Bartleson

1:15 VI. STANDING REPORTS

A. Board of Pharmacy
Herald

B. CDPH

Lee/Woo

C. CSHP
DeMartini

D. CALNOC
Foley

E. ACNL

F. CHPSO
Jaffe

G. CAHF
Hall

1:30 VII. OTHER BUSINESS
All

1:30 A. 340 B Program — Page 89
Amber Ott

B. AHA Executive Dialogue at Leadership Summit — Page 94
Herman

C. Braun IV Solution Shortage — Page 95

D. Hep A Vaccine
Bartleson

VIII. NEXT MEETING

A. Wednesday, January 10, 2018

2:00 IX. ADJOURNMENT
Hanni

MEDICATION SAFETY COMMITTEE
2017

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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
Vicky Ferraresi	Sutter Health, Bay Area	Santa Clara

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
Virginia Herold	California Board of Pharmacy	Sacramento

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

August 28, 2017

TO: Medication Safety Committee Members

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

SUBJECT: Proposed 2018 Meeting Schedule

Following is the proposed meeting schedule for 2018 Medication Safety Committee meetings:

January 10, 2018	Sacramento, CHA Offices Board Room
April 4, 2018	Sacramento, CHA Offices Board Room
July 11, 2018	Sacramento, CHA Offices Board Room
October 10, 2018	Sacramento, CHA Offices Board Room

You will receive a save-the-date approximately one month prior to each meeting to verify your attendance/participation.

Thank you and if you have any questions, please feel free to call me directly at (916) 552-7537.

BJB:br

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
July 5, 2017 / 10:00 a.m. – 2:00 p.m.

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Jeannette Hanni, Vicky Ferraresi, Amy Gutierrez, Candace Fong, Kevin Dorsey-Tyler, Virginia Herold, Rita Shane, Art Woo, Kathy Ghomeshi, Doug O'Brien, Chris Patty, Loriann DeMartini, Nasim Karmali, Cari Lee, Lisa Hall, Diane Schultz, Christine Low, Terri Vidals, Mary Foley, Rory Jaffe

Members on Call: John Christensen, Susan Herman, Sarah Stephens, Dan Ross, Julia Slininger, Carolyn Brown, Eddie Avedikian

Members Absent: Katie Choy, Edna DeLeon, Richard Rabens

Guest: Patti Kienle, Director, Accreditation and Medication Safety Cardinal Health Innovative Delivery Solutions

CHA Staff: BJ Bartleson, Barb Roth, David Perrott

I. CALL TO ORDER/INTRODUCTIONS

The committee meeting was called to order by co-chair Jeannette Hanni at 10:00 a.m. Introduction of new member Chris Patty to the committee.

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the April 5, 2017, Medication Safety Committee meeting were reviewed.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: minutes approved as submitted.*

III. OLD BUSINESS

A. Sterile Compounding Regulations Update

Ms. Herold advised that numerous waivers processed and those waivers denied were offered the option to resubmit. Some were withdrawn. There is a waiver request deadline of July 1, 2018, when USP 800 compliance begins. Any waiver with a date after this will be denied. Construction can continue, but the facility will not be insulated from CMS USP 800 compliance and regulatory review. Any hospital receiving a waiver denial can request a meeting with the Board.

- *ACTION – no action – information only*

B. Medication Safety Toolkit

1. Medication Safety Toolkit Tracking

   - *ACTION: Information only*

2. Anticoagulant Tool

   - *ACTION: Complete - Part 2 in packet*

3. Track and Trace Law FAQs

   - *ACTION: FDA just changed deadlines again. Mr. O'Brien will update.*

4. ED Medication Management Safety Tool

   - *ACTION: Ms. Hanni will review for update*

5. Recommendations for Improving Safety of Opioid Use Tool

   - *ACTION: Mr. Ross and Ms. Ferraresi will update.*
   - *Ms. Shane advised that there is a webinar in a couple of weeks on opioid work. She will provide webinar information – Ms. Roth to send out to committee. (DONE)*
   - *Ms. Ghomeshi also provided a link with information on this topic – Ms. Roth to send out to committee. (DONE)*

6. Nursing Sterile Compounding

   - *ACTION: Ms. Bartleson is following*

7. Reducing Controlled Substance Diversion Tool

   - *ACTION: Complete*

8. Insulin Recommended Safe Practice Tool
   Recommendation made to drop this item from the toolkit because California guidelines are not different from ISMP. Reminder that this tool was requested so that information would be available to small and rural hospitals who may not have access to multiple resources. Mr. Ross submitted a version to committee. However, since then there are updated guidelines he will do another update to the tool

   - *ACTION: Mr. Ross will review and update the guidelines and they will be placed in the toolkit. Add a place in tool giving details on how to find further information.*

9. SB 1039 Implementation

   - *ACTION: No discussion.*

C. Medication Reconciliation

Dr. Perrott works with The Joint Commission and expressed concern about the objectives of the committee regarding medication reconciliation. Previously, TJC pulled back on the National Patient Safety Goals on this topic. At the current time, they are monitoring this issue, but not preparing to put anything out. The received tremendous pushback – challenges with physicians, nursing, patients, flow-through, pharmacy. Dr. Perrott expressed that he does not want to see the committee call for this issue to become a mandate. He suggests that we see how it ties in with Adverse Drug Event (ADE) at HQI.

Ms. Shane indicated that she was engaged in discussions with TJC and has provided evidence of the breadth of the problem. There is a clear need for ownership in California in the acute care setting – need to improve patient safety.

Ms. Hanni expressed that there is a difference between then (TJC discussion) and now and – is there is a potential solution. Is it possible to promote pharmacists and technicians taking ownership of the high-risk patient medical records? Dr. Perrott again stated that TJC has no plans to come forward to address this.

Dr. Jaffe added that there are different types of medication reconciliation, for example, - patient intake and patient discharge points are critical areas. Different solutions can be developed for each of the phases. However, this needs to be done without mandating additional labor or resources, particularly for smaller hospitals.

Dr. Perrott discussed South Carolina's standardized format/system for medication reconciliation upon discharge. He again stressed the need to bring HQI in to discuss with the committee what they're doing.

Ms. Shane expressed that the goal is not to solve the medication reconciliation problem. This is a measure to ensure accurate medication history at the intake point Making the best of use of appropriate personnel to create an intake medication list for the highest risk patients (elderly patients and patients on many medications). Data shows there is a problem along the continuum of care and this is an opportunity to prevent and correct this problem

Ms. DeMartini suggested reviewing long-term care and public health accreditation, for example, the health assessment domain, to look at problematic areas. Language exists in Appendix A and Appendix PP that would allow clarification and establish a framework to address this. There is enough there for this group to create guidelines or initiatives.

Dr. Jaffe suggested that this can be accomplished without regulatory change. This topic needs to be brought to HQI.

Ms. Bartleson indicated a need to re-invigorate the topic. The committee can start with revisiting medication reconciliation. Try to encourage people to do it, raise level of awareness, getting people involved. . Link it to readmission rates, and ADE's HQI can be another communication vehicle ashey have a voice with the CHA board of trustees.

Ms. Foley, suggested a need to review and refocus attention on the topic. – .

- *ACTION: continue committee evaluation and study.*

IV. NEWBUSINESS

A. AHA Quality Advisory Regarding Codeine and Tramadol Warning

Ms. Fong asked the committee what their hospitals are doing about this alert. They received pushback from outpatient medical groups.

Mr. O'Brien advised that pediatricians have been working for a while to eliminate use of codeine.

Ms. Ghomeshi advised that in 2013 their facility eliminated codeine in pediatrics. There remains a concern about breast-feeding mothers and pediatric patients 12-18 years old.

- *ACTION: Information only*

B. USP 800 Impact on Physician Office Practice

Guest – Patti Kienle

Ms. Hanni presented a PowerPoint highlighting information on the topic. (This wasn't in the packet- I need a copy and wondering if it should be distributed to the committee)
Ms. Kienle advised that not every drug needs to be treated the same way. Some antibiotics or antipsychotics require an assessment of risk. Perhaps put in alternative strategies based on individual pharmacy risk
Patti Kienle has published an assessment of risk article

With full attention paid to hospital pharmacies and sterile compounding, there is now attention being focused on non-pharmacy sterile compounding activities. The committee questioned what was being done in physician and non-hospital areas.

- *ACTION: Dan Ross provided the assessment article that Ms. Kienle published. Ms. Roth to send out after the meeting (DONE)*

C. Non Sterile Hazardous Compounding

Ms. Bartleson discussed some proposals recommended by Maria Serpa to the BoP. For example, using/constructing a receiving area for receiving hazardous drugs if, for instance, a drug container comes in broken and is waiting to be returned.

- *ACTION: Information Only*

D. Medication Shortage

Ms. Shane advised her hospitals are doing inventories.
Mr. O'Brien has been talking with clinicians about alternatives, trying to decrease use rates and sharing supplies between hospitals.
Some hospitals are being allowed to import from Australia. Ms. Herold offering to help with approved outsourcing -503b agencies– QUVA in Texas has been approved.
Ms. Bartleson advised that she has only received one call regarding this issue. Most hospitals already know what to do in situations like this.
Ms. Herold emphasized the need to buy from only licensed sources.
Ms. Ghomeshi advised that ASHP has guidelines for managing drug shortages.

- *ACTION: Kathy Ghomeshi to send document to CHA – Ms. Roth to send out to committee. (DONE)*

E. Free Vaccination Programs and Barriers

Debby Rogers and Sarah Cardone discussed the Hep A outbreak in San Diego and free vaccines that are being provided. The outbreak is mostly in the homeless and illicit drug use populations. CDPH offering free vaccines to EDs for those meeting certain criteria.

The regulations are both state and federal. Some hospitals are not taking the free vaccine because, they say it is difficult to meet the temperature monitoring standards (Refrigerator temperatures have to be taken manually twice a day wherever vaccines are

stored (cannot count on the temperature gauge). If the temperature is not maintained the vaccine loses efficacy.

Group consensus is that this is a non-issue for hospital pharmacies

Maybe the concern is with the hospital disaster preparedness group not the pharmacy. All involved need to be working with the pharmacy department.

- *ACTION: information and feedback provided to Ms. Rogers from the committee.*

F. Legislation

BJ Bartleson:
AB 40 – Not controversial at this point. CalACEP's bill to integrate CURES and EHR to improve PDMP access.

SB716 – Add pharm techs on BoP – DeMartini. CHSP is co-sponsoring the bill to have pharm technician representation on the BoP. Also increasing education and expectations of pharm technicians. There is a need to raise the level of leadership and education with the pharm technicians. This bill will add 2 members to the BoP – a pharm tech and another public member. BoP is concerned about the diminished role of pharmacists on the board and the potential addition of a public member.

AB1589 – addresses the number of pharm technician being supervised. BoP advised that this bill is stalled (dead for the year) because organized labor did not like it.

SB351 – Herold - No opposition. Allow organizations to have work flow software in place and have pharmacists there when patient care taking place.

- *ACTION: Information only*

V. STANDING REPORTS

A. Board of Pharmacy (BoP) - Herold

Enforcement committee next week – topics to include:

1. Proposal to require an employee that has stolen drugs be reported to the police so there is a record with the BoP. The person's license can be suspended so they cannot continue working elsewhere.
2. Holding more drug diversion loss webinars
3. Safe medication transition upon discharge
4. Manufacturer's recalls – study over last 3 years
5. Request that wholesalers notify BoP of suspicious reports as well as DEA
6. CA state auditor report on drug takeback programs.
7. Compounding – recommendations.

Technician ratios and skillset review will be discussed at upcoming licensing meeting.

B. CDPH – Lee, Woo, Christensen

Robert Menet retired at the end of May.

Relicensing survey ongoing through February 28, 2018.

C. CSHP - DeMartini

Keynote speaker is Joe Kiani at seminar later this year in Las Vegas.
Launching 4 certificate programs.
Launched compounding class with BoP.
Considering another conference in the spring 2018.

D. CALNOC – Foley

Looking at pilot testing for ambulatory care measures. Talking with agencies across the country.

E. ACNL – Foley

Active search for a new director to replace Pat McFarland.

F. CHPSO – Jaffe

Job vacancy. CHPSO needs a clinician and is targeting a pharmacist – There is a requirement that the person work in Sacramento.
CHPSO continues to issue ADE alerts. Latest one is on entrothecal therapy and one about opioids and benzodiazepines together. –

Tubing connector update. Presently adopting ENFit connectors as there are supplies available. We urge attention on this and the supply issue will resolve in a few months.
HQI and CHA are working together to address the supply issue.
Ms. Khomeshi advised that there is only 1 manufacturer of amber syringes for light affective medication and 2 manufacturers of tamper evident syringes.
ENFit – deadline for this was last January.

G. HQI – Jaffe

No report

H. CAHF - Hall

Summer conference coming up.

VI. WORKGROUP REPORTS –

No reports at this time.

VII. NEXT MEETING

Wednesday, October 11, 2017

VIII. ADJOURNMENT

Having no further business, the committee adjourned at 2:06 PM

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Sterile Compounding Update

SUMMARY

With the extension date of USP 800, members need to understand its impact on BoP waiver deadlines. We also need to advise hospitals to continue USP 800/BoP regulatory gap analysis and vigilance on construction deadlines. Nursing Compounding has been placed on the BRN agenda for review. See outline below for discussion topics.

1. USP 800
    a. Extension Date
    b. Staff Medical Surveillance & Monitoring
    c. Environmental Monitoring
2. BoP Waiver Process
    a. Present and Continuation Status
    b. CDPH Approval Issue and Intersection with CAU Process
3. Nursing Sterile Compounding
    a. BRN
4. Education/Resources
    a. FAQs
    b. Other suggestions
    c. TJC – Learn Ways to Reduce Sterile Medication Compounding Risks (article attached)

ACTION REQUESTED

- BoP response on sterile compounding waiver deadline, and member input on next steps to advise members prepare pharmacy/pharmacists to successfully meet USP 797,800 and BoP deadlines.

DISCUSSION QUESTIONS

1. Will the BoP extend its deadline for pharmacy construction waivers?

2. What educational/informational support do members need to successfully meet deadlines?
3. How do we understand and support non-traditional sterile compounding practices that need to be addressed such as those in clinics, nursing units, medical offices?

BJB:br

Barbara Roth

From: Fong, Candace - SAC <Candace.Fong@DignityHealth.org>
Sent: Friday, September 22, 2017 2:28 PM
To: BJ Bartleson; Barbara Roth; Jeannette Hanni; Doug.C.O'Brien@kp.org
Subject: RE: FAQ Document for SC/USP800

Here is the start of my list:

- CCR 1751.3, 1735.5 (22), Pharmacist Pre-Check - prior to compounding pharmacist required to document sign-off
- CCR 1735.3 Compounding Log Elements – Equipment interpretation (syringe and needles lot number and Exp)
- CCR 1250.4 Alcohol Wipe Test – Testing for non-porous walls
- CCR 1751.4 Rotation (how often daily weekly etc…) of Germicidal and Sporicidal cleaning agent
- CCR 1751.8 and 1735.4 BUD on Label versus on the bag
- CCR 1735.3 Compounding logs need to include diluent quantities (subdivision E)
- CCR 1735.3 Compounding logs need to include unique reference or lot number (subdivision G) (each bag needs a unique number versus all bags having same unique number).
- CCR 1735.2 (e) Master formulas need to include equipment used on the form (define equipment does that mean hood, syringes, needles, pumps etc…).
- CCR ?? Training on new device at start up.
- Training and testing on ALL hoods?
- Maintaining an "immediate" use hood in pharmacy?
- "Cross contamination" plan if both hoods in same segregated area?
- Viable particle testing had to be done by TSS using a volumetric study
- "Smoke test" dynamic conditions ? Simulated compounding?

Candace Fong, PharmD
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USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

USP General Chapter <800> provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients and the environment.

The National Institute for Occupational Safety and Health (NIOSH) considers a drug to be hazardous if it exhibits one or more of the following characteristics in humans or animals: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity, organ toxicity at low doses, genotoxicity, or structure and toxicity profiles of new drugs that mimic existing hazardous drugs.

General Chapter <800> describes requirements including responsibilities of personnel handling hazardous drugs; facility and engineering controls; procedures for deactivating, decontaminating and cleaning; spill control; and documentation. These standards apply to all healthcare personnel who receive, prepare, administer, transport or otherwise come in contact with hazardous drugs and all the environments in which they are handled.

Important Updates

USP is announcing the intent to postpone the official date of General Chapter <800>. The purpose of this postponement is to align the official date of General Chapter <800> with the official date of the next revision of General Chapter <797> *Pharmaceutical Compounding — Sterile Preparations*, to provide a unified approach to quality compounding.

Important Dates

- September 29, 2017: Notification of intent to revise the official date of USP General Chapter <800>
- December 1, 2019: USP General Chapter <800> expected official date

To protect patients and healthcare workers from potential harm, USP General Chapters <800> *Hazardous Drugs – Handling in Healthcare Settings* and <797> *Pharmaceutical Compounding – Sterile Preparations* were developed to provide a complete set of standards for all healthcare workers to help ensure the safe handling of hazardous drugs throughout the healthcare system, including in the practice of compounding. The intent of the Expert Committee has always been to align these standards, providing a unified approach to quality compounding. The next revision to General Chapter <797> is anticipated to be published in the *Pharmacopeial Forum* 44(5) September/October 2018 for a second round of public comment. Both USP General Chapter <797> and USP General Chapter <800> are anticipated to become official on December 1, 2019. Sections of the revised <797> may have longer implementation dates that will allow time for adoption of the standard.

As we all move towards safer handling of hazardous drugs in the work place, USP strongly encourages early adoption and implementation of USP General Chapter <800> to protect the public health in all healthcare settings. We will continue to support our stakeholders through ongoing education and outreach.

