Medication Safety Committee

October 5, 2016

California Hospital Association

CHA Boardroom

1215 K Street. Suite 800

Sacramento, CA, 95814

Conference Call Option: (800) 882-3610 Access Code 4206832#

AGENDA

10:00 **I. CALL TO ORDER/INTRODUCTIONS**
Fong

A. Membership

A. Membership Roster — Page 7

B. Member Updates

A. Potential New Member Memo — Page 11

B. Atrik Aryan - CV — Page 12

C. CHA MSC Guidelines for Committee — Page 18

D. CHA MSC Goals and Objectives — Page 22

E. Member Maps — Page 23

F. CHA MSC Member Breakdown — Page 24

10:15 **II. MINUTES**
Fong

Recommend: Approval

A. MSC Minutes 070616.pdf — Page 25

10:20 **III. OLD BUSINESS**

A. Sterile Compounding Update
Bartleson

A. Memo — Page 31

B. Finalized Regulations — Page 32

11:40 **V. STANDING REPORTS**

A. Board of Pharmacy
Gutierrez

B. CDPH
Lee/Woo

C. CSHP
DeMartini

D. CALNOC
Foley

E. ACNL

F. CHPSO

Jaffe

G. CAHF
Hall

12:00 **VI. LUNCH**

12:30 **VII. WORK GROUP REPORTS**

Which workgroups have been stopped?

A. CHA Medication Safety Toolkit
Bartleson

B. CURES 2.0 Browser
Bartleson

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

1:45 **IX. OTHER BUSINESS**
All

A. Seminar flyer Page 237

X. NEXT MEETING

A. 2017 Meeting Schedule Page 239

2:00 **XI. ADJOURNMENT**
Fong

MEDICATION SAFETY COMMITTEE
2016

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Updated 09/26/16

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CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

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

SUBJECT: Potential New Member – Atrik Aryan, Adventist Health

We will be reviewing Atrick Aryan as a potential new member of the Medication Safety Committee to reprensent Adventist Health. Please refer to the attached CV.

BJB:br

Atrik G. Aryan, PharmD

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EDUCATION

May 2013 **Doctor of Pharmacy**
Arnold & Marie Schwartz College of Pharmacy and Health Sciences (AMSCOP)
Long Island University, Brooklyn Campus

POST-GRADUATE TRAINING

Jul 2014 – Jul 2015 **ASHP-Accredited PGY-2 Medication Use Safety Residency**
Clement J. Zablocki VA Medical Center; Milwaukee, WI
Program Director: Kimberly Bell, PharmD, CGP

- Served as an authoritative resource for medication safety related issues, including but not limited to responding to medication safety alerts published by Institute for Safe Medication Practices (ISMP) as well as food and drug administration (FDA), and conducting a medication use evaluations. Other major roles and responsibilities include:
    - Collaborate with office of quality management for continual survey readiness
    - Leadership of monthly drug safety committee including facilitation of meetings, monthly adverse drug reaction data review and reporting and the analysis of medication use evaluations, pertinent drug safety alerts and other medication safety issues and implementation of corrective action plans
    - Respond to inquiries from other healthcare professionals pertaining to medication safety and clinical pharmacy
    - Serve as active member of quarterly Alaris® infusion pump workgroup meeting to review infusion pump usage data and discuss improvement strategies based on findings
    - Participate in root cause analysis of reported medication errors and reporting findings to quarterly medication errors committee meetings
    - Publish medication safety newsletter on quarterly basis
- Other notable accomplishments:
    - Facilitated failure mode effect analysis of hazardous drug handling process to identify vulnerabilities for exposure to healthcare workers. Acted as a subject matter expert in formulation of action plan to guide facility-wide changes
    - Developed testosterone order set incorporating decision support system based on evidence based guidelines to streamline prescribing practices throughout the organization
    - Developed Pyxis guide for nursing, which is now utilized as reference document to train nursing staff.