Developing USP General Chapter <800>

Public Health Need

The need to help ensure a quality environment and to protect healthcare personnel from hazardous drugs has been a topic of concern for decades. Growing evidence highlights that acute and chronic health effects can occur due to occupational exposure to over 200 hazardous drugs used commonly in healthcare settings. While NIOSH defines criteria and identifies hazardous drugs, USP developed standards for handling these hazardous drugs to minimize the risk to public health. The goals of these standards are to help increase awareness, provide uniform guidance to reduce the risk of managing hazardous drugs, and help reduce the risk posed to patients and the healthcare workforce.

USP Process

USP is a not-for-profit, science-driven organization that has an established process for convening independent experts in the development and maintenance of healthcare quality standards. The process is public health focused, leveraging current science and technology, and draws on the expertise of scientists and healthcare practitioners while

providing opportunities for public input from stakeholders throughout the standard-setting progress.

The **USP Compounding Expert Committee** is responsible for the development of General Chapter <800>. Review their work plan and past meeting summaries. USP General Chapter <800> was published twice in the Pharmacopeial Forum for public comment. USP received over 1,300 comments from approximately 150 stakeholders during the second public comment period (Dec. 1, 2014, to May 31, 2015). All of the public comments were reviewed by the USP Compounding Expert Committee and many of them are incorporated in the final published chapter. Read the Compounding Expert Committee's responses to the public comments in the Commentary (posted Feb. 1, 2016).

Information from usp.org

Joint CommissionOnline

Oct. 4, 2017

In this issue:

Performance measurement

Pioneers in Quality webinar: Learn about ORYX reporting requirements, eCQM direct submission

The ability to receive electronic clinical quality measure (eCQM) data submissions directly from accredited hospitals has been an important goal of The Joint Commission's for several years. Apervita has been selected as The Joint Commission's technology partner in developing an eCQM direct submission platform.

Learn more at a webinar — Pioneers in Quality™: Joint Commission 2017-2018 ORYX Reporting Requirements and eCQM Direct Submission — on Tuesday, Oct. 17, from 9-10 a.m. (PT)/10-11 a.m. (MT)/11 a.m.-noon (CT)/noon-1 p.m. (ET).

Webinar participants will learn:

- Modifications to 2017 ORYX performance measurement reporting requirements, along with 2018 reporting requirements.
- The direct submission process and technical requirements.
- The Joint Commission's strategy and future vision for receiving data directly from hospitals.

Register.

Accreditation and certification

EP deletion: MM.09.01.01, EP 3 going away

Effective Oct. 1, The Joint Commission is deleting element of performance (EP) 3 for Medication Management (MM) 09.01.01 for hospitals and critical access hospitals. This EP will still be in effect for nursing care centers.

The standard states: *The [critical access] hospital educates patients, and their families as needed, regarding the appropriate use of antimicrobial medications, including antibiotics. (For more information on patient education, refer to Standard PC.02.03.01)*

The Joint Commission has received consistent feedback about the value of this education when the patients are too ill to receive and retain the information. Standard Provision of Care, Treatment, and Services (PC) 02.03.01, EP 10 — which requires patient education on the safe and effective use of medications based on the patient's condition and assessed needs — is still applicable when warranted.

The deletion will be posted on The Joint Commission's website. It will no longer be part of the *Comprehensive Accreditation Manuals* for hospitals and critical access hospitals as of the fall 2017 E-dition update and 2018 manuals. (Contact: Mary Brockway, mbrockway@jointcommission.org)

Learn ways to reduce sterile medication compounding risks

Contaminated compounded products continue to pose a safety risk to patients. And while the activities associated with sterile compounding are currently assessed during Joint Commission surveys, accredited organizations performing sterile compounding should now expect increased attention on these processes.

Environmental assessment examples	
Primary Engineering Control Area (for example, IV compounding hoods, biological safety cabinets, compounding aseptic isolators)	• ISO level • Viable particle testing surface • Viable particle testing air • HEPA filter leak test • Evidence of remediation/retesting if assessed levels were not in compliance with those listed in United States Pharmacopeial Convention (USP®) General Chapter <797> Pharmaceutical Compounding — Sterile Preparations
Secondary Engineering Control Area (for example, buffer area and ante area)	• Air exchanges per hour • Pressure differential • ISO level • Viable particle testing surface • Viable particle testing air — HEPA filter leak test • Evidence of remediation/retesting if assessed levels were not in compliance with those listed in USP General Chapter <797>
Building Structure	• Ceiling, wall, and floor evaluation • Compounding suite design evaluation

The Joint Commission wants to ensure that any potential risks presented during on-site surveys are appropriately identified in order to assist those organizations with effective risk reduction. To help identify potential risks, organizations surveyed within the Hospital and Critical Access Hospital Accreditation programs can expect additional dialogue in tracer activities, including:

- Life Safety Code® Surveyor Document Review
- Medication Management System Tracer
- Infection Control System Tracer
- Competency Assessment System Tracer

Additional surveyor time also will be spent in the compounding area itself for observation of compounding processes. Contaminants can be introduced into the medical compounding area from a variety of sources, but they are typically placed in three categories: people, products, and environment.

The preparation of hazardous medications, such as those used in chemotherapy, introduces an additional risk to compounding staff. It is important that staff understand unique workflows and additional precautions that should be taken when handling these products. During on-site evaluations, surveyors will expect to see those additional competencies as it relates to garbing and written didactic testing.

Product preparation assessment examples
• Proper handwashing and personal protective equipment use • Primary engineering control cleaning • Proper aseptic technique • Compounding workflow assessments • Beyond-use date assignments

Also, while high-risk compounding (for example, nonsterile to sterile compounding) is rare, it is necessary in certain circumstances to ensure proper treatment. Accredited organizations are reminded that additional steps are required, including, but not limited to, increased frequency of staff competency testing, adjustments in competency evaluations to assure adequate testing of compounding techniques, quality assurance testing of the sterilization method listed by the manufacturer, and any required end-product testing.

Compounding staff competency assessment examples	
Low- and medium-risk category compounding (to be completed annually)	**High-risk category compounding** (to be completed every 6 months)
• Media fill testing • Gloved fingertip sampling (initial and ongoing testing) • Written didactic testing	• Media fill testing representing complexity steps for high-risk compounding • Gloved fingertip sampling (initial and ongoing testing) • Written didactic testing
Note: Risk categories represent those listed within United States Pharmacopeial Convention (USP®) General Chapter <797> Pharmaceutical Compounding — Sterile Preparations.	

Questions about sterile medication compounding and reducing risk may be submitted via The Joint Commissions website.

New revisions for swing beds for Joint Commission-accredited hospitals, critical access hospitals
In October 2016, the Centers for Medicare & Medicaid Services (CMS) published a final rule in the *Federal Register* entitled, "Medicare and Medicaid Programs: Reform of Requirements for Long-Term Care Facilities" (See pages 68689-68690 of the final rule for the "Summary of Provisions" section). This final rule revised conditions for participation (CoPs) for swing beds in hospitals and critical access hospitals, at 482.58 and 485.645 respectively. This final rule took effect in late November 2016.

However, several technical errors were identified in this final rule. In an effort to address these errors, a corrected final rule was published in the *Federal Register* this past July. The corrected final rule should be used for hospitals and critical access hospitals to determine the regulations, beginning with CoP 483, that apply to them.

The Joint Commission has made several changes to its swing bed requirements based on this corrected final rule, which will begin to be implemented in early 2018 for critical access hospitals and hospitals using Joint Commission accreditation for deemed status purposes, once CMS has accepted them.

Some of the changes for swing beds include:

- Coordination of assessments with the pre-admission screening and resident review (PASARR) — Hospitals
- Reporting of alleged violations related to abuse and neglect within two hours or 24 hours after the allegation, depending on the type of allegation — Hospitals and Critical Access Hospitals
- Dental services policy addressing when it is the organization's responsibility for lost or damaged dentures — Hospitals and Critical Access Hospitals
- Referral of residents with lost or damaged dentures for dental services within three days — Hospitals and Critical Access Hospitals
- Incorporation of any specialized rehabilitation services into the treatment plan as a result of PASARR recommendations — Critical Access Hospitals
- Focus on patient-centered care and involvement of resident in care planning — Critical Access Hospitals
- Organization provides written notification of closure to required agencies and residents prior to impending closure — Critical Access Hospitals

The Joint Commission will begin surveying to the updated swing bed regulatory requirements on Nov. 28. Any findings related to these requirements for surveys will be cited at Leadership (LD) 04.01.01, element of performance (EP) 2 — *The hospital complies with law and regulation*. The final standards will be published in the E-dition in January 2018, once acceptance from CMS is received.

The revised CoPs will appear in the hospital and critical access hospital crosswalks. Organizations can view partial crosswalks featuring the new and revised regulations on their extranet sites. (Contact: Laura Smith, lsmith@jointcommission.org)

Phase 4 revisions for EP Review Project take effect Jan. 1
Phase 4 of The Joint Commission's EP Review Project — a multiphased component of Project REFRESH — has started, with elements of performance (EPs) across all accreditation programs being evaluated for streamlining and consolidation. Revisions from the first part of Phase 4 will be effective Jan. 1, 2018.

Consolidation was considered for requirements that were either: integral to a concept, and thus be evaluated together; and concepts that were implicit in a requirement, eliminating the need for an additional EP.

An example of an integral concept could be:

- EP A: Staff participate in ongoing education and training to maintain or increase their competency. Staff participation is documented.
- EP B: Staff participate in ongoing education and training whenever staff responsibilities change. Staff participation is documented.

EPs A and B will be consolidated into:

- EP C: Staff participate in ongoing education and training to maintain or increase their competency, and as needed whenever staff responsibilities change. Staff participation is documented.

An example of consolidation for implicit concepts is:

- EP A: The hospital has a written policy addressing the privacy of health information.
- EP B: The hospital implements its policy on the privacy of health information.

EPs A and B will be consolidated into:

- EP C: The hospital follows a written policy addressing the privacy of health information.

Phases 1 and 2 of the EP Review Project resulted in the deletion of 225 hospital EPs. Phase 3 evaluated the deleted hospital EPs that also existed in the other accreditation programs.

View the prepublication standards for revisions related to Phase 4 of the EP Review Project:

- Ambulatory health care
- Behavioral health care
- Critical access hospital
- Hospital
- Laboratory
- Nursing care center
- Office-based surgery
- Home care

Patient safety

Joint Commission president pens op-ed on role of private accreditors in improving health care

Mark R. Chassin, MD, FACP, MPP, MPH, president and chief executive officer of The Joint Commission, recently penned an op-ed in *The Hill* detailing the role of a private accreditor in improving quality and safety practices in health care.

Dr. Chassin offers a unique perspective since he has worked in both the public and private sectors to ensure health care quality, first as Commissioner of the New York State Department of Health, and now as the head of the nation's largest private healthcare accreditation organization.

"Among the many things I've learned over my career is that being a state health commissioner is very different than being a private accreditor," Dr. Chassin states in the op-ed. "The former has a duty to protect and improve the health of the public while the latter is a means of improving the way health care is delivered."

Read the op-ed.

October *JQPS*: Cancer care patients, families prioritize high-quality relationships, communication

A new study in the October issue of *The Joint Commission Journal on Quality and Patient Safety* suggests that cancer care patients and their family members prioritize high-quality relationships and communication over quality and safety concerns. Study authors suggest this may be because cancer care is primarily delivered in outpatient settings, which typically require long-term relationships with providers and frequent visits, given the complexity of care.

Limited data exists about complaints related to cancer care, with reports generally focusing on inpatient care. The study — "Evaluation of Patient and Family Outpatient Complaints as a Strategy to Prioritize Efforts to Improve Cancer Care Delivery," by Jennifer W. Mack, MD, MPH, associate professor, Pediatrics, Harvard Medical School, Boston, and associate program director, Pediatric

Hematology/Oncology Fellowship, Pediatric Oncology, Dana-Farber Cancer Institute, Boston, and co-authors — focuses on outpatient complaints made to the Patient/Family Relations Office at the Dana-Farber Cancer Institute in a two-year period.

After reviewing the complaints, the study authors found that while 48 percent of complaints involved management issues, the next largest number of complaints — 41 percent — related to relationships, including:

- Communication breakdowns — 15 percent
- Patient-staff dialogue — 5 percent
- Humanness and caring — 18 percent

Only 11 percent related to quality and safety concerns. However, these complaints were frequently of higher severity than others — emphasizing the need for high-quality relationships and communication, as well as for high-quality and safety.

Open access is available to the full cancer care study, as well as the accompanying editorial.

Also featured in the October issue are:

- "Missed Diagnosis of Cardiovascular Disease in Outpatient General Medicine: Insights from Malpractice Claims Data"
- "Clinician Perspectives on the Management of Abnormal Subcritical Tests in an Urban Academic Safety-Net Health Care System"
- "Optimizing an Enhanced Recovery Pathway Program: Development of a Postimplementation Audit Strategy"
- "Psychometric Evaluation of the Hospital Culture of Transitions Survey"
- "Toward More Proactive Approaches to Safety in the Electronic Health Record Era"
- "Quality of Septic Shock Care in the Emergency Department: Perceptions vs. Reality"

MMWR: Survey results for flu vaccination rates of health care personnel
According to an opt-in internet survey in a September issue of the Centers for Disease Control and Prevention's (CDC) *Morbidity and Mortality Weekly Report* (*MMWR*), 78.6 percent of respondents reported receiving an influenza vaccination during the 2016-2017 season.

The survey indicated higher vaccination coverage among hospital health care personnel (92.3 percent), which is similar to reported coverage in the previous three flu seasons. Vaccination coverage continued to be lower in ambulatory care (76.1 percent) and long-term care (68 percent) settings.

The survey — "Influenza Vaccination Coverage Among Health Care Personnel — United States, 2016–17 Influenza Season" — included responses from 2,438 health care personnel, and showed vaccination coverage to be highest among those required by their employer to be vaccinated (96.7 percent), with 76.5 percent of those getting vaccinated at their workplace.

According to the survey, vaccination coverage was highest among:

- Physicians – 95.8 percent
- Pharmacists – 93.7 percent
- Nurses – 92.6 percent
- Nurse practitioners and physician assistants – 92 percent

The Joint Commission's accreditation programs address influenza vaccination under the Infection Prevention and Control (IC) standard IC.02.04.01 — *The organization offers vaccination against influenza to licensed independent practitioners and staff. Note: This standard is applicable to staff and licensed independent practitioners only when care, treatment, or services are provided on site. When care, treatment, or services are provided off site, such as with telemedicine or telephone consultation, this standard is not applicable to off-site staff and licensed independent practitioners.*

The Joint Commission also has several resources and education on influenza vaccination, such as:

- Infection Prevention and HAI Portal
  - Influenza (internal)
  - Influenza (external)
  - Vaccination
- Speak Up: Prevent the Spread of Infection (video)

Read the *MMWR*.

Resources

Now available: Cultural Sensitivity for Health Care Professionals app
Health care professionals serve diverse patient populations. The need to communicate clearly, effectively, and in a way that doesn't scare or offend a patient is a must in order to provide that patient with a positive experience.

To help with the fast-moving pace of today's health care world, Joint Commission Resources is offering its best-selling guide, "Cultural Sensitivity: A Pocket Guide for Health Care Professionals," in a convenient mobile application, which can be purchased and downloaded via the iTunes or Google Play apps.

The Cultural Sensitivity app offers health care professionals supportive information to strengthen their communication with patients, while respecting cultural needs. The app covers the following cultures:

- African American
- Anglo American
- Asian
- Hispanic/Latino
- Middle Eastern
- Native American
- Russian
- South Asian
- Southeast Asian

Learn more about Joint Commission Resources' offerings online or call 877-223-6866.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Medication Safety Toolkit

SUMMARY

The CHA Medication Safety Toolkit resource site has been added to the CHA website. It can be found at https://www.calhospital.org/general-information/medication-safety-toolkit. Several finalized tools have been added.

1. Anticoagulant Tool Part I and Part II
2. Reducing Controlled Substance Diversion
3. Insulin Safe Practice

The following tool are outstanding:

1. ED Medication Management
2. Track and Trace Law FAQs
3. Sterile Compounding Grids/Tools
4. Improving Safe Opioid Use
5. Sterile Compounding Matrices
6. Nursing Sterile Compounding
7. SB 1039 Implementation

ACTION REQUESTED

- Please finalize outstanding tools to add to tool kit and recommend additional resources for future additions.