Jul 2014 – Present **Patient Safety Fellowship: VA Chief Residents in Quality and Safety (CRQS)**
Clement J. Zablocki VA Medical Center; Milwaukee, WI
Program Director: Kathlyn Fletcher, MD

- Member of interprofessional team including physicians, nurses and pharmacists focused on quality improvement and patient safety
- Completed interdisciplinary patient safety elective (4-week) held at Milwaukee Regional Medical Center
- Attended CRQS boot-camp to collaborate with physicians and nursing fellows

- Attended monthly conference calls with other CRQS teams from various VA hospitals throughout the nation to collaborate in learning and in project management

Jul 2013 – Jun 2014 **ASHP-Accredited PGY-1 Pharmacy Practice Residency**
North Shore LIJ – Lenox Hill Hospital; New York, NY
Program Director: Paul T. Nowierski, BSPharm, RPh
Major roles & responsibilities:

- Precept students from Arnold & Marie Schwartz College of Pharmacy, Brooklyn, NY.
- Attend multidisciplinary rounds and make pharmacotherapeutic recommendations
- Perform literature evaluation and answer drug information questions
- Staff as a licensed pharmacist. Major duties:
    - Interpreting and verifying physician orders for medications
    - Quality assurance check of prepared medications (including compounded IVs)
    - Supervision of controlled substance vault
    - Troubleshooting technical issues for automatic dispensing cabinets
- Assist pharmacy leadership with controlled substance audits on monthly basis
- Assist pharmacy leadership to prepare for joint commission survey
- Troubleshoot frequently encountered computer hardware and software problems
- P&T Committee involvement:
    - Present analysis of pharmacist intervention to identify opportunities for improvement on monthly basis
    - Summarize pertinent drug safety alerts from ISMP Acute Care newsletter.

LICENSURES AND CERTIFICATIONS

Mar 2016 - Present	California State Board of Pharmacy: Pharmacist #74509
Nov 2014	VA LEAN Yellow Belt Training
Oct 2014	Institute for Healthcare Improvement (IHI) Patient Safety & Quality Improvement – Basic Level
June 2014	LIU Pharmacy Residency Teaching Certificate
Sep 2013 – Present	New York State Board of Pharmacy: Pharmacist #058673, Immunization Privilege
May 2013 – Present	American Heart Association Basic Life Support (CPR and AED) Certified

PROFESSIONAL EXPERIENCES

Aug 2015 – Present **Medication Safety Officer**
San Joaquin Community Hospital; Bakersfield, CA
Supervisor: Adrian Gonzales, PharmD, Director of Pharmacy

May 2010 – Oct 2013 **Pharmacy Intern**
Rite Aid Pharmacy (Store #04552); Floral Park, NY
Supervisor: Shyla J. Mathew, RPh, Pharmacy Manager

May 2008 – May 2010 **Pharmacy Technician**
Rite Aid Pharmacy (Store #04552); Floral Park, NY
Supervisor: Dipesh K. Shah, PharmD, Pharmacy Manager

UNIVERSTIY TEACHING ACTIVITIES

July 2015 – Present **Preceptor:** Advanced Pharmacy Practice Experience for University of Pacific

- Medication Safety
- Hospital Pharmacy Administration

April 2015 **Instructor**: Medication Safety in Health-Systems at Concordia University of Wisconsin

- Failure Mode Effect Analysis (FMEA)

Sep 2013 – Dec 2013 **Facilitator**: Pharmacotherapeutics II Recitation at Long Island University, Brooklyn, NY.

PGY-1 PHARMACY RESIDENCY EXPERIENCES

May 2014 **Infectious Diseases and Internal Medicine**
Preceptor: Julia Slavin, BS, PharmD, BCPS

Apr 2014 **Elective: Pharmacy Informatics**
Preceptor: Paul T. Nowierski, BSPharm, RPh

Mar 2014 **Hematology and Oncology**
Preceptor: Kenny V Bui, PharmD

Feb 2014 **Cardiology**
Preceptor: Raisa Telis, BS, PharmD, BCPS

Jan 2014 **Neonatal Intensive Care Unit (NICU)**
Preceptor: Julia Slavin, BS, PharmD, BCPS

Dec 2013 **Research and Medical Intensive Care Unit (MICU)**
Preceptor: Nick Zerilli, PharmD, BCPS

Nov 2013 **Emergency Medicine**
Preceptor: Lori Nisanyan, PharmD

Oct 2013 **Elective Informatics II & Pharmacy Management**
Preceptors: Christopher Emerson, PharmD; Paul T. Nowierski, BSPharm, RPh

Sep 2013 **Internal Medicine**
Preceptor: Raisa Telis, BS, PharmD, BCPS

Aug 2013 **Pharmacy Informatics**
Preceptor: Christopher Emerson, PharmD

Jul 2013 **NSLIJ & Pharmacy Department Orientation**
Preceptor: Paul T. Nowierski, BSPharm, RPh

PGY-2 MEDICATION USE SAFETY RESIDENCY EXPERIENCES

April 2015 Concordia Teaching Experience
Preceptor: Kimberly Bell, PharmD, CGP

Jul 2014 – Jul 2015 Office of Quality Management (Longitudinal)
Preceptor: Lindsey Ladell, PharmD, BCPS

Jul 2014 – Jul 2015 Drug Safety Committee (Longitudinal)
Preceptor: Kimberly Bell, PharmD, CGP

Jul 2014 – Jul 2015 Medication Errors Committee (Longitudinal)
Preceptor: Janice Fuchsen, RN

Nov 2014 Pharmacovigilance (Elective)
Preceptor: Fran Cunningham, PharmD

Jul 2014 – Jul 2015 Staffing (Longitudinal)
Preceptor: Kimberly Bell, PharmD, CGP

Jul 2014 – Jul 2015 Pharmacy Informatics (Longitudinal)
Preceptor(s): Kimberly Bell, PharmD, CGP; Edward Pelikan, RPh

Jul 2014 – Aug 2014 Orientation
Preceptor: Kimberly Bell, PharmD, CGP

FORMAL PRESENTATIONS

April 2015	Proactive Risk Assessment of Hazardous Drug Handling Using Healthcare Failure Mode and Effect Analysis (HFMEA) Framework (Project Presentation)
Jan 2015	The Joint Commission, Safety Requirements and National Patient Safety Goals
Jun 2014	Implementing ADC Stocking Verification Using Bar-Code Scanning: Project Presentation
May 2014	Patent Ductus Arteriosus (PDA): Clinical Pearl Presentation
Feb 2014	Upcoming Changes in Pregnancy & Lactation Labeling: Staff Education
Jan 2014	Treatment of Acute Pericarditis: A Case Presentation
Dec 2013	Management of Diabetic Ketoacidosis in adults: A Case Presentation
Nov 2013	Analysis of Heparin Interventions made by Pharmacist during year 2013 (P&T Committee Presentation)
Sep 2013	Pharmacotherapy of Ulcerative Colitis
Sep 2013	Management of Ulcerative Colitis: A Case Presentation
Sep 2013	Management of Healthcare Associated Pneumonia
Aug 2013	Analysis of Therapeutic Duplication Interventions made by Pharmacist during year 2012 & 2013 (P&T Committee Presentation)

POSTERS

Apr 2015	Adverse Drug Event Prevention with Electronic Medical Safety Alerts in Acute Care Settings - In collaboration with students at Carroll University school of nursing - Presented at Interdisciplinary Poster Session at Carroll University
Mar 2015	Improving Safety of Using Intravenous Medications through Appropriate Use of Smart Pumps - Presented at 2015 Patient Safety Fair at Clement J. Zablocki VA Medical Center
Dec 2014	Improving Safety of Testosterone Replacement Therapy Using Clinical Decision Support System - Presented at Federal Poster Forum at 49th ASHP Midyear Clinical Meeting
Dec 2014	Ensuring Patient Safety through Medication Reconciliation - In collaboration with students at Carroll University school of nursing - Presented at Interdisciplinary Poster Session at Carroll University

PROJECTS

April 2015	Streamlining prescribing and monitoring of Testosterone Replacement Therapy using decision support tool
Nov 2014	Aggregate Root Cause Analysis of fall occurrences
Jan 2015 - Present	Improving patient outcomes through adequate discharge medication reconciliation
Jan 2015 – Present	Improving Respiratory Safety using end-tidal CO_2 Monitoring and STOP-BANG questionnaire in the ICU
Dec 2014 – Present	Proactive risk assessment of hazardous drug handling using Healthcare Failure Mode Effect Analysis (HFMEA^{TM}) Framework (Residency Project)
Feb 2015	Root Cause Analysis: patient identification
Nov 2014	Developing a framework for alemtuzumab registry for VA Center for Medication Safety (VA Center for Medication Safety - VAMedSAFE)

Nov 2014 – Dec 2014	Validation of tool to identify patients with incomplete allergy assessment at veterans affairs medical centers – national initiative (VAMedSAFE)
Oct 2014 – Nov 2014	Rapid Cycle Evaluation of patients receiving Dimethyl Fumarate (VAMedSAFE) (report of findings later served as a basis for nationally implemented DMF safety initiative)
Aug 2014 – Current	Aggregate Root Cause Analysis of medication errors
Aug 2014	Development of Pyxis® guide for nursing
Aug 2013 – Jun 2014	Implementation of Bar-coded restock verification of automatic dispensing cabinets at Lenox Hill Hospital (Residency Project)
Feb 2014 – Jun 2014	Configuration of Omnicell® cabinets to maximize efficiency and medication safety in a stand-alone emergency department
July 2013 – Jun 2014	Monthly audit of controlled substance transactions (Longitudinal project)