BJB:br

Medication Safety Toolkit

Resources for key medication safety topics

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

BJ BARTLESON, RN, MS, NEA-BC

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

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

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

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

Part II - Anticoagulantion Tool for Direct Oral Anticoagulants

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

1. ANTICOAGULANT TOOL 2. REDUCING CONTROLLED SUBSTANCE DIVERSION
3. INSULIN SAFE PRACTICE 4. ED MED MANAGEMENT
5. IMPROVING SAFE OPIOID USE 6. STERILE COMPOUNDING MATRICES
7. NURSING STERILE COMPOUNDING 8. SB 1039 IMPLEMENTATION
9. TRACK AND TRACE LAW FAQS

Insulin Recommended Safe Practice Guidelines

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

1. ANTICOAGULANT TOOL 2. REDUCING CONTROLLED SUBSTANCE DIVERSION
3. INSULIN SAFE PRACTICE 4. ED MED MANAGEMENT
5. IMPROVING SAFE OPIOID USE 6. STERILE COMPOUNDING MATRICES
7. NURSING STERILE COMPOUNDING 8. SB 1039 IMPLEMENTATION
9. TRACK AND TRACE LAW FAQS

Reducing Controlled Substances Diversion in Hospitals

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

Draft pending final approval by CSHP and CHA

FACILITIES AND ENGINEERING CONTROLS REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP <797> (7/1/18) Requirements

BOARD OF PHARMACY REGULATIONS -- CCR§1735 and CCR §1751 -- NON-HAZARDOUS DRUGS (Low and Medium Risk)				
SECONDARY ENGINEERING CONTROL (Sterile Compounding Space)	**PRIMARY ENGINEERING CONTROL (PEC=Sterile Compounding Hoods)**			
		LOW RISK • **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**APPLIES TO ALL**
>ISO Class 7 clean room (clean area or buffer area) with ISO 8 or better ante-area • No sink in clean room • Sink in ante-area • Minimum of 30 air changes per hour • 0.02-0.05" w.c. positive pressure differential relative to all adjacent spaces OR • Displacement airflow method: requires air velocity of >40 feet per minute from the clean area across the line of demarcation into the ante area, from floor to ceiling and wall to wall CCR §1735.1(m) & §1250.4 (1-4)	**Any ISO Class 5 PEC:** • Laminar Flow Hood OR • Biological Safety Cabinet with unidirectional flow OR • Compounding automated robots OR • Compounding Aseptic Isolators (CAI) with unidirectional flow. Air within the CAI shall not be recirculated or turbulent. CAI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State *** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Document **daily** pressure differential or air velocity, or use **continuous recording device**, between adjoining ISO rooms and spaces with immediate entry to ISO rooms. 1751.1(a)(8)
Segregated sterile compounding area • Any preparation area that is not ISO classed, exceeds ISO 7 limits, or does not meet pressure or air flow differentials • Sterile to sterile compounding only • PEC within demarcated area (at least 3 ft. perimeter) or separate room • Shall not have unsealed windows/doors that connect to outdoors • Not in high traffic area • Not adjacent to construction sites, warehouses or food preparation • Sink at least 3 ft. from PEC • Emergency eye wash station acceptable CCR §1735.1(af) & §1250.4 (1-4)	• CAI • Manufacturer of CAI must provide documentation for meeting requirements in 1751.4(f)(1-3) AND CAI must be certified as part of the certification process 1751.4(f)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Requires use of sterile gloves over isolator gloves 1751.4 (h) • PEC requires certification at least every 6 months CCR 1751.4(f) • Sink can be within 3 ft of CAI
	• Laminar Flow Hood • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	12 hours CCR §1751.8 (d)	• 12 hours BUD for low-risk, non-hazardous preparations only 1751.8(d)(2) • PEC requires certification at least every 6 months CCR 1751.4(f)

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

Does not meet requirements for ISO Class 7 clean room or Segregated Compounding area	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	Labeled "Immediate Use" and shall be administered no later than 1 hour after mixing CCR §1751.8 (e)	N/A	Compounded only in limited situations where failure to administer could result in loss of life or intense suffering, and in quantity to meet immediate need

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

•			
•	•	•	•
•	•	**Sterile to Sterile, No Preservatives, Aseptic Technique** Sterility Testing / Room Temp BUD / Refrigerated BUD / Freezer BUD NO / 6 days / 9 days / 45 days YES / 28 days / 42 days / 45 days	
	•		

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

Draft pending final approval by CSHP and CHA

Facilities and Engineering Controls: Hazardous Drugs

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17) and USP <797> &7/1/18) Requirements

BOARD OF PHARMACY REGULATIONS CCR§1735 **Effective January 1, 2017**				
		Beyond Use Dates		
		LOW RISK • **Sterile to sterile** • **=< 3 commercial packages** **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	
• **ISO Class 7 or better** • Sink in ante area • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 30 Air Changes Per Hour (ACPH) • Ante-area ISO 7 or better CCR §1735.6(e)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent. CACI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Document daily Pressure Differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8) • Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4)
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft from PEC • Minimum of at least 3 ft line of demarcation around PEC • Emergency eye wash station acceptable • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 12 ACPH 1735.6 (e) (1)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • Compounding Aseptic Containment Isolators (CACI) with unidirectional flow. Air within the CACI shall not be recirculated or turbulent CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	NA	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification by a CETA certified vendor at least q 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces within the room shall be smooth, seamless, impervious, and non-shedding 1735.6(e)(4) • Sink can be within 3 ft of CACI if CACI meets requirements in 1751.4 (f) (1-3)
Non-Hazardous Drugs Prepared in a Hazardous Drug Primary Engineering Control (Chemo Hood)				

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

HAZARDOUS DRUGS : USP <800> Requirements July 1, 2018				
		BEYOND USE DATES (July 1, 2018)		
		Low Risk	Medium Risk	
• **HEPA filtered air in Negative Pressure Physically Separate Room** • **ISO Class 7 or better buffer room** • **0.01" to 0.03" w.c. negative pressure** • **Minimum 30 ACPH HEPA filtered air** • **Sink placed at least 1 meter from the entrance of buffer room**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	
• **Containment Segregated Compounding Area (C-SCA)** • **Must be a negative pressure separate room** • **0.01" to 0.03" w.c. negative pressure** • **Unclassified room** • **Minimum 12 ACPH** • **Sink at least 1 meter from C-PEC**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	12 hours	12 hours **(not allowed by BOP)**	

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

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

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

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Last Revised 10/5/17

TEMPERATURE REQUIREMENTS AND MONITORING

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

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

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

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

MONITORING REQUIREMENTS

Location	Comment	USP 37 NF33	CDC (Vaccines) May 2014	BOP
Freezers		Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Refrigerators		Daily	Twice daily	Daily-§1735.5(c)(10) §1751.5(b)(5)(A,B,C)
Ambient Room	Includes all drug storage location rooms: no specific requirements for monitoring inside ADCs	Daily		

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Last Revised 10/4/17

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Medication Reconciliation/Safety Medication Transitions

SUMMARY

Members are interested in how we leverage pharmacy staff to prevent harm from inaccurate medication lists and medication transactions between transitions of care. The Hospital Quality Institute will report on its work with Adverse Drug Events, particularly with readmissions. The CHA Medication Safety Reconciliation Subcommittee will report on its updated infographics Rita Shane will discuss two studies recently published and attached.

ACTION REQUESTED

- Continued discussion on how to effectuate pharmacy ensurance on the accuracy of the medication list at admission and discharge

DISCUSSION QUESTIONS

1. What opportunities exist to increase use of pharmacists in this process?
2. What prevents pharmacists from doing this now? Is it based on size of hospital and type of pharmacy staffing provided?
3. Is there a way to develop a campaign around HQI work with readmissions and med list reconciliation, use the established benefit business case to justify increased pharmacy staff?

BJB:br

Information from Rita Shane: As a follow up to our discussion regarding next steps to illustrate the business case for ensuring accurate medication lists in our high risk patients, we have put together the attached infographic. I have also cut and pasted some relevant language from the State Board law below. I know LoriAnn was also looking at regulatory language with respect to CDPH and potentially CMS new requirements. Look forward to our discussion at the October meeting. Thank you.

State Board Language
Could we insert something like the following:

In health systems, the pharmacist is responsible for ensuring the accuracy of the medication profile for high risk patients upon admission and discharge

1707.1.
Duty to Maintain Medication Profiles (Patient Medication Records).
(a) A pharmacy shall maintain medication profiles on all patients who have prescriptions filled in that pharmacy except when the pharmacist has reasonable belief that the patient will not continue to obtain prescription medications from that pharmacy.
(1) A patient medication record shall be maintained in an automated data processing or manual record mode such that the following information is readily retrievable during the pharmacy's normal operating hours.
(A) The patient's full name and address, telephone number, date of birth (or age) and gender;
(B) For each prescription dispensed by the pharmacy:
(1). The name, strength, dosage form, route of administration, if other than oral, quantity and directions for use of any drug dispensed;
(2). The prescriber's name and where appropriate, license number, DEA registration number or other unique identifier;
(3). The date on which a drug was dispensed or refilled;
(4). The prescription number for each prescription; and
(5). The information required by section 1717.
(C) Any of the following which may relate to drug therapy: patient allergies, idiosyncrasies, current medications and relevant prior medications including nonprescription medications and relevant devices, or medical conditions which are communicated by the patient or the patient's agent.
(D) Any other information whichthe pharmacist, in his or her professional judgment, deems appropriate.

1707.3.
Duty to Review Drug Therapy and Patient Medication Record Prior to Delivery.
Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

Up to 70% of Patients Have Errors on Their Medication Lists

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

Problem

- ❑ 20% of admissions are medication-related[1]
- ❑ High risk patients have 8 errors on admission medication lists.[2]
- ❑ Only 5.3% of patients 65 year or older on ≥5 medications have accurate lists[3]
- ❑ One third of inpatient orders have errors and 85% originate from the medication history[4]
- ❑ Up to 59% of errors can cause harm[5]
- ❑ Up to 80% of patients have at least 1 medication error at discharge[6]

Solution

On admission, studies demonstrate increased accuracy of medication lists obtained by pharmacy staff vs usual care

- ❑ Accuracy rates: Nurses, 20%; Hospitalists, 50%; Technicians, 100% [7]
- ❑ Nurses 14% vs pharmacy technicians 94% ($p<0.0001$)[8]

At discharge, pharmacists identified errors in medication lists in 49% of patients and problems in an additional 16% vs usual care[9]

Business Case

Cost of Harm

- ❑ Cost of adverse drug event (ADE): $2,262- $5,790[7,10-13]
- ❑ Increased length of stay due to ADE: 3.1 days[13]
- ❑ Cost/readmission ~ $12,300-13,800[14]

Benefits

- ❑ 75% reduction in ADEs[7]
- ❑ 41 minutes of nursing time saved/patient [16]
- ❑ Cost-effective to utilize technicians for medication histories; $830,000[7]
- ❑ Patients have an accurate medication list upon discharge
- ❑ Reduced readmissions
- ❑ Enables clinicians to practice at the highest level of their license and training

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

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Improving admission medication reconciliation with pharmacists or pharmacy technicians in the emergency department: a randomised controlled trial

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ABSTRACT

Background Admission medication history (AMH) errors frequently cause medication order errors and patient harm.

Objective To quantify AMH error reduction achieved when pharmacy staff obtain AMHs before admission medication orders (AMO) are placed.

Methods This was a three-arm randomised controlled trial of 306 inpatients. In one intervention arm, pharmacists, and in the second intervention arm, pharmacy technicians, obtained initial AMHs prior to admission. They obtained and reconciled medication information from multiple sources. All arms, including the control arm, received usual AMH care, which included variation in several common processes. The primary outcome was severity-weighted mean AMH error score. To detect AMH errors, all patients received reference standard AMHs, which were compared with intervention and control group AMHs. AMH errors and resultant AMO errors were independently identified and rated by ≥2 investigators as significant, serious or life threatening. Each error was assigned 1, 4 or 9 points, respectively, to calculate severity-weighted AMH and AMO error scores for each patient.

Results Patient characteristics were similar across arms (mean±SD age 72±16 years, number of medications 15±7). Analysis was limited to 278 patients (91%) with reference standard AMHs. Mean±SD AMH errors per patient in the usual care, pharmacist and technician arms were 8.0±5.6, 1.4±1.9 and 1.5±2.1, respectively (p<0.0001). Mean±SD severity-weighted AMH error scores were 23.0±16.1, 4.1±6.8 and 4.1±7.0 per patient, respectively (p<0.0001). These AMH errors led to a mean±SD of 3.2±2.9, 0.6±1.1 and 0.6±1.1 AMO errors per patient, and mean severity-weighted AMO error scores of 6.9±7.2, 1.5±2.9 and 1.2±2.5 per patient, respectively (both p<0.0001).

Conclusions Pharmacists and technicians reduced AMH errors and resultant AMO errors by over 80%. Future research should examine other sites and patient-centred outcomes.

Trial registration number NCT02026453.

INTRODUCTION

Bates *et al* defined an adverse drug event (ADE) as an 'injury resulting from medical intervention related to a drug'.[1] The Institute of Medicine estimates that hospitalised US patients suffer from 400 000 preventable ADEs annually.[2] Among the most frequent causes of preventable ADEs are errors in admission medication histories (AMH).[3–5]

Using pharmacists to check AMHs reduces preventable ADEs.[6] Nonetheless, many organisations have encountered difficulties in disseminating pharmacist-led medication reconciliation interventions. We have previously attributed poor uptake of such interventions to the complexity of implementing medication reconciliation interventions, which affect multiple interacting workflows, and to the cost of employing pharmacists.[7]

To address both implementation complexity and cost, we modified this intervention by stationing pharmacists in the emergency department (ED) to obtain AMHs *before* admitting physicians place admission medication orders (AMO). This allows admitting physicians to work from an accurate AMH, which is especially important in an era when electronic health records (EHR) allow physicians to convert AMHs into AMOs with just a few mouse clicks, and when patients are often admitted by hospitalists unfamiliar with patients' home medication regimens.

To quantify the reduction in AMH errors achieved by pharmacists and pharmacist-supervised pharmacy technicians

(PSPT) obtaining AMHs in the ED, we conducted a three-arm randomised controlled trial comparing these providers with usual care processes in a population of medically complex patients. To better understand the effect on more downstream outcomes, including preventable ADEs occurring in the hospital and after discharge, we also compared rates of AMO errors resulting from AMH errors.

METHODS

Trial design overview

We conducted a three-arm randomised controlled trial. Intervention arms used pharmacists or PSPTs to obtain AMHs before AMOs were placed. The Cedars-Sinai Medical Center (CSMC) Institutional Review Board agreed that informed consent of patients should be waived in this randomised allocation of services that had heretofore been allocated via operational convenience.

Setting and study population

CSMC is a large university-affiliated hospital. Providers placing orders for trial patients included community, hospitalist, and resident physicians, as well as nurse practitioners and physician assistants. Pharmacists included licensed resident pharmacists.

Eligible participants were medically complex patients admitted to CSMC through the ED. Enrolment screening occurred Mondays through Thursdays from approximately 11:00 to 20:00 beginning 7 January 2014 through 14 February 2014. Enrolment ceased at the end of the first day on which the intended sample size was exceeded. Screening was occasionally paused when pharmacy staff were otherwise occupied with clinical or research duties. Inclusion criteria were: ≥10 active chronic prescription medications in the EHR, history of acute myocardial infarction or congestive heart failure in the EHR problem list, admission from a skilled nursing facility (SNF), history of transplant, or active anticoagulant, insulin or narrow therapeutic index medications (online supplementary appendix). Patients were excluded if they had previously been enrolled in the study, or if admitted to paediatric or trauma services or transplant services with pharmacists.

Randomisation

Investigators reviewed the EHR to identify ED patients for whom providers had already placed an admission order. Upon identifying trial candidates, investigators reviewed inclusion/exclusion criteria. After enrolling patients meeting criteria, investigators used RANDI2 randomisation software to randomise each patient.[8] Each block of six consecutively enrolled patients was allocated in a 2:2:2 distribution across the three study arms (figure 1). Patients who left the ED before an AMH could be obtained and patients not ultimately admitted (despite an initial decision to admit) were considered lost to follow-up. Because the number of patients assessed for eligibility on 30 January 2014 was lost, we substituted the mean assessed patient count using all other enrolment days.

Interventions

Patients were randomly allocated to usual care or to one of two intervention arms in which either a pharmacist or a PSPT had primary responsibility for obtaining the AMH. Obtaining the initial AMH usually began with reviewing the medication regimen present in the EHR if one was available from a prior encounter. Next, patients, families and caregivers present in the ED were interviewed. Pill bottles, medication lists and SNF medication administration records were also reviewed. In cases where sources matched convincingly, no further efforts were undertaken. However, in most cases, other sources including family, pharmacies and/or providers were contacted until questions were resolved. This is consistent with a published protocol for obtaining a 'best possible medication history'.[4] Pharmacists and PSPTs attempted to complete all intervention-arm AMHs soon after the ED decision to admit was made and before any AMOs were placed, such that the workflow of admitting physicians would not be affected, and that there would be no need to contact and convince admitting physicians to fix AMHs or AMOs retroactively.

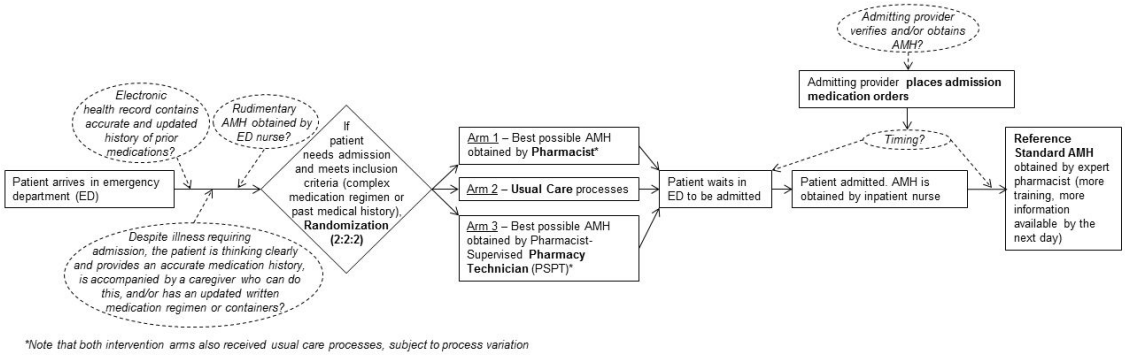

Figure 1 Workflow diagram of admission medication history (AMH) processes occurring during usual care and study randomisation. Common usual care process variations italicised and circumscribed by dotted lines.

PSPTs presented their AMHs to a supervising pharmacist to allow the pharmacist to decide whether data sources needed further review, or whether the AMH was ready to be entered into the EHR. Requiring pharmacists to enter PSPTs' AMHs into the EHR ensured that pharmacists reviewed all medications in the AMH, and constituted the pharmacist supervision of PSPTs.

Didactic and experiential training of pharmacists and pharmacy technicians

All pharmacists and pharmacy technicians underwent standardised training in obtaining AMHs. Didactic training generally took 8–16 hours and included: review of background publications; review of locally created general and ED-specific medication reconciliation manuals with detailed guides of AMH workflows, the patient interview and EHR utilisation; and a didactic training evaluation. Experiential training included observing ≥5 AMHs obtained by an expert pharmacist, followed by the trainee obtaining ≥5 AMHs under the proctoring of an expert pharmacist. Training continued until proctors deemed trainees competent.