ADVANCED PHARMACY PRACTICE EXPERIENCES (APPEs)

Apr 2013	**Drug Information** Brookdale University Hospital Medical Center (BUHMC); Brooklyn, NY *Preceptor:* Suzanna Gim, BA, PharmD, MPH
Feb 2013	**Institutional Practice** Montefiore Medical Center; Bronx, NY *Preceptor:* Mark J. Sinnett, PharmD, FASHP
Jan 2013	**Acute Care** Staten Island University Hospital; Staten Island, NY *Preceptor:* Elaena Quattrocchi, BS, PharmD
Nov 2012	**Internal Medicine** The Brooklyn Hospital Center; Brooklyn, NY *Preceptor:* John Papadopoulos, BS, PharmD, FCCM, BCNSP
Oct 2012	**Ambulatory Care** Veterans Affairs New York Harbor Healthcare System; Brooklyn, NY *Preceptor:* Christopher Ho, BS, PharmD, BCACP
Sep 2012	**Elective: Information Technologies in Healthcare** Lenox Hill Hospital; New York, NY *Preceptor:* Paul T. Nowierski, BSPharm, RPh
Jul 2012	**Elective: Medication Safety** Lenox Hill Hospital; New York, NY *Preceptor:* Paul T. Nowierski, BSPharm, RPh
May 2012	**Community Pharmacy** Shore Drug; Bay Shore, NY *Preceptor:* Larry Leon, RPh

INTRODUCTORY PHARMACY PRACTICE EXPERIENCES (IPPEs)

Jun – July 2011	**Community Pharmacy** CVS Pharmacy (Store #1906); Bayside, NY *Preceptor:* Fozia Ali, PharmD
Jan – April 2011	**Institutional Introductory Pharmacy Practice Experience** Lenox Hill Hospital; New York, NY *Preceptor(s):* Paul T. Nowierski, BSPharm, RPh; Theologia Ternas, PharmD

PROFESSIONAL MEMBERSHIP AND LEADERSHIP

Mar 2015 – Present	Medication Safety Officer's Society (MSOS) at the Institute for Safe Medication Practices
Sep 2014 – Present	Institute for Healthcare Improvement (IHI)
Nov 2013 – Present	American College of Clinical Pharmacy (ACCP)
Sep 2013 – Oct 2014	New York State Council of Health-system Pharmacists (NYSCHP)
Sep 2011 – Present	American Society of Health-System Pharmacists (ASHP)
Aug 2009 – Present	American Pharmacists Association – Academy of Student Pharmacists (APhA-ASP)
Aug 2009 – Dec 2012	American Society of Consultant Pharmacists (ASCP) • Chapter Treasurer, *Sep 2009 – May 2010*

SYSTEMS EXPERIENCE AND PROFICIENCY

Pharmacy and Automation Systems:

- Allscripts™ Emergency Dept. Info System (EDIS) (Version 7.0.1)
- NexGen® Pharmacy System (utilized by Rite-Aid Pharmacy)
- Omnicell® OmniCenter Console (Up to Version SV 16.3.0)
- Omnicell® WorkflowRx™ Pharmacy Automation Software (up to Version 7.3)
- Sunrise Clinical & Medication Manager® (Up to Suite 5.5) [developed by Eclipsys™ (now Allscripts™)]
- CPRS (Computerized Patient Record System) /VistA: Utilized by Veteran's Health Administration
- CAPRI: Utilized by Veteran's Health Administration
- JLV (Joint Legacy Viewer): Utilized by VHA and DoD

Operating Systems:

- Windows XP/NT/2000 and later
- Mac OS X (Up to version 10.9 - Mavericks)

Applications:

- Microsoft Office Suite: Excel, PowerPoint, Word, Publisher
- Microsoft Visio

SKILLS AND ABILITIES

- Proficient in process assessment and redesign to minimize failures and vulnerabilities for errors
- Advanced skills in data extraction, analysis and reporting
- Can troubleshoot frequently encountered technical problems with computer hardware and software
- Excellent verbal and written communication skills
- Multi-lingual: can speak, read and write: Hindi and Gujarati

REFERENCES

Available upon request

GUIDELINES FOR THE CALIFORNIA HOSPITAL ASSOCIATION MEDICATION SAFETY COMMITTEE

I. NAME

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

II. MISSION

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

III. PURPOSE

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

IV. COMMITTEE

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

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

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

A. MEMBERSHIP

1. Membership on the Committee shall be based upon membership in CHA, or organizations that have a direct relationship to the purpose and mission of the committee. Non hospital member representatives can only be appointed to the Committee at the discretion of the CHA President.

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

3. Hospital members are appointed by CHA Staff.

4. Term:

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

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

B. MEMBER RESPONSIBILITIES

1. Provide hospital-industry leadership to the Committee.

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

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

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

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

C. COMMITTEE MEETINGS

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

2. To maintain continuity substitution of members is not acceptable.

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

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

D. VOTING

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

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

E. QUORUM

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

F. MINUTES

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

V. OFFICERS

The officers of the Committee shall be the Committee Chair, Vice Chair, Immediate Past Chair and CHA staff.

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

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

A. SUB-COMMITTEES

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

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

VI. GENERAL PROVISIONS

The strategic plan defining the goals, objectives, and work plans shall be developed annually by the Committee with approval by CHA staff. Quarterly updates and progress reports shall be completed by the Committee and CHA staff.

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

The Committee staff shall be an employee of CHA.

VII. AMENDMENTS

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

VIII. LEGAL LIMITATIONS

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

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

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

IX. CONFIDENTIALITY FOR MEMBERS

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

X. CONFLICT OF INTEREST

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

CHA Medication Safety Committee, Mission, Purpose and 2016 Objectives

Mission:

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

Purpose:

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

2016 Goals and Objectives

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

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

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

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

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

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

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

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

Medication Safety Committee Representation

Rev. January 2015

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

Medication Safety Committee
Member Geographics - July 2016

HOSPITAL COMMITTEE MEMBERS

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

NON-HOSPITAL COMMITTEE MEMBER:

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

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

CHA
1215 K Street, Suite 800
Sacramento, CA

Members Present: Jeannette Hanni, Candace Fong, Eddie Avedikian, Maryanne Bobrow, Carolyn Brown, Katie Choy, Kevin Dorsey-Tyler, Amy Gutierrez, Cari Lee, Lisa Hall, Christine Low, Rory Jaffe, Randy Kajioka, Lori Nolan, Doug O'brien, Diana Schultz, Rita Shane, Richard Rabens, Kethen So, Sara Stevens, Dan Ross, Terri Vidals, Art Woo, Alicia Munoz, Jenna Fischer

Members Absent: John Christensen, Edna DeLeon, Mary Foley, Nasim Karmali, Virginia Herold, Pat McFarland, Rob Menet, Susan Reed

Invited Guests: Robert Eastin, Alyssa Keefe

CHA Staff: BJ Bartleson, Ronda Fricke

I. CALL TO ORDER/INTRODUCTIONS

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

A. Member Updates

Ms. Hanni reviewed the membership items included in the meeting book. Ms. Bartleson introduced the new committee members, Mses. Shane, Blake and Mr. So. She also thanked those members leaving the committee.

B. Committee Guidelines

Ms. Hanni reminded the committee guidelines and goals mentioning new members should take a moment to review them. Ms. Bartleson discussed the 2016 goals that have ongoing activity.

II. REVIEW OF PREVIOUS MEETING MINUTES

The minutes of the April 6, 2016, Medication Safety Committee meeting were reviewed as submitted.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: To approve the minutes of the April 6, 2016, Medication Safety Committee meeting.*

III. NEW BUSINESS

A. FDA – New Draft Guidelines

Ms. Bartleson initiated the discussion on the FDA new draft guidelines regarding Hospital and Health System Compounding. Three guidance documents have been under review by a sub- group of hospital central packaging pharmacy pharmacists, and CHA Medication Safety pharmacist leaders. BJ has also been working with Alyssa Keefe from CHA's Federal Office. Alyssa has been working directly with AHA and ASHP contacts to assemble issues of concern across multiple stakeholders. Ms. Bartleson introduced Mr. Robert Eastin, Pharm D with Scripps Central Pharmacy who has worked with a sub-group of CHA pharmacy members to inform CHA staff on issues. Ms. Keefe mentioned that our goal is to speak with one voice to be effective with the FDA and that the additional documents from AHA and FDA Listening session are old and should not be construed as a confirmed position on the topic.

The committee discussed the following issues: 1) the one mile radius, 2) common ownership and control, 3) storage and integrity of drugs during transportation, 4) 503(b) guidance, 5) anticipatory prescription guidance, 6) quality control, 7) physician offices and infusion clinics.

Ms. Shane stated that Anthem released a letter effective July 18, that all infusion therapies will require prior authorization, however, chemotherapy is excluded. Ms. Shane will send the letter to Ms. Bartleson.