Usual care

All arms received usual care for patients admitted from the ED, which commonly involves multiple process variations. EHR-derived medication regimen accuracy is subject to variation in the knowledge and efforts of prior providers, which are often driven by patient acuity and patient care priorities. Patients and caregivers' recall of medication regimens varies over time and across patients. Nurse and physician contributions likely vary in accordance with their pharmacological training and with competing obligations, including patients' requests for home medications. Finally, physicians may place AMOs before or after patients have had their AMH obtained by an inpatient nurse (dotted lines and italicised text highlight common process variations in figure 1). To minimise unnecessary overlap, inpatient pharmacists and nurses were advised not to initiate new efforts to improve upon pharmacist-approved AMHs. However, they were able to address any concerning AMH or AMO data that arose during clinical care.

Outcome measurement

Reference standard AMHs

As per prior studies, we attempted to obtain reference standard AMHs from patients in all arms on the day following admission.[4] When a reference standard AMH was not obtained, patients were considered lost to follow-up. Reference standard AMHs were more comprehensive than initial AMHs in several ways. First, pharmacists obtaining reference standard AMHs started with initial AMH data. As such, study arm could not be masked. Second, reference standard AMHs were only obtained by pharmacists considered to be 'expert' in this clinical skill based on their previous experience in obtaining medication histories. These pharmacists were advised to take additional time and to consider additional information (eg, previous hospital discharge orders) as necessary. Third, these pharmacists often had new information available to them (eg, medication lists brought in after admission, improved patient mental status). Finally, these pharmacists identified errors that arose during clinical care prior to the reference standard AMH. Some of these pharmacists were study authors. To maximise patient benefit from the study, reference standard AMH findings, including any impact on AMOs, were communicated to the appropriate clinician.

Primary outcome: mean severity-weighted AMH error score

In obtaining reference standard AMHs, expert pharmacists identified AMH errors in the initial AMHs and classified each error according to a previously developed taxonomy as significant, serious or life threatening.[1] Error severity weights of $1^2=1$, $2^2=4$ and $3^2=9$, respectively, were chosen to reflect the relative capacity of each error type to cause patient harm. A second pharmacist reviewed classifications, and a physician adjudicated disagreements. Because the reference standard pharmacist obtained their AMH while the patients were still hospitalised and used contemporaneous information (eg, conversations with patients and family members), study arm could not be masked. Because of the vast amount of complex information that might be consulted in determining error severity, we also chose not to mask study arm with case summaries for other reviewers.

For each patient, we calculated a severity-weighted AMH error score. We used this novel error score because it provides a single, severity-weighted measure of error for each AMH. This allowed our power analysis to account for the different potential clinical consequences of different error severities. For each trial arm, we calculated a mean severity-weighted AMH error score.

Secondary outcome: mean severity-weighted AMO error score

For each AMH error identified, two physicians independently reviewed the relevant medications ordered at hospital admission in the context of the clinical chart. They classified each AMH error as either resulting in no AMO error, or an AMO error of significant, serious or life-threatening severity. In cases where the admitting physician's knowledge of an AMH error was unclear and where the resultant orders were clinically reasonable (eg, the AMH erroneously omitted hydrocodone and it was not ordered at admission, but where it may have been intentionally held for altered mental status, rather than unintentionally omitted), we determined that the AMH error did not clearly lead to any AMO error. A third physician adjudicated disagreements. All adjudicating physicians were study authors. Because all AMO determinations began with

a previously identified AMH error, we did not address AMO errors unrelated to AMH errors.

Tertiary outcomes

Kruskal-Wallis and Fisher's exact tests were used to compare the three arms in terms of patients' mean length of stay and the per cent of patients readmitted to Cedars-Sinai Medical Center within 30 days, respectively. The study was not powered to detect differences in these tertiary outcomes.

Statistical analysis

Using single-factor analysis of variance (ANOVA), we determined that a sample of 300 patients would achieve 80% power to detect absolute error score differences of at least 11.2 using the Tukey-Kramer (pairwise) multiple comparison test with an alpha of 0.05.[9 10] Based on pilot data, we expected patients in the usual care group to have a mean severity-weighted error score of 20.7, with an SD of 16.2. A difference of 11.2 units is clinically significant, representing 1 life threatening, almost 3 severe, or 11 significant AMH errors.

Clinical and demographic variables were summarised using mean or count. Error counts per patient and error scores per patient were summarised by study arm using mean. In accordance with the a priori analysis plan for this randomised trial, we used linear regression models to compare primary outcome and secondary measures across study arms (ANOVA). Because baseline characteristics were balanced across study arms, the linear regression models were not adjusted for any other variables. Post hoc pairwise comparisons between study arms used a Tukey-Kramer adjustment for multiple testing. The outcomes were transformed for the models due to outliers in the distributions. To test whether results were robust to the unknown outcomes of patients admitted but lost to follow-up, we conducted a sensitivity analysis where all such intervention patients were assumed to have the worst AMH error score measured for any patient, and where all such usual care patients were assumed not to have any AMH errors.

To minimise the effect of outliers in the distributions of error counts and scores, a rank transformation was applied to the outcomes in the regression models. The results of hypothesis testing for transformed and non-transformed outcomes were similar, but the residuals in the rank-transformed data better fit the model assumptions as the variance of the outcomes in the usual care group was larger than the other two groups. The following variables were compared across study arms with Kruskal-Wallis tests: number of medications, zip code median income, weighted Charlson comorbidity score and length of stay. Insurance type, race, ethnicity and readmission rate were analysed across study arms using Fisher's exact test. Analyses used SAS V.9.3.

RESULTS

Enrolment and baseline characteristics

We enrolled 306 patients. Patient characteristics, including age, sex, race, ethnicity, insurance, number of medications, income and comorbidities, were similar across study arms (table 1). The mean±SD patient age was 72±12 and number of medications present in the EHR prior to obtaining an AMH was 15±7.

Of 103 and 102 patients randomised to the pharmacist and PSPT arms, only 5 (5%) and 9 (9%) did not receive the intervention, respectively. These patients and 14 others for whom a reference standard AMH was not obtained were classified as dropouts (figure 2). The primary outcome was not measurable for these 28 (9.2%) patients lacking a reference standard AMH. Therefore, except for the sensitivity analyses, further results are based on the 278 remaining patients.

Identification and adjudication of AMH errors and resultant AMO errors

Pharmacist raters found that 192 (69%) of 278 patients had 1016 AMH errors. They determined that 399 (39%) AMH errors were significant, 605 (60%) were serious and 12 (1%) were life-threatening errors. These errors occurred in the AMHs of 138, 164 and 11 patients, respectively.

Physician raters agreed that 419 (41%) of these AMH errors clearly led to an AMO error. The 419 AMO errors occurred among 142 (74%) of the 192 patients who had an AMH error. Raters found that 261 (62%) AMO errors occurring among 117 patients were significant, 155 (37%) among 84 patients were serious and 3 (1%) among 3 patients were life-threatening errors. Examples of AMH and AMO errors identified are detailed in online supplementary table 1.

Outcome comparisons across arms

There was a mean±SD of 8.0±5.6 AMH errors per patient in the usual care arm versus 1.4±1.9 and 1.5±2.1 AMH errors per patient in the pharmacist and PSPT arms, respectively (pairwise t-tests, $p<0.0001$) (table 2). When we accounted for error severity via the primary outcome of severity-weighted AMH error score, patients in the usual care arm had a mean±SD severity-weighted AMH error score of 23.0±16.1 versus scores of 4.1±6.8 and 4.1±7.0 in the pharmacist and PSPT arms, respectively ($p<0.0001$).

Our sensitivity analysis, which assumed that all intervention patients lost to follow-up had the worst measured AMH severity score (100), but that usual care patients lost to follow-up had no AMH errors, resulted in the usual care arm having a mean±SD severity-weighted AMH error score of 22.0±16.4 versus scores of 9.0±22.1 and 13.8±29.8 in the pharmacist and PSPT arms, respectively ($p<0.0001$).

Patients in the usual care arm had a mean±SD of 3.2±2.9 AMO errors per patient versus 0.6±1.1 and 0.6±1.1 AMO errors per patient in the pharmacist and PSPT arms, respectively ($p<0.0001$). Accounting for

Table 1 Baseline characteristics of patients

Characteristic	Admission medication history obtained via: Usual care (n=101)		Usual care plus pharmacist (n=103)		Usual care plus pharmacist-supervised pharmacy technician (n=102)	
Age, mean (SD), year	71	18	72	16	71	16
Female (n, %)	48	(48%)	54	(52%)	55	(54%)
Latino (n, %)	7	(7%)	5	(5%)	5	(5%)
Race (n, %)						
White	66	(65%)	75	(73%)	65	(64%)
Black	22	(22%)	28	(28%)	25	(26%)
Asian	5	(5%)	6	(6%)	6	(6%)
Other	0	(0%)	0	(0%)	1	(1%)
Insurance (n, %)						
Commercial	14	(14%)	14	(14%)	17	(17%)
Medicaid only	7	(7%)	12	(12%)	9	(9%)
Medicare	78	(77%)	76	(74%)	75	(74%)
Other	2	(2%)	1	(1%)	1	(1%)
Inclusion criteria, accessed via EHR (n, %)*						
>10 active chronic prescription medications	65	(64%)	71	(69%)	71	(70%)
History of acute myocardial infarction or congestive heart failure	42	(42%)	34	(33%)	38	(37%)
Admission from skilled nursing facility	16	(16%)	12	(12%)	17	(17%)
History of transplant	2	(2%)	4	(4%)	3	(3%)
Anticoagulant, insulin or other narrow therapeutic index medication	81	(80%)	97	(94%)	91	(89%)
Other						
Number of active medications in EHR at randomisation (mean, SD)	15	7	15	7	15	6
Neighbourhood household income, median (IQR), annual US$†	66 063	(42 615, 71 132)	66 063	(43 202, 77 165)	66 063	(42 615, 79 233)
Weighted Charlson comorbidity score, mean (SD)	3.1	(2.4)	3.5	(2.8)	3.6	(2.6)
Inpatient stay within 3 months prior to admission (n, %)	40	(40%)	42	(41%)	40	(40%)
>2 encounters with PCP or internal medicine consultants within 3 months prior to admission (n, %)	49	(49%)	41	(40%)	51	(50%)

*Many patients qualified for multiple inclusion criteria, such that the percentages sum to more than 100%.
†Neighbourhood household income was estimated by linking patients' zip codes to 2010 US Census median household income data.
EHR, electronic health record; PCP, primary care physician.

error severity showed that patients in the usual care arm had a mean±SD severity-weighted AMO error score of 6.9±7.2 vs 1.5±2.9 and 1.2±2.5 in the pharmacist and PSPT arms, respectively (p<0.0001).

Using Cohen's d to standardise the magnitude of the measured effect revealed that for the primary outcome of AHM error score, the effect size for each intervention was 1.5 (table 3). For the more downstream outcome of severe or life-threatening AMO errors, the effect size for each intervention was approximately 0.8. These measurements are accepted to represent very large and large effect sizes, respectively.[11] Although this trial was not designed to test for non-inferiority, we found no differences in any outcomes between pharmacists and PSPTs.

Of 183 patients randomised to either intervention, 29 (16%) had a serious or life-threatening AMO. Compared with 56 (59%) of 95 control patients with such errors, this represents a number needed to treat of 3 (point estimate 2.3, 95% CI 1.8 to 3.2). This number underestimates the intervention's impact because many patients had multiple serious AMO errors. Although there were no statistically significant differences in utilisation outcomes across arms, point estimates for length of stay were approximately 1 day longer in the intervention arms (p=0.13), and point estimates for 30-day readmission rates were approximately 10% lower in the intervention arms (p=0.16).

DISCUSSION

In this three-arm randomised controlled trial, adding AMH interviews by pharmacists or PSPTs to usual care processes reduced AMH errors by over 80%. The most downstream and clinically meaningful result was reducing the severe and life-threatening AMO error rate from 1.2 per patient in the usual care arm to 0.2 per patient in the intervention arms. Preventing AMOs should allow patients to avoid ADEs, which are known to increase length of stay, cost, morbidity and mortality.[2 12]

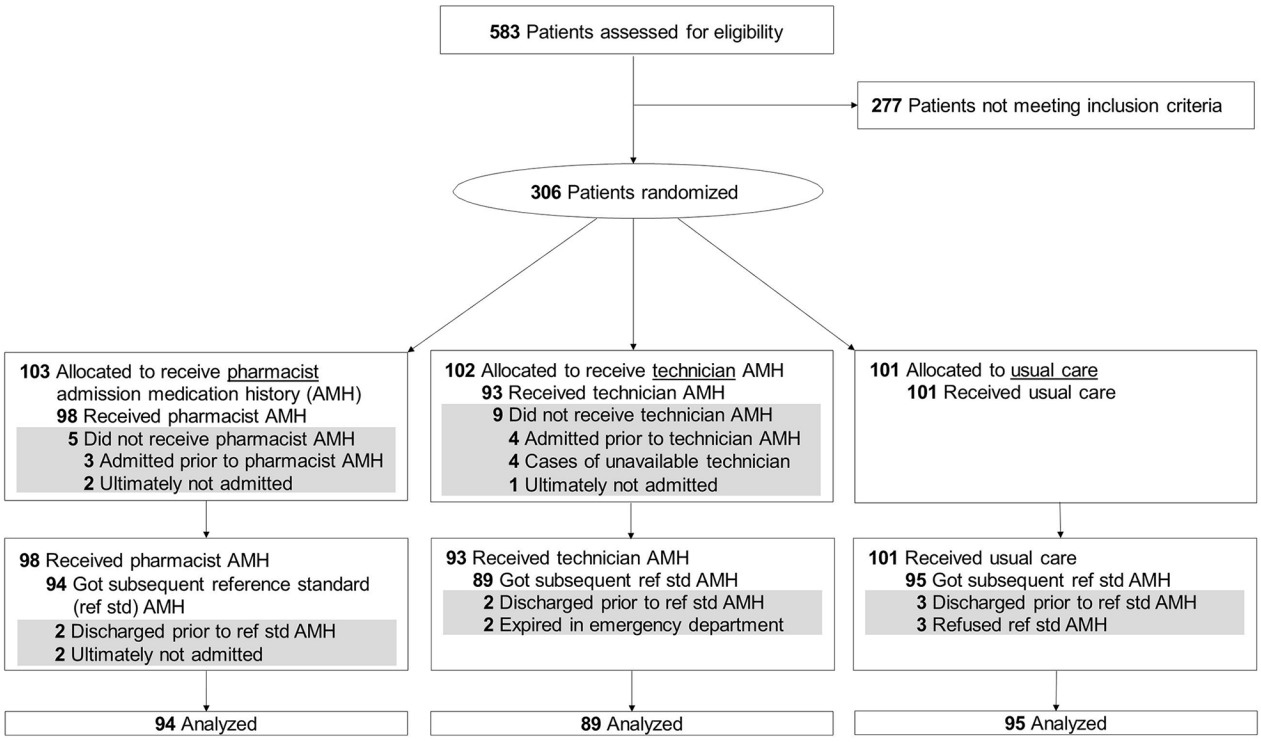

Figure 2 Consort flow diagram.

We found a much larger benefit than prior research. Many prior studies checked AMHs after AMOs were placed, thus resembling our usual care arm. For example, one systematic review found that the median study only identified (and in some cases addressed) 0.35 clinically significant unintentional medication discrepancies per patient.[13] In contrast, our usual care arm reference standard AMHs identified a mean of 1.2 severe or life-threatening AMO errors per patient, which translated to a much greater opportunity for reductions.

We attribute the high baseline error rate to the medically complex patient population we studied, which resulted from our inclusion criteria. Two prior systematic reviews had conflicting findings regarding targeting interventions at high-risk patients. One review found

Table 2 Outcomes of 278 patients with reference standard AMH

Result	Usual care (n=95)		Usual care plus pharmacist (n=94)		Usual care plus pharmacist-supervised pharmacy technician (n=89)		p Value*
Mean AMH error outcomes (95% CI)							
AMH errors per patient	8.0	(6.8 to 9.1)	1.4	(1.0 to 1.8)	1.5	(1.0 to 1.9)	<0.0001
AMH errors per patient, severe or life threatening only	4.6	(3.8 to 5.3)	0.8	(0.49 to 1.1)	0.7	(0.45 to 1.1)	<0.0001
AMH error score per patient†	23.0	(19.7 to 26.2)	4.1	(2.7 to 5.5)	4.1	(2.6 to 5.6)	<0.0001
Mean AMO error outcomes (95% CI)							
AMO errors per patient	3.2	(2.6 to 3.8)	0.6	(0.42 to 0.85)	0.6	(0.41 to 0.97)	<0.0001
AMO errors per patient, severe or life threatening only	1.2	(0.85 to 1.5)	0.2	(0.12 to 0.36)	0.1	(0.06 to 0.24)	<0.0001
AMO error score per patient	6.9	(5.5 to 8.4)	1.5	(0.89 to 2.1)	1.2	(0.67 to 1.7)	<0.0001
Mean utilisation outcomes							
Length of stay (95% CI)	5.2	(4.3 to 6.1)	6.5	(5.1 to 7.9)	6.2	(5.0 to 7.3)	0.13
Readmission within 30 days (%)	27	(27%)	17	(17%)	19	(19%)	0.16

*Rank-transformed analysis of variance F-test.
†Primary outcome.
AMH, admission medication history; AMO, admission medication order.