- *ACTION: Rita send Anthem letter to BJ. BJ will research the information and then distribute. Rita was asked to update the group after the call about this item.*

B. Creating an Inventory of Efforts Statewide (hospitals, health systems, aligned professional groups) on Addressing Opioid Use

Ms. Munoz asked the committee if an inventory of statewide activity on opioid use would be supportive to the members. The regional Hospital Quality Institute coordinators will collect the information with help from the association regional vice presidents. The committee agreed and requested the ED physician information be included as well. Ms. Munoz agreed and will present at an upcoming meeting.

- *ACTION: Committee members can send information to Ms. Munoz and she will report back to the committee when the inventory is finalized.*

IV. OLD BUSINESS

A. Sterile Compounding Update

Ms. Bartleson shared the entire portfolio of work done on sterile compounding including the letter from Mr. Dauner to all the CEO's, COO's, CNO's and Pharmacists which included FAQ's, a high level assessment tool, the CSHP and CHA compounding

grids and instructions. She also discussed the successful sterile compounding webinar with over 200 attendees and 60 plus questions. The webinar recording can be obtained from the CHA website. A brief discussion on the Board of Pharmacy proposed waiver language occurred. Also, there was a question regarding the change of BUD to 12 hours once the regulations are finalized.

- *ACTION: Ms Bartleson will work with CHA staff to provide a written document of webinar questions and answers*

B. Revision of Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Tool Kit Update

Ms. Munoz provided an update for the group. She has submitted the $125,000 grant and is awaiting feedback.

- *ACTION: Ms. Munoz will keep the committee informed of the grant work and outcomes.*

C. Drug Reconciliation and Inventory Regulations

Ms. Fong reported on the proposed reconciliation and Inventory of Controlled Substances Regulations. Ms. Guiterrez reported that the inventory count for automated dispensing cabinets is not required now, however, a process must be in place and issues must be reported**.**

- *ACTION: Ronda will send current regulations to the committee.*

D. Small Bore Connectors

Ms. Rogers reported that the law that prohibits hospitals from using tubing connectors that would fit into a connector other than the type it was intended for goes into effect this year. Hospitals are encouraged to create a methodical transition once the evaluation of the market place availability shows a stable supply. Currently, all the tubing attached to one of three connector types can be interconnected. Progress is being made to update the standards for connector manufacturing but until all three connector types are reengineered and readily available, the present connections can still be interconnected. Hospitals are at risk of technical non-compliance with the law if the products are not available when the legal prohibition takes place.

- *ACTION: Information only.*

E. Medication Safety Toolkit Manual

Ms. Bartleson reminded the group regarding the status of the Medication

Safety Toolkit. It is time to review all the tools again in the kit and evaluate next steps, either adding sterile compounding tools or making separate documents once the sterile compounding regulations are completed

- *ACTION: Committee members agreed to be content experts for updating the tools. Once the update occurs and the sterile compounding regulations are finalized, CHA will reapproach education on next steps for website and catalogue production. The following committee members have been assigned:*
  Jeannette Hanni– Emergency Department
  Sara Stephens– Anticoagulants
  Rita Shane and Amy Gutierrez – Controlled Substance Diversion
  Dan Ross- Insulin
  Opioid / Fentanyl Safe Use –Alicia Munoz

VI. PHARMACY LEGISLATIVE UPDATE

- ***ACTION:** Informational Only.*

VII. STANDING REPORTS

A. Board of Pharmacy (BOP)

Ms. Gutierrez reported that a new website regulations tracking should be released soon and that the Advanced Pharmacist regulations should be finalized by the end of the week. The drug take back regulations will be presented to the BoP by the end of the month. Local ordinances don't want to be preempted. Presently the BoP language is permissive and states "may elect" versus "must elect". The BoP has finalized its process and review, however they have not been finalized by the OAL.

- *ACTION: Informational Only.*

B. CDPH

Ms. Lee reported that the new CDPH survey procedure was fully implemented as of March 2016. For the first 12 months, the state scheduled 100 hospitals for the new survey and it's going well. Mr. Woo added that it looks like all the stakeholders are getting use to the new survey process.

- *ACTION: Informational Only.*

C. CSHP

Mr. So provided an update that they posted the documents for sterile compounding

for their members. AB 2084 died at the assembly appropriation committee and may come back at a later date. They will hold their annual conference in Disneyland in October. They are working to do additional education efforts partnering with pharmacy school to roll out webinars and other initiatives to members and nonmembers.

- *ACTION: Informational Only.*

C. **CALNOC –** No report

D. **ACNL** –

An update was provided and a question arose on the the "RX Destroyer" for meds. Some facilities are having difficulty since narcotics cannot be used in the "RX Destroyer". This is a jug that you put the medication in and it emulsifies. The point of discussion is why can't narcotics be used in the product? Clarification is needed.

- *ACTION: CHA and the committee will investigate.*

F. CHPSO

Mr. Jaffee reported that the CHPSO annual report has been distributed and includes drug related events, categorized based on name and type of drug. They have about 950,000 events and opioid medications were the most mentioned drug class. Mr. Jaffee suggested members go to the website and review. CHPSO also has " Safe Tables " or confidential discussions with hospitals for performance improvement activity. Of note is the problem with IV Thrombin injections and how they are packaged and dispensed. Mr. Jaffe discussed his additional role as a special advisor for working on improving patient safety nationally. Rory mention CHPSO is hiring clinicians.

- *ACTION: Informational Only.*

G. CAHF – No update provided.

VIII. WORKGROUP REPORTS –

A. Sterile Compounding –

Discussed earlier under new business.

B. CURES 2.0 Browser –

The workgroup has not met. There have been no issues or concerns expressed to CHA at this time.

C. CHA Medication Safety Toolkit Plan –

Discussed in Old Business section.

D. CHA Antineoplastic Drug Handling –

E. Still waiting to hear back from Cal-OSHA. They have agreed to pause because they are working on work place safety.

F. Member Discussion

Ms. Shane asked that a topic for future consideration be electronic health records and allergies. She continues to advocate the need for effective medication reconciliation particularly with EHR. The group suggested that Rita, share her work again with the group and discuss next steps for the committee.

- ACTION: The new medication reconciliation workgroup members are: Rita Shane, Lori Nolan, Diane Schultz, Christine Low, Kevin Dorsey

IX. NEXT MEETING

October 5, 2016

XI. ADJOURNMENT

The Committee Adjourned at 2pm.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Committee Members

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

RE: Sterile Compounding Update

SUMMARY

The final regulations are attached. CHA is in the process of answering the Sterile Compounding Regulations Webinar Questions to post on the CHA Sterile Compounding site. All the tools, and information can be found at http://www.calhospital.org/sterile-compounding . Waiver information will be covered in new business.

ACTION REQUESTED

- ***Informational Only***

Board of Pharmacy

Order of Adoption

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

1735. Compounding in Licensed Pharmacies.

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

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

(2) Altering the strength of a drug

(3) Combining components or active ingredients

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

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

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

~~(d)~~(c) The parameters and requirements stated by ~~this~~ Article 4.5 (Section 1735 et seq.) apply to all compounding practices. Additional parameters and requirements applicable solely to sterile ~~injectable~~ compounding are stated by Article 7 (Section 1751 et seq.).

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

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

1735.1. Compounding Definitions.

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

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

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

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

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

(1) For nonhazardous compounding a positive pressure differential of 0.02- to 0.05-inch water column relative to all adjacent spaces is required.

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

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

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

(h) "Controlled cold temperature" means 2 degrees to 8 degrees C (35 degrees to 46 degrees F).

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

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

(k) "Copy or essentially a copy" of a commercially available drug product includes all preparations that are comparable in active ingredients to commercially available drug

products, except that it does not include any preparations in which there has been a change, made for an identified individual patient, which produces for that patient a clinically significant difference, as determined by a prescribing practitioner, between that compounded preparation and the comparable commercially available drug product.

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

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

(n) "Dosage unit" means a quantity sufficient for one administration to one patient.

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

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

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

(r) "Hazardous" means all anti-neoplastic agents identified by the National Institute for Occupational Safety and Health (NIOSH) as meeting the criteria for a hazardous drug and any other drugs, compounds, or materials identified as hazardous by the pharmacist-in-charge.

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

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

ingredient(s).

(u) “Media-fill test” means a test used to measure the efficacy of compounding personnel in aseptic techniques whereby compounding procedures are mimicked using a growth-based media and then the resulting preparation is evaluated for sterility. The media-fill test must mimic the most complex compounding procedures performed by the pharmacy.

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

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

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

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

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

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

(ab) “Primary Engineering Control (PEC)” means a device that provides an ISO Class 5 or better environment through the use of non-turbulent, unidirectional HEPA-filtered first air for

compounding sterile preparations. Examples of PEC devices include, but are not limited to, laminar airflow workbenches, biological safety cabinets, sterile compounding automated robots, compounding aseptic isolators, and compounding aseptic containment isolators.