Table 3 Comparing AMH error and AMO error rates across study arms

Result	Usual care minus pharmacist (n=95, 94)			Pharmacist minus pharmacist-supervised pharmacy technician (n=94, 89)			Usual care minus pharmacist-supervised pharmacy technician (n=95, 89)		
Mean AMH error outcomes	**Δ**	**pSD**	**C**	**Δ**	**pSD**	**C**	**Δ**	**pSD**	**C**
AMH errors per patient	*6.6**	4.2	1.6	−0.08	2.0	−0.04	*6.5**	4.2	1.5
AMH errors per patient, severe or life threatening only	*3.8**	2.9	1.4	0.04	1.5	0.03	*3.8**	2.8	1.4
AMH error score per patient†	*18.8**	12.4	1.5	0.05	6.8	0.01	*18.9**	12.4	1.5
Mean AMO error outcomes									
AMO errors per patient	*2.5**	2.2	1.2	−0.002	1.1	−0.002	*2.5**	2.2	1.2
AMO errors per patient, severe or life threatening only	*0.92**	1.2	0.76	0.10	0.55	0.17	*1.0**	1.2	0.85
AMO error score per patient	*5.4**	5.5	0.99	0.29	2.7	0.11	*5.7**	5.4	1.1

*p<0.0001 (pairwise comparison with Tukey-Kramer adjustment for multiple testing).
†Primary outcome.
Δ, difference in means; AMH, admission medication history; AMO, admission medication order; C, Cohen's d calculated as difference in means divided by pooled SD of the two groups; pSD, pooled SD.

such targeting in 13 of 26 studies, and deemed it to be a 'key aspect of successful interventions'.[14] The other review found such targeting in 7 of 20 interventions, and determined that 'commonly used criteria for selecting high-risk patients do not consistently improve the effect of medication reconciliation.'[13] Our study patients had a mean of 15 medications present at enrolment versus prior study population means ranging from 7 to 11 medications.[15] The strong effect of our intervention suggests that targeting may be helpful if it is used to identify these patients at extremely high risk for ADEs. Such patients are already prevalent at CSMC, and this cohort is growing quickly throughout the developed world due to population ageing and increasing prescription drug use.[16]

The second factor likely contributing to the strong effect, and likely related to the high-risk patient population, is the substantial time spent by the pharmacist and PSPTs who conducted the intervention. In a time and motion study reported elsewhere, we found that they spent 58.5 and 79.4 min per patient, respectively (p=0.14).[17] Although one other study reported similar results,[18] this represents substantially more time than the 20–40 min reported in several prior studies conducted on younger, healthier patients.[19 20] Beyond these substantial time requirements, these interventions also require pharmacy personnel to be stationed in the ED and able to attend to AMHs as soon as a determination to admit a patient has been made—before AMOs are placed. As such, these interventions may be best suited to large hospitals with sufficient ED patient volume to justify stationing pharmacy personnel in the ED.

To better understand the potential impact of the studied interventions, we consulted previous literature showing that 0.9% of AMO errors result in an ADE during hospitalisation.[21] Critically, the studied interventions have potential advantages that we did not evaluate. The intervention workflows should be more efficient than using pharmacists to retrospectively check usual care processes and to contact and convince ordering physicians to request changes before errors cause harm. Furthermore, it seems likely that the interventions streamlined physicians' workflows and saved them time by allowing them to order from accurate AMHs, to minimise downstream pharmacist contacts and to reduce the need for corrections. Finally, and most importantly, prior research has shown the greatest benefit of reducing AMH errors to be a reduction in postdischarge prescription errors and resultant ADEs.[4] Future research should endeavour to evaluate these hypothesised benefits.

Because one sought-after benefit of using PSPTs is to reduce costs, it is notable that we found no difference in the benefit provided by PSPTs versus pharmacists. This is consistent with other similar studies.[22 23] However, our aforementioned time and motion analysis also did not find intervention costs to be lower in the PSPT arm, as compared with the pharmacist arm, once the costs of pharmacist supervision were included.[17] Nonetheless, the current study may allay concerns of effectiveness that have hindered PSPT adoption. With effectiveness established, these results point to an opportunity to improve PSPT efficiency, through altered work processes and the use of electronic pharmacy claims data (EPCD), which could make PSPT both a better and less expensive intervention.

Generalisability is a known gap in medication reconciliation intervention research.[7] Beyond embracing an intervention that we thought would improve efficiency and reduce implementation complexity, we also designed our trial to be pragmatic. In contrast to prior work,[15] we included many patients admitted by community physicians. Because the interventions did not require physician workflow changes, many physicians were unaware of the trial entirely. We included

resident pharmacists to ensure that experience was unnecessary. We minimised biases associated with requiring patients to opt-in. All of these factors should contribute to strong external validity.

The findings must be interpreted in the context of limitations. First, the study was powered on intermediate endpoints, rather than on patient-centred outcomes (PCO). Although there is an established linkage between AMH errors and PCO,[1] it would be useful to study PCO directly, especially because systematic reviews have drawn conflicting conclusions about whether previously studied medication reconciliation interventions affect PCO.[6 13 15 24] Second, we only used one site. Third, not all aspects of randomisation were masked from study personnel. Because block size was not masked, selection bias could have occurred. Furthermore, we could not practicably mask arm allocation. Fortunately, we were able to increase objectivity by leveraging accepted methodology, which used agreement of independent raters to identify and rate the severity of AMH and AMO errors.[4] Finally, study providers could not access EPCD. Because EPCD is likely now available in most US hospitals, and because it has good potential to reduce AMH errors and to reduce the time needed to obtain AMHs, it will be important to retest these interventions with EPCD.[25]

CONCLUSIONS

Among medically complex older adults, pharmacists and pharmacist-supervised pharmacy technicians reduced admission medication history errors and resultant admission medication order errors by over 80% by obtaining admission medication histories in the ED. This effect was robust to severity weighting, and thus shows promise for reducing patient harm. We attribute the strong effect to a high-risk patient population and an intensive intervention. Future research should test whether these results generalise to other settings and affect patient-centred outcomes, and whether hypothesised efficacy and efficiency benefits are indeed demonstrable.

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Contributors JP had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Concept and design: JP, CN, CJ, KP, RS, AR, MB, DB. Acquisition, analysis or interpretation of data: JP, CN, CJ, KP, RS, GCW, AR, MB, OR, DS, BD, AD, DB. Drafting of the manuscript: JP, CN, GCW. Critical revision of the manuscript for important intellectual content: JP, CN, CJ, KP, RS, GCW, AR, OR, BD, DB. Statistical analysis: JP, CJ, GCW, AR. Administrative, technical or material support: JP, CN, KP, RS, MB, OR, DS, DB. Study supervision: JP, CN, KP, RS, DB.

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The Enhanced Care Program: Impact of a Care Transition Program on 30-Day Hospital Readmissions for Patients Discharged From an Acute Care Facility to Skilled Nursing Facilities

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BACKGROUND: Increased acuity of skilled nursing facility (SNF) patients challenges the current system of care for these patients.

OBJECTIVE: Evaluate the impact on 30-day readmissions of a program designed to enhance the care of patients discharged from an acute care facility to SNFs.

DESIGN: An observational, retrospective cohort analysis of 30-day hospital readmissions for patients discharged to 8 SNFs between January 1, 2014, and June 30, 2015.

SETTING: A collaboration between a large, acute care hospital in an urban setting, an interdisciplinary clinical team, 124 community physicians, and 8 SNFs.

PATIENTS: All patients discharged from Cedars-Sinai Medical Center to 8 partner SNFs were eligible for participation.

INTERVENTION: The Enhanced Care Program (ECP) involved the following 3 interventions in addition to standard care: (1) a team of nurse practitioners participating in the care of SNF patients; (2) a pharmacist-driven medication reconciliation at the time of transfer; and (3) educational in-services for SNF nursing staff.

MEASUREMENT: Thirty-day readmission rate for ECP patients compared to patients not enrolled in ECP.

RESULTS: The average unadjusted, 30-day readmission rate for ECP patients over the 18-month study period was 17.2% compared to 23.0% among patients not enrolled in ECP ($P < 0.001$). After adjustment for sociodemographic and clinical characteristics, ECP patients had 29% lower odds of being readmitted within 30 days ($P < 0.001$). These effects were robust to stratified analyses, analyses adjusted for clustering, and balancing of covariates using propensity weighting.

CONCLUSIONS: A coordinated, interdisciplinary team caring for SNF patients can reduce 30-day hospital readmissions. *Journal of Hospital Medicine* 2017;12: XXX-XXX. © 2017 Society of Hospital Medicine

Public reporting of readmission rates on the Nursing Home Compare website is mandated to begin on October 1, 2017, with skilled nursing facilities (SNFs) set to receive a Medicare bonus or penalty beginning a year later.[1] The Centers for Medicare & Medicaid Services (CMS) began public reporting of hospitals' 30-day readmission rates for selected conditions in 2009, and the Patient Protection and Affordable Care Act of 2010 mandated financial penalties for excess readmissions through the Hospital Readmission Reduction Program.[2] In response, most hospitals have focused on patients who return home following discharge. Innovative interventions have proven successful, such as the Transitional Care model developed by Naylor and Coleman's Care Transitions Intervention.[3-5] Approximately 20% of Medicare beneficiaries are discharged from hospitals to SNFs, and these patients have higher readmission rates than those discharged home. CMS reported that in 2010, 23.3% of those with an SNF stay were readmitted within 30 days, compared with 18.8% for those with other discharge dispositions.[6]

Some work has been undertaken in this arena. In 2012, the Center for Medicare and Medicaid Innovation (CMMI) and the Medicare-Medicaid Coordination Office jointly launched the Initiative to Reduce Avoidable Hospitalizations among Nursing Facility Residents.[7] This partnership established 7 Enhanced Care and Coordination Provider organizations and was designed to improve care by reducing hospitalizations among long-stay, dual-eligible nursing facility residents at 143 nursing homes in 7 states.[8] At the time of the most recent project report, there were mixed results regarding program effects on hospitalizations and spending, with 2 states showing strongly positive patterns, 3 states with reductions that were consistent though not statistically strong, and mixed results in the remaining states. Quality measures did not show any pattern suggesting a program effect.[9] Interventions to Reduce Acute Care Transfers (INTERACT) II was a 6-month, collaborative, quality-improvement project implemented in 2009 at 30 nursing homes in 3 states.[10] The project evaluation found a statistically significant, 17% decrease in self-reported hos-

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pital admissions among the 25 SNFs that completed the intervention, compared with the same 6 months in the prior year. The Cleveland Clinic recently reported favorable results implementing its Connected Care model, which relied on staff physicians and advanced practice professionals to visit patients 4 to 5 times per week and be on call 24/7 at 7 intervention SNFs.[11] Through this intervention, it successfully reduced its 30-day hospital readmission rate from SNFs from 28.1% to 21.7% ($P < 0.001$), and the authors posed the question as to whether its model and results were reproducible in other healthcare systems.

Herein, we report on the results of a collaborative initiative named the Enhanced Care Program (ECP), which offers the services of clinical providers and administrative staff to assist with the care of patients at 8 partner SNFs. The 3 components of ECP (described below) were specifically designed to address commonly recognized gaps and opportunities in routine SNF care. In contrast to the Cleveland Clinic's Connected Care model (which involved hospital-employed physicians serving as the SNF attendings and excluded patients followed by their own physicians), ECP was designed to integrate into a pluralistic, community model whereby independent physicians continued to follow their own patients at the SNFs. The Connected Care analysis compared participating versus nonparticipating SNFs; both the Connected Care model and the INTERACT II evaluation relied on pre–post comparisons; the CMMI evaluation used a difference-in-differences model to compare the outcomes of the program SNFs with those of a matched comparison group of nonparticipating SNFs. The evaluation of ECP differs from these other initiatives, using a concurrent comparison group of patients discharged to the same SNFs but who were not enrolled in ECP.

METHODS

Setting

Cedars-Sinai Medical Center (CSMC) is an 850-bed, acute care facility located in an urban area of Los Angeles. Eight SNFs, ranging in size from 49 to 150 beds and located between 0.6 and 2.2 miles from CSMC, were invited to partner with the ECP. The physician community encompasses more than 2000 physicians on the medical staff, including private practitioners, nonteaching hospitalists, full-time faculty hospitalists, and faculty specialists.

Study Design and Patients

This was an observational, retrospective cohort analysis of 30-day same-hospital readmissions among 3951 patients discharged from CSMC to 8 SNFs between January 1, 2014, and June 30, 2015. A total of 2394 patients were enrolled in the ECP, and 1557 patients were not enrolled.

ECP Enrollment Protocol

Every patient discharged from CSMC to 1 of the 8 partner SNFs was eligible to participate in the program. To respect the autonomy of the SNF attending physicians and to facilitate a collaborative relationship, the decision to enroll a patient in the ECP rested with the SNF attending physician. The ECP team maintained a database that tracked whether each SNF attending physician (1) opted to automatically enroll all his or her patients in the ECP, (2) opted to enroll patients on a case-by-case basis (in which case an ECP nurse practitioner [NP] contacted the attending physician for each eligible patient), or (3) opted out of the ECP completely. When a new SNF attending physician was encountered, the ECP medical director called the physician to explain the ECP and offer enrollment of his or her patient(s). Ultimately, patients (or their decision-makers) retained the right to opt in or out of the ECP at any time, regardless of the decision of the attending physicians.

Program Description

Patients enrolled in the ECP experienced the standard care provided by the SNF staff and attending physicians plus a clinical care program delivered by 9 full-time NPs, 1 full-time pharmacist, 1 pharmacy technician, 1 full-time nurse educator, a program administrator, and a medical director.

The program included the following 3 major components:

1. Direct patient care and 24/7 NP availability: Program enrollment began with an on-site, bedside evaluation by an ECP NP at the SNF within 24 hours of arrival and continued with weekly NP rounding (or more frequently, if clinically indicated) on the patient. Each encounter included a review of the medical record; a dialogue with the patient's SNF attending physician to formulate treatment plans and place orders; discussions with nurses, family members, and other caregivers; and documentation in the medical record. The ECP team was on-site at the SNFs 7 days a week and on call 24/7 to address questions and concerns. Patients remained enrolled in the ECP from SNF admission to discharge even if their stay extended beyond 30 days.
2. Medication reconciliation: The ECP pharmacy team completed a review of a patient's SNF medication administration record (MAR) within 72 hours of SNF admission. This process involved the pharmacy technician gathering medication lists from the SNFs and CSMC and providing this information to the pharmacist for a medication reconciliation and clinical evaluation. Discrepancies and pharmacist recommendations were communicated to the ECP NPs, and all identified issues were resolved.
3. Educational in-services: Building upon the INTERACT II model, the ECP team identified high-yield, clinically relevant topics, which the ECP nurse educator turned into monthly educational sessions for the SNF nursing staff at each of the participating SNFs.[10]

Primary Outcome Measure

An inpatient readmission to CSMC within 30 days of the hospital discharge date was counted as a readmission, whether the patient returned directly from an SNF or was readmitted from home after an SNF discharge.

TABLE 1. Distribution of Patient Characteristics

Patient Characteristics	Total n = 3951	ECP n = 2394 (60.6%)	Comparison n = 1557 (39.4%)
Mean age at index discharge, years (SD)	78.1 (12.3)	78.1 (12.6)	78.2 (12.0)
<65 years	12.8	13.3	12.0
65-84 years	51.4	50.5	52.9
≥85 years	35.8	36.2	35.1
Male gender	40.8	39.7	42.4
Race and/or ethnicity			
Non-Hispanic white	72.3	74.3[a]	69.3[a]
Black or African American	19.1	18.0[a]	20.8[a]
Hispanic and/or Latino	5.1	4.3[b]	6.3[b]
Asian	2.9	3.1	2.8
Other	0.6	0.4	0.9
Preferred language			
English	74.8	81.6[b]	64.4[b]
Russian	9.2	6.7[b]	13.2[b]
Farsi	8.4	5.0[b]	13.6[b]
Spanish	3.4	2.8[a]	4.3[a]
Other	4.2	3.9	4.6
Payer			
Medicare fee for service	45.9	52.9[b]	35.0[b]
Dual eligible	42.9	35.1[b]	55.0[b]
Other	11.2	12.0	10.0
Hospital clinical service line			
Orthopedic surgery	25.7	28.7[b]	21.1[b]
General internal medicine	20.6	20.1	21.4
General surgery	8.5	9.1	7.7
Cardiology, medical	8.3	7.4[b]	9.7[b]
Cardiology, interventional	2.0	2.1	1.9
Gastroenterology	7.0	6.1[a]	8.2[a]
Pulmonary	7.4	6.0[b]	9.7[b]
Neurology	6.1	5.9	6.6
Other surgical	7.9	9.2[b]	5.8[b]
Psychiatry	0.5	0.5	0.6
Other service	5.6	5.1[b]	7.4[b]
APR-DRG severity of illness	(n = 3946)	(n = 2389)	(n = 1557)
Minor	8.1	8.7	7.1
Moderate	27.1	26.8	27.7
Major	43.2	42.9	43.6
Extreme	21.6	21.6	21.6
Index discharge length of stay in days (SD)	8.04 (8.45)	8.28 (8.94)	7.66 (7.62)
Index hospitalization length of stay			
1 to 3 days	25.1	24.6	26.0
4 to 5 days	24.4	23.8	25.4
6 to 9 days	26.9	26.9	26.9
>9 days	23.6	24.8[a]	21.7[a]

[a]Percentages between the ECP and comparison differ at $P < .05$.

[b]Percentages differ at $P < .001$.

NOTE: Values are percentages unless otherwise indicated. Totals may not add to 100% due to rounding. Unless otherwise indicated, n = 3951. Abbreviations: APR-DRG, All Patients Refined Diagnosis Related Group; ECP, Enhanced Care Program; SD, standard deviation.

Data

ECP patients were identified using a log maintained by the ECP program manager. Non-ECP patients discharged to the same SNFs during the study period were identified from CSMC's electronic registry of SNF discharges. Covariates known to be associated with increased risk of 30-day readmission were obtained from CSMC's electronic data warehouse, including demographic information, length of stay (LOS) of index hospitalization, and payer.[12] Eleven clinical service lines represented patients' clinical conditions based on Medi-

TABLE 2. Multivariable Logistic Regression: Odds of 30-day Same-Hospital Readmission From SNFs

Patient Characteristics	Odds Ratio	95% CI	*P* Value
ECP participation	0.71	0.60-0.85	<.001
Age category			
<65 years	1.25	0.95-1.64	.105
65-84 years	Reference	0.84-1.23	.845
≥85 years	1.02		
Gender			
Male	1.27	1.07-1.50	.005
Female	Reference		
Race			
White	Reference		
Black or African American	1.07	0.86-1.33	.559
Hispanic and/or Latino	0.54	0.30-0.97	.041
Asian	0.90	0.52-1.52	.667
Other	Dropped	NA	NA
Preferred Language			
English	Reference		
Russian	0.79	0.56-1.12	.192
Farsi	0.82	0.58-1.15	.242
Spanish	1.83	0.96-3.50	.069
Other	1.62	1.05-2.48	.028
Payer			
Medicare fee-for-service	Reference		
Dual eligible	1.37	1.10-1.69	.004
Other	0.96	0.69-1.34	.818
Hospital clinical service line			
Orthopedic surgery	Reference		
General internal medicine	1.35	1.01-1.79	.042
General surgery	1.11	0.78-1.58	.562
Cardiology, medical	1.89	1.35-2.65	<.001
Cardiology, interventional	1.31	0.71-2.41	.381
Gastroenterology	1.91	1.33-2.73	<.001
Pulmonary	1.66	1.16-2.37	.005
Neurology	1.12	0.74-1.69	.590
Other surgical	0.98	0.67-1.42	.901
Psychiatry	1.01	0.28-3.63	.986
Other service	1.53	1.04-2.25	.031
APR-DRG severity			
Minor	1.35	0.89-2.06	.158
Moderate	Reference	1.42-2.30	<.001
Major	1.81	1.66-2.97	<.001
Extreme	2.22		
Index hospital length of stay			
1 to 3 days	0.68	0.53-0.89	.004
4 to 5 days	0.81	0.64-1.03	.092
6 to 9 days	Reference	1.16-1.82	.001
>9 days	1.45		

NOTE: Abbreviations: APR-DRG, All Patients Refined Diagnosis Related Group; CI, confidence interval; ECP, Enhanced Care Program; NA, not applicable, SNF, skilled nursing facility.

care-Severity Diagnosis-Related groupings. The discharge severity of illness score was calculated using 3M All Patients Refined Diagnosis Related Group software, version 33.[13]

Analysis

Characteristics of the ECP and non-ECP patients were compared using the χ^2 test. A multivariable logistic regression model with fixed effects for SNF was created to determine the program's impact on 30-day hospital readmission, adjusting for patient characteristics. The Pearson χ^2 goodness-of-fit test and the link test for model specification were used to evaluate model specification. The sensitivity of the results to

differences in patient characteristics was assessed in 2 ways. First, the ECP and non-ECP populations were stratified based on race and/or ethnicity and payer, and the multivariable regression model was run within the strata associated with the highest readmission rates. Second, a propensity analysis using inverse probability of treatment weighting (IPTW) was performed to control for group differences. Results of all comparisons were considered statistically significant when $P < 0.05$. Stata version 13 was used to perform the main analyses.[14] The propensity analysis was conducted using R version 3.2.3. The CSMC Institutional Review Board (IRB) determined that this study qualified as a quality-improvement activity and did not require IRB approval or exemption.

RESULTS

The average unadjusted 30-day readmission rate for ECP patients over the 18-month study period was 17.2%, compared to 23.0% for patients not enrolled in ECP ($P < 0.001$) (Figure 1). After adjusting for patient characteristics, ECP patients had 29% lower odds (95% confidence interval [CI], 0.60-0.85) of being readmitted to the medical center within 30 days than non-ECP patients at the same SNFs. The characteristics of the ECP and comparison patient cohorts are shown in Table 1. There were significant differences in sociodemographic characteristics: The ECP group had a higher proportion of non-Hispanic white patients, while the comparison group had a higher proportion of patients who were African American or Hispanic. ECP patients were more likely to prefer speaking English, while Russian, Farsi, and Spanish were preferred more frequently in the comparison group. There were also differences in payer mix, with the ECP group including proportionately more Medicare fee-for-service (52.9% vs 35.0%, $P < 0.001$), while the comparison group had a correspondingly larger proportion of dual-eligible (Medicare and Medicaid) patients (55.0% vs 35.1%, $P < 0.001$).

The largest clinical service line, orthopedic surgery, had the lowest readmission rate. The highest readmission rates were found among patients with medical cardiology hospitalizations, pulmonary diseases, and gastroenterology conditions. There was a significant monotonic relationship between quartiles of index hospital LOS and 30-day readmission (Supplemental Table 1).

The largest clinical differences observed between the ECP and non-ECP groups were the proportions of patients in the clinical service lines of orthopedic surgery (28.7% vs 21.1%, $P < 0.001$), medical cardiology (7.4% vs 9.7%, $P < 0.001$), and surgery other than general surgery (5.8% vs 9.2%, $P < 0.001$). Despite these differences in case mix, no differences were seen between the 2 groups in discharge severity of illness or LOS of the index hospitalization. The distribution of index hospital LOS by quartile was the same, with the exception that the ECP group had a higher proportion of patients with longer LOS.

Results of the multivariable logistic regression analysis are shown in Table 2. Males had 27% higher odds of readmission

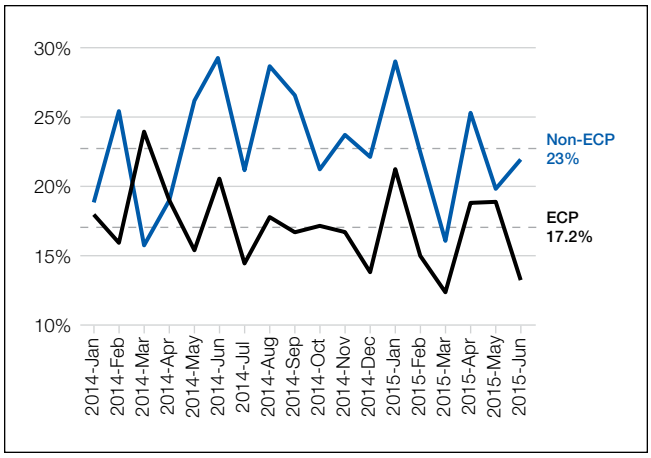

FIG 1. Monthly rate of 30-day readmissions to CSMC, ECP vs Non–ECP.

Abbreviations: CSMC, Cedars-Sinai Medical Center; ECP, Enhanced Care Program; Non-ECP, Non—Enhanced Care Program

(95% CI, 1.07-1.50), and patients who were dually eligible for Medicare and Medi-Cal (California's Medicaid program) had 37% higher odds of readmission (95% CI, 1.10-1.69). Compared with patients who had orthopedic surgery, the clinical service lines with significantly higher rates of readmission were gastroenterology (odds ratio [OR] 1.91; 95% CI, 1.33-2.73), medical cardiology (OR 1.89; 95% CI, 1.35-2.65), and pulmonary (OR 1.66; 95% CI, 1.16-2.37). Severity of illness at discharge and index hospital LOS were both positively associated with readmission in the adjusted analysis.

Sensitivity Analyses

The results were robust when tested within strata of the study population, including analyses limited to dual-eligible patients, African American patients, patients admitted to all except the highest volume facility, and patients admitted to any service line other than orthopedic surgery. Similar results were obtained when the study population was restricted to patients living within the medical center's primary service area and to patients living in zip codes in which the proportion of adults living in households with income below 100% of the poverty level was 15% or greater (see Supplementary Material for results).

The effect of the program on readmission was also consistent when the full logistic regression model was run with IPTW using the propensity score. The evaluation of standardized cluster differences between the ECP and non-ECP groups before and after IPTW showed that the differences were reduced to <10% for being African American; speaking Russian or Farsi; having dual-eligible insurance coverage; having orthopedic surgery; being discharged from the clinical service lines of gastroenterology, pulmonary, other surgery, and other services; and having an index hospital LOS of 4 to 5 days or 10 or more days (results are provided in the Supplementary Material).

Figure 2 displays the 30-day readmission rate for all Cedars-Sinai patients discharged to any SNF in the 3 years

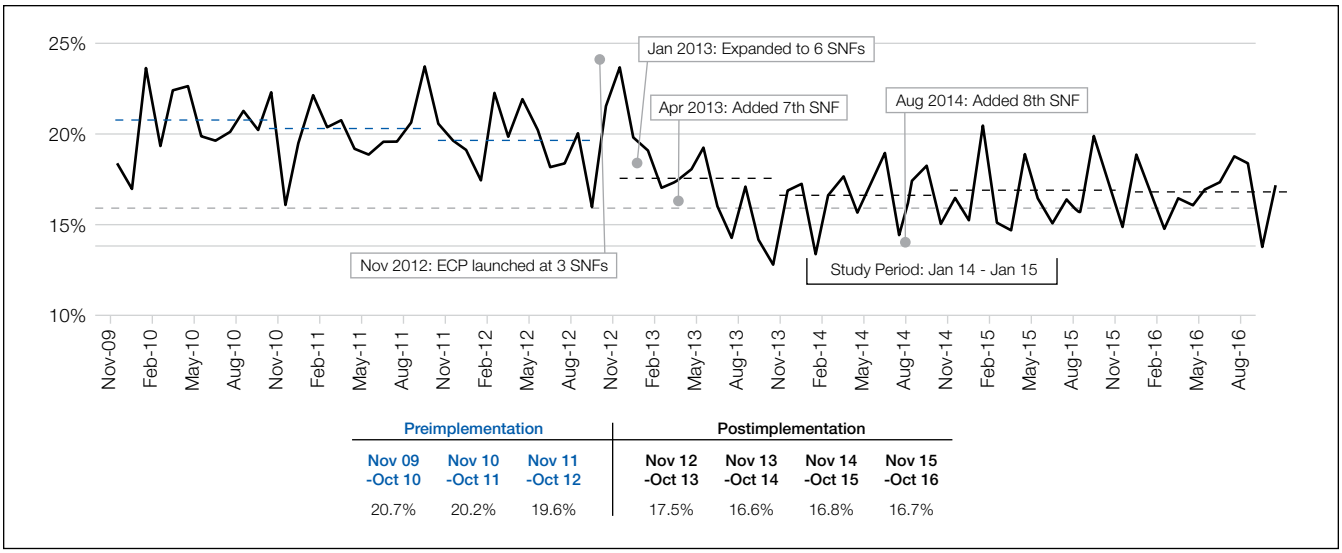

FIG 2. Mean 12 month same-hospital readmission rates of all patients discharged to SNF, pre- and postimplementation of ECP.

Abbreviations: ECP, Enhanced Care Program; SNF, skilled nursing facility.

preceding and 4 years following the intervention. The readmission rate in the 12-month period immediately prior to the launch of the ECP was 19.6%. That rate dropped significantly to 17.5% in the first 12-month period postimplementation ($P = 0.016$) and to 16.6% in the next 12 months ($P > 0.001$ for the overall decline). During the study period, 66% of all Cedars-Sinai patients who were discharged to a SNF were admitted to 1 of the 8 participating SNFs. More than half of those patients (representing approximately 40% of all CSMC SNF discharges) were enrolled in the ECP.

DISCUSSION

Hospitals continue to experience significant pressure to manage LOS, and SNFs and hospitals are being held accountable for readmission rates. The setting of this study is representative of many large, urban hospitals in the United States whose communities include a heterogeneous mix of hospitalists, primary care physicians who follow their patients in SNFs, and independent SNFs.[15] The current regulations have not kept up with the increasing acuity and complexity of SNF patients. Specifically, Medicare guidelines allow the SNF attending physician up to 72 hours to complete a history and physical (or 7 days if he or she was the hospital attending physician for the index hospitalization) and only require monthly follow-up visits. It is the opinion of the ECP designers that these relatively lax requirements present unnecessary risk for vulnerable patients. While the INTERACT II model was focused largely on educational initiatives (with an advanced practice nurse available in a consultative role, as needed), the central tenet of ECP was similar to the Connected Care model in that the focus was on adding an extra layer of direct clinical support. Protocols that provided timely initial assessments by an NP (within 24 hours), weekly NP rounding (at a minimum), and 24/7 on-call availability all contributed to helping patients stay on track. Although the ECP had patients visited less frequently than the Connected Care model, and the Cleveland Clinic started with a higher baseline 30-day readmission rate from SNFs, similar overall reductions in 30-day readmissions were observed. The key point from both initiatives is that an increase in clinical touchpoints and ease of access to clinicians generates myriad opportunities to identify and address small issues before they become clinical emergencies requiring hospital transfers and readmissions.

Correcting medication discrepancies between hospital discharge summaries and SNF admission orders through a systematic medication reconciliation using a clinical pharmacist has previously been shown to improve outcomes.[16-18] The ECP pharmacy technician and ECP clinical pharmacist discovered and corrected errors on a daily basis that ranged from incidental to potentially life-threatening. If the SNF staff does not provide the patient's MAR within 48 hours of arrival, the pharmacy technician contacts the facility to obtain the information. As a result, all patients enrolled in the ECP during the study period received this intervention (unless they were rehospitalized or left the SNF before the process was completed), and 54% of ECP patients required some form of intervention after medication reconciliation was completed (data not shown).

This type of program requires hospital leadership and SNF administrators to be fully committed to developing strong working relationships, and in fact, there is evidence that SNF baseline readmission rates have a greater influence on patients' risk of rehospitalization than the discharging hospital itself.[19-21] Monthly educational in-services are delivered at the partner SNFs to enhance SNF nursing staff knowledge and clinical acumen. High-impact topics identified by the ECP team include the following: fall prevention, hand hygiene, venous thromboembolism, cardiovascular health, how to report change in condition, and advanced care planning, among others. While no formal pre–post assessments of the

SNF nurses' knowledge were conducted, a log of in-services was kept, subjective feedback was collected for performance improvement purposes, and continuing educational units were provided to the SNF nurses who attended.

This study has limitations. As a single-hospital study, generalizability may be limited. While adherence to the program components was closely monitored daily, service gaps may have occurred that were not captured. The program design makes it difficult to quantify the relative impact of the 3 program components on the outcome. Furthermore, the study was observational, so the differences in readmission rates may have been due to unmeasured variables. The decision to enroll patients in the ECP was made by each patient's SNF attending physician, and those who chose to (or not to) participate in the program may manifest other, unmeasured practice patterns that made readmissions more or less likely. Participating physicians also had the option to enroll their patients on a case-by-case basis, introducing further potential bias in patient selection; however, <5% of physicians exercised this option. Patients may have also been readmitted to hospitals other than CSMC, producing an observed readmission rate for 1 or both groups that underrepresents the true outcome. On this point, while we did not systematically track these other-hospital readmissions for both groups, there is no reason to believe that this occurred preferentially for ECP or non-ECP patients.

Multiple sensitivity analyses were performed to address the observed differences between ECP and non-ECP patients. These included stratified examinations of variables differing between populations, examination of clustering effects between SNFs, and an analysis adjusted for the propensity to be included in the ECP. The calculated effect of the intervention on readmission remained robust, although we acknowledge that differences in the populations may persist and have influenced the outcomes even after controlling for multiple variables.[22-25]

In conclusion, the results of this intervention are compelling and add to the growing body of literature suggesting that a comprehensive, multipronged effort to enhance clinical oversight and coordination of care for SNF patients can improve outcomes. Given CMS's plans to report SNF readmission rates in 2017 followed by the application of financial incentives in 2018, a favorable climate currently exists for greater coordination between hospitals and SNFs.[26] We are currently undertaking an economic evaluation of the program.

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Hospice Facility and Use of ADD

SUMMARY

CHA recently had an inquiry from a hospice facility on the use of automated delivery devices (ADD) in a hospice facility. The facility wants to use an ADD and was informed by a surveyor that it is prohibited. Attached is the email response from CDPH.

ACTION REQUESTED

- CHA requests addition of hospice facility into appropriate code section to allow ADD devices.

DISCUSSSION QUESTIONS

1. Where and what code sections need to be changed?
2. Are there any other types of facilities that need to be added, presently the statute calls out SNF and ICF's?

Barbara Roth

From: BJ Bartleson
Sent: Friday, September 01, 2017 2:22 PM
To: Barbara Roth
Subject: FW: Hospice Facility and the use of Automated Drug Delivery Systems (ADDs)

For next med safety packet

BJ BARTLESON, RN, MS, NEA-BC
Vice President, Nursing & Clinical Services
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bjbartleson@calhospital.org

From: David Perrott
Sent: Friday, September 01, 2017 9:34 AM
To: Debby Rogers <drogers@calhospital.org>; BJ Bartleson <BJbartleson@calhospital.org>
Subject: FW: Hospice Facility and the use of Automated Drug Delivery Systems (ADDs)

I appreciate their responses. They must follow the current regulations. But this another example of regulations not fitting the new healthcare delivery system. If we are to be an integrated delivery system, then regulations must be changed to permit operational efficiency and safety. Having oversight of the hospital pharmacy would be in everyone's best interest.

Are we keeping a list of such regulatory changes that are needed? In the future, I anticipate inquiries regarding these opportunities.

Dave

David Perrott, MD, DDS
Senior Vice President & Chief Medical Officer
California Hospital Association

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information. Please contact the sender immediately by return e-mail and delete the original message from your system.

From: Yamashiro, Virginia (CDPH-LNC-HQ) [mailto:Virginia.Yamashiro@cdph.ca.gov]
Sent: Friday, September 1, 2017 8:30 AM
To: Debby Rogers <drogers@calhospital.org>; David Perrott <dperrott@calhospital.org>; Vivona, Scott (CDPH-LNC-HQ) <Scott.Vivona@cdph.ca.gov>
Cc: Lee, Cari (CDPH-LNC-DO) <Cari.Lee@cdph.ca.gov>; Lincer, Jacqueline (CDPH-L&C) <Jackie.Lincer@cdph.ca.gov>; Christensen, John (CDPH-L&C) <John.Christensen@cdph.ca.gov>; Obair, Samuel (CDPH-LNC) <Samuel.Obair@cdph.ca.gov>
Subject: FW: Hospice Facility and the use of Automated Drug Delivery Systems (ADDs)

Debby,
See response below on this issue. Let me know if you want to do a conference call to discuss further. Thanks.

Cari,
Thanks for the follow-up and response.

From: Lee, Cari (CDPH-LNC-DO)
Sent: Friday, September 01, 2017 6:53 AM
To: Lincer, Jacqueline (CDPH-L&C); Yamashiro, Virginia (CDPH-LNC-HQ)
Cc: Christensen, John (CDPH-L&C); Obair, Samuel (CDPH-LNC)
Subject: Fwd: Hospice Facility and the use of Automated Drug Delivery Systems (ADDs)

Hi Jackie and Virginia,

Here is the answer to Debby's question:

Bonitaview is a hospice facility owned by Grossmont Hospital Corporation, one of the 3 hospice residences under Sharp. As expected, the hospice facility is owned by the hospital but is not located within the hospital nor licensed as part of the hospital (I don't think this is an option).

I spoke with Ken Schell, the Director of Sharp Central Pharmacy Services, on Tuesday and found out that Sharp Central Pharmacy Services current supplies the drugs to the residents in the hospice home. I can only imagine that they are being handled as outpatient prescriptions. The hospital wants to put a Pyxis in the hospice home. The intent is to make medications more timely available for the hospice patients, however, based on the detailed response from the Board of Pharmacy, putting drugs owned by a hospital pharmacy in an ADDS located outside of the hospital is not currently permitted.

On the other hand, if Sharp wants to use their retail pharmacy license to place an ADDS in a health facility, HSC 1261.6 would apply but the retail pharmacy is only allowed to place an ADDS in health facilities licensed pursuant to subdivision (c), (d), or (k), of HSC Section 1250, which does not include hospice facilities. Such ADDS will also need to be registered with the Board of Pharmacy.

Ken Schell is well aware of the restrictions and understands why it is not permitted under existing regs for hospice facilities to use an ADDS for drug distribution.

Drugs in ADDS are owned by the pharmacies (except in the case of physician owns) and pharmacies are regulated by the BoP. If Debby wants to discuss, I would be happy to explain the BoP requirements around the subject to her. Thanks.

Cari

Begin forwarded message:

From: "Yamashiro, Virginia (CDPH-LNC-HQ)" <Virginia.Yamashiro@cdph.ca.gov>
Date: August 22, 2017 at 10:00:04 AM PDT
To: Debby Rogers <drogers@calhospital.org>
Cc: "Vivona, Scott (CDPH-LNC-HQ)" <Scott.Vivona@cdph.ca.gov>, "Lincer, Jacqueline (CDPH-L&C)" <Jackie.Lincer@cdph.ca.gov>, "Lee, Cari (CDPH-LNC-DO)" <Cari.Lee@cdph.ca.gov>, "Christensen, John (CDPH-L&C)" <John.Christensen@cdph.ca.gov>, "Obair, Samuel (CDPH-LNC)" <Samuel.Obair@cdph.ca.gov>
Subject: Re: Hospice Facility and the use of Automated Drug Delivery Systems (ADDs)

Debby,
Let me check with the lead pharmacists and Jackie will let you know. Thanks.

Sent from my iPhone

On Aug 22, 2017, at 11:56 AM, Debby Rogers <drogers@calhospital.org> wrote:

> Hello Scott and Virginia-
>
> Hope this note finds you well.
>
> I'm not sure who lead is on hospice facilities, but I've been asked by Bonitaview Hospice facility (license attached) a question about the use of ADDs in a hospice facility. I don't see a prohibition, but there is a section in the long-term care section of the law that specifically calls out SNF, ICFs and SNF (Medicare).
>
> This facility wants to use an ADD, but was told by a pharmacy surveyor that it is prohibited by HSC 1261.6. Using that logic, then an acute care hospital could not use an ADD.
>
> I would appreciate it if we could discuss this. Thanks. Debby

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<BVH DPH 11-19-16 to 11-18-17.pdf>

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Issues Facing the Pharmacy Workforce

SUMMARY

An informational hearing of the Senate Subcommittee on Professions and Licensure was held on Monday, October 2, 2017.

ACTION REQUESTED

- Discussion on issues facing the pharmacy workforce

DISCUSSION QUESTIONS

1. Why was this hearing held and what issues were gleaned from the meeting?
2. What are the short, mid and long term issues facing the pharmacy workforce? Specifically pharmacists and pharm tech's……

BJB:br

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SENATOR
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COMMITTEES
BUSINESS, PROFESSIONS & ECONOMIC DEVELOPMENT
CHAIR
APPROPRIATIONS
ENERGY, UTILITIES & COMMUNICATIONS
ENVIRONMENTAL QUALITY
GOVERNMENTAL ORGANIZATION

Informational Hearing of the Senate Subcommittee on Professions and Licensure

Issues Facing the Pharmacy Workforce

Monday, October 2, 2017
2:00 – 3:30 pm

California State University, Fullerton
Titan Student Union, Portola - Pavilion B
800 N State College Blvd.
Fullerton, CA 92831

AGENDA

1. Opening Remarks
    a. *State Senator Josh Newman*, Chair, Senate Subcommittee on Professions and Licensure

2. Perspectives from Labor
    a. *Jon R. Roth, MS, CAE,* CEO, California Pharmacists Association
    b. *Rebecca Cupp, RPh,* President, Cupp Health Innovations
    c. *Keith Fung, RPh,* Member, UFCW Local 770
    d. *Cheryl Butler, PharmD*, Vice President, UFCW Local 770
    e. *Lawrence Louie, PharmD,* United Nurses Association of California, Union of Health Care Professionals

3. Perspectives from Industry
    a. *Angie Manetti,* Director of Government Affairs, California Retailers Association
    b. *Sandra Kay Guckian, IOM, MS, RPh,* Vice President of State Government Affairs, National Association of Chain Drug Stores

4. Perspective from the State Regulator
    a. *Anne Sodergren,* Assistant Executive Officer, California State Board of Pharmacy

5. Questions/ Closing
    a. *State Senator Josh Newman*, Chair, Senate Subcommittee on Professions and Licensure

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: 09/08/2017
DISPOSITION: To Governor
LOCATION: To Governor
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 CURES database, available to the practitioner, or a pharmacist. Authorizes a practitioner or pharmacist to submit a query on an online internet web portal or an authorized health information technology system, under certain conditions. Requires a maintenance fee to establish an integration with the CURES database.

STATUS:

09/25/2017 *****To GOVERNOR.

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

CA AB 265

AUTHOR: Wood [D]
TITLE: Prescription Drugs: Prohibition on Price Discount
INTRODUCED: 01/31/2017
LAST AMEND: 09/07/2017
DISPOSITION: To Governor
LOCATION: To Governor
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 individuals health insurance, health care service plan, or other health coverage on a lower cost sharing. Authorizes a manufacturer to offer a pharmaceutical product free of charge to patients and insurers.

STATUS:

09/20/2017 *****To GOVERNOR.

INDEX: 89

ISSUES: DG

LOBBYIST: AH

POSITION: F

CA AB 315

AUTHOR: Wood [D]

TITLE: Pharmacy Benefit Management

INTRODUCED: 02/06/2017

LAST AMEND: 07/11/2017

DISPOSITION: Pending

LOCATION: Senate Inactive File

SUMMARY:

Requires pharmacy benefit managers to be registered with the Department of Managed Health Care. Requires the department to develop applications for the registration, and specifies certain information to be provided in those applications. Requires a pharmacy benefit manager to exercise a duty of good faith and fair dealing in the performance of its contractual duties to a purchaser. Requires a pharmacy benefit manager to notify a pharmacy network provider of certain contract changes.

STATUS:

09/07/2017 In SENATE. From third reading. To Inactive File.

INDEX: 39, 89

ISSUES: DG

LOBBYIST: AH

POSITION: F

CA AB 401

AUTHOR: Aguiar-Curry [D]

TITLE: Pharmacy: Remote Dispensing Site Pharmacy: Telepharmacy

INTRODUCED: 02/09/2017

LAST AMEND: 09/07/2017

DISPOSITION: To Governor

LOCATION: To Governor

SUMMARY:

Prohibits the Board from issuing specified licenses to clinics that share a clinic office space until the board is provided with documentation relating to MediCal financing and other regulatory issues. Authorizes primary care clinics and specialty clinics to operate, as specified, in shared clinic space with the government clinics.

STATUS:

09/20/2017 *****To GOVERNOR.

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
VETOED: 09/28/2017
DISPOSITION: Vetoed
LOCATION: Vetoed
SUMMARY:

Clarifies that a court may collaborate with outside organizations on 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:

09/28/2017 Vetoed by GOVERNOR.
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: 07/12/2017
DISPOSITION: Pending
LOCATION: Senate Appropriations Committee
SUMMARY:

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

STATUS:

08/21/2017 In SENATE Committee on APPROPRIATIONS: Not heard.
INDEX: 89
ISSUES: DG
LOBBYIST: AH
POSITION: F

CA AB 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: 09/05/2017
DISPOSITION: To Governor
LOCATION: To Governor
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 certain manufacturers with a specified wholesale acquisition cost of a prescription drug that is purchased or reimbursed by specified purchasers. Makes an appropriation.

STATUS:

09/20/2017 *****To GOVERNOR.
INDEX: 65, 89
ISSUES: AO, DG*
LOBBYIST: AH*, BG
POSITION: S, X

CA SB 351

AUTHOR: Roth [D]
TITLE: Hospital Satellite Compounding Pharmacy: License
INTRODUCED: 02/14/2017
LAST AMEND: 09/08/2017
DISPOSITION: To Governor
LOCATION: To Governor
SUMMARY:

Authorizes the State Board of Pharmacy to issue a license to a hospital satellite compounding pharmacy meeting specified requirements. Redefines a hospital pharmacy to include a pharmacy that is located in any physical plant regulated as a general acute care hospital. Authorizes the board to issue a license to a hospital satellite compounding pharmacy meeting specified requirements. Requires a hospital satellite compounding pharmacy to compound sterile drug products for registered patients on the premises.

STATUS:

09/21/2017 *****To GOVERNOR.
INDEX: 89
ISSUES: BJ*, PW
LOBBYIST: AH
POSITION: S, X

CA SB 443

AUTHOR: Hernandez [D]
TITLE: Pharmacy: EMS Automated Drug Delivery System
INTRODUCED: 02/15/2017
LAST AMEND: 09/05/2017
DISPOSITION: To Governor
LOCATION: To Governor
SUMMARY:

Authorizes a pharmacy, or licensed wholesaler that is also an emergency medical services provider agency, to restock dangerous drugs or devices into an

emergency medical services automated drug delivery system that is licensed by the board, if specified conditions are met. Requires the provider agency to obtain a license from the board to operate the system.

STATUS:

09/22/2017 *****To GOVERNOR.

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: To Governor

LOCATION: To Governor

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:

09/14/2017 Enrolled.

09/14/2017 *****To GOVERNOR.

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:

09/01/2017 In ASSEMBLY Committee on APPROPRIATIONS: Held in committee.

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
LOCATION: Assembly Public Safety Committee

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 Appropriations Committee

SUMMARY:

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

STATUS:

07/19/2017 In ASSEMBLY Committee on APPROPRIATIONS: Not heard.

INDEX: 89
ISSUES: BJ*, DP
LOBBYIST: AH
POSITION: N, X

CA SB 752

AUTHOR: Stone [R]
TITLE: Pharmacy: Designated Representative Reverse Distributor
INTRODUCED: 02/17/2017
LAST AMEND: 09/07/2017
DISPOSITION: To Governor
LOCATION: To Governor

SUMMARY:

Amends existing law relating to requirements of licensure examinations. Provides that an applicant who fails certain licensure examinations be required to wait at a specified period of time before being permitted to retake the examination.

STATUS:

09/22/2017	*****To GOVERNOR.
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:	09/08/2017
DISPOSITION:	To Governor
LOCATION:	To Governor

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:

09/21/2017	*****To GOVERNOR.
INDEX:	89
ISSUES:	BJ, DP, LR*
LOBBYIST:	AH
POSITION:	F

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: IV Solutions

SUMMARY

Several issues have surfaced relative to ample IV solutions for hospitals. Braun has history of FDA citings and may appear to have supply issues out of its southern California sites. Puerto Rico drug manufacturers have been affected due to Hurricane Maria, however the FDA Commissioner reported Friday, October 6, that no severe distribution issues had been uncovered.

ACTION REQUESTED

- Discussion among members on issues affecting their IV solution supplies.

DISCUSSSION QUESTIONS

1. What do hospitals /organizations do when they sole source a vendor who has supply issues and they need to obtain additional resources?
2. Are any other hospital/organizations facing this issue?

BJB:br

FDA Statement

Statement from FDA Commissioner Scott Gottlieb, M.D. on FDA's continued assistance following the natural disaster in Puerto Rico

For Immediate Release

October 6, 2017

Statement

FDA continues extensive efforts to provide direct assistance to the residents of Puerto Rico following Hurricanes Irma and Maria, and is taking new steps to mitigate the impact of these twin disasters on the island's vibrant medical product manufacturing sector. Our top priority is the people of Puerto Rico.

As part of that commitment, FDA has an important mission to help Puerto Rico recover its medical product manufacturing base. These facilities are a key component of the island's economic vigor. The pharmaceutical and biological drug products and medical devices produced on the island account for about 30 percent of Puerto Rico's gross domestic product. Moreover, about 80 percent of the drug products manufactured on the island are consumed by U.S. citizens in Puerto Rico and across all fifty states. Securing this manufacturing base is vital to maintaining access to many important medical products.

According to data from the Bureau of Economic Analysis, the pharmaceutical products manufactured in Puerto Rico make up nearly 10 percent of all drugs consumed by Americans. And that doesn't even account for medical devices. Puerto Rico is vital to the health and wellbeing of all Americans.

Some of these facilities were hit harder than others. But even the facilities that sustained relatively minor damage are running on generator power. They could be without commercial power for months while crews work to restore stable power to the island. The generators allowed many facilities to re-start production, but certainly not all. Moreover, most of the facilities that we know of, that have resumed production, maintain only partial operations. New shortages could result from these disruptions and shortages that existed before the storms could potentially be extended. We've been in touch with all the firms. In the case of products we're most concerned about, FDA leadership is in contact with senior management teams.

We're keeping a close watch on the most critical medical products. These are the products for which a shortage could have substantial impact on the public health. This list currently comprises about 40 pharmaceutical and biological drug products. In some cases, we're in daily communication with the companies to stay on top of the evolving challenges and to act quickly when we can to prevent drug and device shortages. In urgent cases, when critical products are at issue, we've intervened over the last two weeks to help firms secure fuel to maintain production lines, get clearance to move logistical support into the island or finished goods to their recipients.

I've been asked over the last couple weeks if I can provide more details on the specific products impacted. We'll continue to provide as much information as we can appropriately make public and we'll update regularly on our progress. We expect that, as we learn more about the supply chain and take additional steps to help restore production, FDA will pare its list of about 40 products to a smaller number that we're monitoring. We'll be proactive in communicating about products that reach a shortage situation.

The FDA remains committed to Puerto Rico's future. Everyone is dedicated to these relief efforts. Last Friday I visited with FDA's staff in San Juan. I was moved by their courage and commitment. I'm also inspired by the work of everyone assisting this relief effort from our White Oak, Maryland headquarters. This will be a long recovery. The devastation was significant. But we're in this for the long run. We'll continue to partner with the people of Puerto Rico to help them recover, and secure their economic future.

###

Inquiries

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Jennifer Dooren (mailto:Jennifer.Dooren@fda.hhs.gov)
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Consumers

888-INFO-FDA

Related Information

- HHS activates aid for uninsured Puerto Rico residents needing medicine (https://www.hhs.gov/about/news/2017/10/05/hhs-activates-aid-for-uninsured-puerto-rico-residents-needing-medicine.html)
- FDA Fast Facts: FDA's Support of the Hurricane Relief Effort (/NewsEvents/Newsroom/ucm578139.htm)

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: BJ Bartleson, VP Nursing & Clinical Services

SUBJECT: Hep A Vaccine

SUMMARY

With the advent of the Hep A outbreak in Southern, and now northern California, the demand and supply of the Hep A vaccine, along with other pre-emptory activity, such as mandatory staff Hep A vaccination, are in question.

San Diego, Santa Cruz and Los Angeles Counties are currently experiencing outbreaks of hepatitis A infection. Public health officials have also identified cases due to the same strain of hepatitis A virus (HAV) in other areas of California.

On August 15th, the California Department of Public Health Issue an All Facilities Letter (AFL) to all Acute Care General Hospitals (See attached). Included in the AFL was a recommendation that Hospitals, particularly hospital emergency departments, should work with their local health departments to offer hepatitis A vaccines to all patients who are homeless, users of injection or non-injection illicit drugs, infected with hepatitis B or hepatitis C, or have other liver disease, e.g., alcoholic cirrhosis. Included in the AFL is information on patient billing, storage of the vaccination, immunization schedules and efficacy.

CDC has obtained vaccinations under the Centers for Disease Control (CDC) Section 317 of the Public Health Service Act which authorizes the federal purchase of vaccines to vaccinate children, adolescents, and uninsured adults of high priority populations. For the past 20 years, all newborns (except in rare exceptions) in California have received the HAV Vaccination as have many adults that are at high risk, including those traveling outside the United States.

There are two manufacturers of HAV vaccinations in the United States of which one has just recently resumed production. As the current time, CDPH indicates there are no shortages of vaccinations.

Hospitals in the outbreak areas should offer the HAV vaccine to health care personnel who have frequent close contact with patients who are homeless and/or use injection or non-injection illicit drugs and ensure appropriate cleaning of restrooms frequented by persons who are homeless and/or use injection or non-injection illicit drugs. Environmental cleaning methods similar to those used for norovirus should be implemented.

Hospitals should be in contact with their local public health officers for additional guidance on the availability of patient vaccinations, current outbreak data and additional collaborative efforts to mitigate risks and vaccinate high risk patients.

Additional current information will be shared at the meeting.

ACTION REQUESTED

- Input on supply and demand of Hep A vaccines, and, thoughts on mandatory staff vaccinations.

DISCUSSSION QUESTIONS

1. Are hospitals experiencing supply issues with Hep A vaccine?
2. Thoughts regarding mandatory vaccinations?

State of California—Health and Human Services Agency
California Department of Public Health

KAREN L. SMITH, MD, MPH
Director and State Public Health Officer

EDMUND G. BROWN JR.
Governor

August 15, 2017 AFL 17-13

TO: Hospital Emergency Departments, Hospital Infection Preventionists, and Hospital Administrators

SUBJECT: California Hepatitis A Outbreaks and use of Hepatitis A Vaccine for At-risk Patients and Health Care Personnel

All Facilities Letter (AFL) Summary

San Diego and Santa Cruz Counties are currently experiencing outbreaks of hepatitis A infection among homeless persons and/or users of injection or non-injection illicit drugs. The purpose of this AFL is to share California Department of Public Health's (CDPH) recommendations to address this issue.

San Diego and Santa Cruz Counties are currently experiencing outbreaks of hepatitis A infection. Public health officials have also identified cases due to the same strain of hepatitis A virus (HAV) in other California jurisdictions, as well as Arizona and Utah. CDPH may identify additional outbreak jurisdictions in California.

CDPH determined transmission occurs person-to-person; no commercial product is identified as being contaminated. Current information indicates all homeless populations and persons using injection or non-injection illicit drugs are considered at risk of outbreaks if exposed to HAV.

Public health departments face difficulties in providing access to vaccination efforts to the homeless and illicit drug use populations; such persons receive episodic health care in emergency departments. Offering vaccination in this setting is crucial to improving the vaccination opportunities of at-risk persons.

In response this outbreak, CDPH recommends:

- Hospitals, particularly hospital emergency departments, should work with their local health departments to offer hepatitis A vaccines to all patients who are homeless, users of injection or non-injection illicit drugs, infected with hepatitis B or hepatitis C, or have other liver disease, e.g., alcoholic cirrhosis*.

  - Screening for serological immunity prior to vaccination is not necessary; however, previous doses of the vaccine may be recorded in the California Immunization Registry (CAIR2) or your local immunization registry.
  - Use standing orders/order sets to ensure vaccination of the at-risk population.
  - Record vaccine doses administered in CAIR2 or your local immunization registry.
  - Ensure all vaccines are stored and handled appropriately. †
- Hospitals must contact the local health department immediately during business hours (or 24/7 in San Diego) to report suspected hepatitis A infection in patients who are homeless and/or use injection or non-injection illicit drugs, while the patient is still in the facility, as this may be the only opportunity for public health to interview the patient. Hospitals should not test asymptomatic persons for hepatitis A infection.
- Hospitals should promptly report all confirmed HAV cases to the local health department and save the blood (serum and EDTA or citrate plasma) from hepatitis A serological testing.
- Hospitals in outbreak jurisdictions should:
  - Offer the hepatitis A vaccine to health care personnel who have frequent close contact with patients who are homeless and/or use injection or non-injection illicit drugs.
  - Ensure appropriate cleaning of restrooms frequented by persons who are homeless and/or use injection or non-injection illicit drugs. Environmental cleaning methods similar to those used for norovirus should be implemented.

Additional Information About the Vaccine

- The first dose of single-antigen hepatitis A vaccine appears to provide protection to more people than the first dose of the combined hepatitis A/hepatitis B (Twinrix®) vaccine (see Table 3, product insert). This apparent advantage disappears when the respective series are completed.
- Providers should consider short-term risks of exposure to HAV, the likelihood of follow-up to complete multi-dose immunization and the need for protection from hepatitis B when selecting vaccines for those at risk. Immunization against HAV with existing vaccine supplies should not be delayed to obtain a different formulation of vaccine.
- CDPH recommends hepatitis B vaccine for injection drug users who are not known to be immune. A complete vaccination series is needed for full protection.
- Persons who have been exposed to HAV in the prior 2 weeks who are not known to be immune should also receive hepatitis A vaccine and/or immune globulin.

Billing Information

- An emergency department, clinic or network pharmacy may provide hepatitis A vaccine to Medi-Cal patients (Fee-for-Service or Managed Care) without prior authorization.
- Hepatitis A vaccine for adults is reimbursable when billed with CPT-4 code 90632. When using code 90632, document medical necessity in the *Remarks* field (Box 80)/*Additional Claim Information* field (Box 19). In this situation, relevant conditions indicating medical necessity are:
  - User of illicit injectable or non-injectable "street" drugs
  - Chronic liver disease
  - Residing in a high-risk community (in the current situation a homeless patient's medical necessity would be residing in a high-risk community)

***HAV vaccine is routinely recommended for adults who:**

- Want to be protected from hepatitis A
- Are traveling to countries that have high or intermediate levels of hepatitis A transmission (i.e., all except the U.S., Canada, Japan, Australia, New Zealand, and Western Europe).
- Are male and have sex with other males
- Use street drugs (injection and non-injection)
- Have a diagnosis of chronic liver disease, including hepatitis B and C
- Have a diagnosis of a clotting-factor disorder, such as hemophilia
- Anticipate close personal contact with an international adoptee from a country of high or intermediate endemicity during the first 60 days after the adoptee's arrival in the United States.
- Are employed in a research laboratory requiring work with hepatitis A virus or hepatitis A-infected primates.

†Vaccine Storage and Handling Information

- Hepatitis A vaccine should be maintained at refrigerator temperature between 36°F and 46°F (2°C and 8°C). Manufacturer package inserts contain additional information.
- Monitor vaccine temperatures twice daily, paying close attention to CURRENT temperature (unit's temperature now), as well as MIN/MAX temperatures (the coldest and warmest temperatures in the refrigerator since the last reading/thermometer reset).
- Vaccine exposure to temperatures outside the manufacturer's recommended range may result in vaccine damage and loss of potency.

- Liquid vaccines that contain an aluminum adjuvant, such as hepatitis A vaccine, can permanently lose potency when exposed to a single freezing temperature event (0°C [32°F] or colder), regardless of exposure time. Therefore, immediate action must be taken to prevent further use of vaccine that has been exposed to an out of range temperature until a determination of vaccine viability has been provided by the vaccine manufacturer.
- The Advisory Committee on Immunization Practices' General Recommendations on Immunization state, "Vaccine exposed to inappropriate temperatures that is inadvertently administered should generally be repeated."
- For complete information on best practices and recommendations for vaccine storage, please refer to Centers for Disease Control and Prevention's (CDC) Vaccine Storage and Handling Recommendations and Guidelines and Vaccine Storage and Handling Toolkit.

Helpful Links:

- San Diego County Hepatitis A Outbreak Announcement
http://www.sandiegocounty.gov/content/sdc/hhsa/programs/phs/community_epidemiology/dc/Hepatitis_A.html
- County of Santa Cruz Hepatitis A Outbreak Announcment
http://www.santacruzhealth.org/HSAHome/HSADivisions/PublicHealth/CommunicableDiseaseControl/HepatitisA.aspx
- California Immunization Registry (CAIR2)
http://cairweb.org/
- Hepatitis A Questions and Answers for Health Professionals
https://www.cdc.gov/hepatitis/hav/havfaq.htm#general
- Vaccine Recommendations and Guidelines of the ACIP
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html
- Healthcare Providers/Professionals: Vaccine Storage and Handlikng Recommendations and Guidelines
https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/storage.html

Helpful Documents:

- Standing Orders for Administering Hepatitis A Vaccine to Adults
http://www.immunize.org/catg.d/p3077.pdf
- Guideline for the Prevention and Control of Norovirus
https://www.cdc.gov/infectioncontrol/pdf/guidelines/norovirus-guidelines.pdf
- Food and Drug Administration Vaccines info
https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM110079.pdf
- Prevention of Hepatitis A Through Active or Passive Immunization Recommendations of the ACIP

https://archive.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf

- CDPH Hepatitis A Postexposure Prophylazis Guidance https://archive.cdph.ca.gov/programs/immunize/Documents/CDPH_HAV%20PEP%20Clinical%20Guidance.pdf
- Vaccine Storage and Handling Toolkit https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

If you have any questions about hepatitis A infection or vaccine, please contact the CDPH Immunization Branch at (510) 620-3737. Thank you for your efforts to protect Californians from hepatitis A infection.

Sincerely,

Original signed by Jean Iacino

Jean Iacino
Deputy Director

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 11, 2017

TO: CHA Medication Safety Committee

FROM: Amber Ott, Vice President, Strategic Financing Initiatives

SUBJECT: **340B Drug Pricing Program**

STATE ACTIVITY

In the May revision of the 2017-18 state budget, the Department of Healthcare Services (DHCS) proposed trailer bill language that would have prohibited hospitals from using contract pharmacies to dispense 340B drugs to Medi-Cal beneficiaries. As a result of CHA's advocacy efforts, the Senate and Assembly health committees rejected the proposal – with the understanding that stakeholders would continue to explore solutions to address DHCS' concerns. Notably, DHCS has significant concerns that 340B drugs dispensed by contract pharmacies are not properly identified as 340B, and therefore DHCS is erroneously claiming a rebate from the manufacturer. This leads to duplicate discounts being claimed on 340B drugs, which is prohibited under the federal rules of the program.

In mid-September, CHA met with DHCS to further discuss their concerns and we learned that the 340B manufacturers are hiring vendors to audit states, hospitals and contract pharmacies to ensure duplicate discounts are not occurring. If the vendor identifies duplicate discounts, the state is required to return the refund to the manufacturer. DHCS' position is that the only way they can prevent these duplicate discounts from occurring is to prohibit the use of contract pharmacies. This proposed prohibition is concerning because it would eliminate the option for 340B hospitals to replenish 340B drugs dispensed by a contract pharmacy and recoup the associated 340B savings. CHA is exploring alternative solutions that would allow DHCS to identify the 340B drugs that were dispensed through the contract pharmacies and we will continue to meet with DHCS to examine our options.

FEDERAL ACTIVITY

The CY 2018 OPPS proposed rule would drastically cut Medicare payments for drugs that are acquired under the 340B Drug Pricing Program. Specifically, CMS proposed to pay separately payable, non pass-through drugs (other than vaccines) purchased through the 340B program at the average sales price minus 22.5 percent, rather than average sales price plus 6 percent.

CHA submitted comments strongly opposing the proposal, and urged the agency to withdraw this policy from consideration. CHA believes that the proposal, as outlined, lacks sufficient policy rationale and will have unintended consequences contrary to the intended goals CMS laid out in the proposed rule, while doing nothing to address the underlying issues of rising drug costs. In addition, CHA issued an Advocacy Alert urging members to contact their representatives in support of a letter urging the administration to withdraw the proposal.

Smart in your world
Arent Fox

LEGAL ALERT
Health Care Counsel
September 6, 2017

5 min read

340B Program Participants Take Note: New Technical Changes Are Coming

On September 5, 2017, the Health Resources and Services Administration announced the transition to a new Office of Pharmacy Affairs Information System (340B OPAIS), which will impact and modernize the current 340B covered entity database and will also impact the mechanism through which drug manufacturers report 340B drug prices to HRSA. To educate both covered entities and drug manufacturers about the details of the new 340B OPAIS, the Office of Pharmacy Affairs will be conducting two public webinars later this month.

Since the announcement has not been published on HRSA's website as of the time of this post, the full text of the announcement has been reprinted below. We encourage all 340B program stakeholders to take advantage of this educational opportunity.

HRSA
Health Resources & Services Administration

Dear 340B Stakeholders,

The Health Resources and Services Administration (HRSA), Healthcare Systems Bureau (HSB), Office of Pharmacy Affairs (OPA) is transitioning to a new Office of Pharmacy Affairs Information System (340B OPAIS).

The 340B OPAIS will have two separate components – a new registration system and a new secure pricing system. The registration component of the new 340B OPAIS will be released in mid-September and the pricing system will be released at a later date. The registration component of the new 340B OPAIS will modernize the current 340B Database to enhance its functionality and security for both manufacturers and covered entities. This new system will increase the integrity and effective use of 340B stakeholder information.

OPA will hold two webinars on September 13, 2017. The first webinar is from 1:00-2:00 PM EST to prepare covered entities for the new registration component of the system.

Key Contacts

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View Online

The second webinar will be held from 2:00-3:00 PM EST for manufacturers to update them on the new registration component of the system. While all stakeholders can attend the webinars, there is a limited amount of space. Therefore, we encourage that you only attend the session that is pertinent to you. Both webinars will be recorded and can be viewed on the OPA website after September 13, 2017.

HRSA OPA 340B Covered Entity Update
When: September 13th, 2017 1:00 PM - 2:00 PM EST
Conference Number(s): 800-857-9665
Participant Code: 4780274
To join the meeting:
https://hrsaseminar.adobeconnect.com/hrsa_opa_340b/

HRSA OPA 340B Manufacturer Update
When: September 13th, 2017 2:00 PM - 3:00 PM EST
Conference Number(s): 800-857-9665
Participant Code: 4780274
To join the meeting:
https://hrsaseminar.adobeconnect.com/hrsa_opa_340b/

Questions regarding registration, change requests, or recertification can be directed to the 340B Prime Vendor Program at (888) 340-2787 or ApexusAnswers@340bpvp.com.

Arent Fox's Health Care group regularly monitors and counsels clients with respect to compliance with the 340B Drug Pricing Program. If you have any questions or need assistance, please contact Stephanie Trunk or Erin Atkins in our Washington, DC office, or the Arent Fox professional who regularly handles your matters.

Recent Posts

In case you missed them, here are links to our recent updates:

Can a Healthcare Plan Dictate Where a Medical Provider May Sue It?

Uncertainty Becomes the Norm…for 340B Rulemaking, at Least

FDA and Duke University to Explore Expanded Use of Real-World Evidence for Drugs in Public Workshop

Questions? Wondering how this impacts your business? **Contact Us**

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: October 11, 2017

TO: Medication Safety Committee Members

FROM: Susan Herman, CNO & VP Patient Care Services
San Joaquin Community Hospital/Adventist Health

SUBJECT: AHA Executive Dialogue at Leadership Summit

SUMMARY

At this summer's AHA Leadership Summit in San Diego, the American Hospital Association's Health Forum convened a group of panelists comprised of hospital executives from around the country. Comprehensive Pharmacy Services sponsored this executive dialogue to discuss how Pharmacy can be used as a strategic asset to enhance outcomes of patient care and the patient experience.

A series of questions were asked to the group to define how Pharmacists were utilized to support value based care delivery in both inpatient and ambulatory settings. Many innovative ways were presented on the ambulatory side including pharmacists performing annual wellness visits, educational sessions, advanced practice pharmacists as provider extenders and transitions of care. The biggest challenge most states face with these models are billing and reimbursement. On the inpatient side Pharmacists are often used in progression or multidisciplinary rounds to reduce readmissions, Meds to Beds or providing RX refills prior to discharge, antibiotic stewardship initiatives, patient education, and assistance with documentation and coding. Overall the trends are toward more clinically focused pharmacy departments getting increasing involved with direct patient care across the continuum, especially in complex, chronic conditions and high cost pharmaceuticals. Pharmacists are now involved in the development of evidence based medicine to maximize appropriate treatment order sets and protocols.

In summary there were 4 key take-aways from this dialogue:

1. Continue to foster more collaboration with pharmacists throughout the continuum of care for prevention of readmissions, enhanced discharge planning and med reconciliation.
2. Hospital Executives need to design and implement Pharmacy strategies for sustained organizational success.
3. Pharmacists can be used as physician extenders as well as an integral part of the care team.
4. Pharmacists are critically important to include to maximize patient outcomes and engagement through the utilization of drug standards and optimization.

Manufacturing

FDA warning letter slams B. Braun management for persistent failures at U.S. plant

by *Eric Palmer* | May 30, 2017 6:58pm

An FDA warning letter had severe language for the executive management of a B. Braun Medical plant in California that failed to resolve issues with leaking bags of parenteral drugs.

The FDA has brought its regulatory hammer down on a B. Braun plant in California that makes parenteral drugs, saying management let problems go on for more than two years, even after the agency repeatedly told them the plant needed to get its act together.

A warning letter issued three weeks ago and posted Tuesday by the agency pointed out that some of the problems, or similar issues, were cited by investigators during inspections in 2013, 2014, and 2015. The FDA laid everything out in an untitled letter in July 2014, then followed that up with a regulatory meeting with FDA staff in November 2015.

Despite all of that, the warning letter said, some of the issues had still not been addressed when investigators returned in April 2016 for their last inspection.

The FDA told the company the "repeated violations demonstrate a failure of your executive management to exercise proper oversight and control over the manufacture of drugs." It said the Melsungen, Germany-based company should do a comprehensive assessment of its "global manufacturing operations" and suggested it get an outside consultant to help.

Among B. Braun's failures, the FDA pointed to nearly four dozen unresolved customer complaints the company received for its Excel and Titan XL lines of flexible containers for irrigation and parenteral nutrition solutions for compounding. While the complaints went on for months, the company never fully resolved the underlying issues, the FDA said, including some of mold in bags.

The agency said B. Braun began receiving complaints of leaking bags containing 0.9% sodium chloride irrigation in October 2013, just a month after the plant had launched its Titan XL line. The plant's investigation, opened in January 2014, indicated the likely cause was failing port welds that were damaged during shipping. Tests to simulate shipping, which were not done until December 2016, pretty much confirmed that as the cause of the problem.

"However, our May 2016 inspection found that, approximately 28 months after the investigation was opened, you had not implemented corrective actions," the FDA said.

Investigators found a similar pattern with complaints about mold in bags, the letter said, noting that during the 2016 inspection the plant had not "adequately implemented corrective actions to address repeated instances of leaking IV bags and visible particulate matter."

Read more on FDA warning letter, parenteral delivery, B. Braun

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