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

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

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

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

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

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

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

preparation.

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

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

1735.2. Compounding Limitations and Requirements; Self-Assessment.

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

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

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

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

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

(3) Is sufficient for administration or application to patients solely in the prescriber's office, or

for furnishing of not more than a 120-hour supply for veterinary medical practices, solely to the prescriber's own veterinary patients seen as part of regular treatment in the prescriber's office, as fairly estimated by the prescriber and documented on the purchase order or other documentation submitted to the pharmacy prior to furnishing; and

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

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

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

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

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

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

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

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

(1) Active ingredients to be used.

(2) Equipment to be used.

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

(4) Inactive ingredients to be used.

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

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

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

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

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

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

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

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

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

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

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

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

(D) 180 days for non-aqueous formulations,

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

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

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

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

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

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

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

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

(A) Method Suitability Test,

(B) Container Closure Integrity Test, and

(C) Stability Studies

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

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

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

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

~~(j)~~ (k) Prior to allowing any drug product preparation to be compounded in a pharmacy, the pharmacist-in-charge shall complete a self-assessment for compounding pharmacies developed

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

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

(1) such ingredients cannot be used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

(2) such ingredients cannot be used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Authority cited: Sections 4005, 4127, and 4169, Business and Professions Code.
Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127, Business and Professions Code.

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

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

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

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

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

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

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

(5) The date compounded; and

(6) The lot number or pharmacy reference number.

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

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

~~A statement that the drug has been compounded by the pharmacy shall be included on the container or on the receipt provided to the patient.~~

(c) Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy. ~~Drug products preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with subdivisions (a) and (b) shall be labeled with at least the name(s) of the active ingredient(s), concentration or strength, volume or weight of the preparation, pharmacy reference or lot number, and expiration date.~~

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

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

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

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

1735.5. Compounding Policies and Procedures.

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

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

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

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

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

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

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

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

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

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

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

(9) Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.

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

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

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

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

1735.6. Compounding Facilities and Equipment.

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

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

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

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

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

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

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

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

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

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

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

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

1735.7. Training of Compounding Staff.

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

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

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

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

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

1735.8. Compounding Quality Assurance.

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

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

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

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

(e) The quality assurance plan shall include a written procedure for responding to out-of-range

temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing.

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

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

Article 7. Sterile ~~Injectable~~ Compounding

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

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

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

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

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

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

~~(4) Be~~ Each ISO environment shall be certified ~~annually~~ at least every six months by a qualified

technician ~~who is familiar with the methods and procedures for certifying laminar air flow hoods and clean room requirements, in accordance with standards adopted by the United States General Services Administration~~ in accordance with Section 1751.4. Certification records must be retained ~~for at least 3 years~~ in the pharmacy.

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

~~(6)~~ (3) A sink shall be included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains shall not be present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area. When the PEC in the segregated sterile compounding area is a CAI or CACI and the documentation provided by the manufacturer shows it meets the requirements listed in 1751.4(f)(1)-(3) the sterile compounding area is exempt from the room requirement listed in 1751(b)(3).

~~(7)~~ (4) There shall be a refrigerator and, ~~/or~~ where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan to ensure continuity of available compounded drug preparations in the event of a power outage.

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

Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4005, 4036, 4037, 4051, 4052, and 4127 ~~and 4127.7~~, Business and Professions Code; and Section 18944, Health and Safety Code.

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

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

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

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

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

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

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

(4) Results of viable air and surface sampling.

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

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

(A) Controlled room temperature.

(B) Controlled cold temperature.

(C) Controlled freezer temperature.

(7) Certification(s) of the sterile compounding environment(s).

(8) Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity

measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.

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

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

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

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

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

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

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

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

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

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

~~(b) Name and concentration of ingredients contained in the sterile injectable drug product.~~

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

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

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

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

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

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

(1) Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove

fingertip, and viable air sampling and actions to be taken when the levels are exceeded.

(2) Airflow considerations and pressure differential monitoring.

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

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

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

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

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

(8) Depyrogenation of glassware (if applicable)

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

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

(11) Hand hygiene and garbing.

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

(13) Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.

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

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

(16) Procedures for handling, compounding and disposal of hazardous agents. The written

policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.

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

(18) Proper use of equipment and supplies.

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

(20) Record keeping requirements.

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

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

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

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

~~(a) Any pharmacy engaged in compounding sterile injectable drug products shall maintain a written policy and procedures manual for compounding that includes, in addition to the elements required by section 1735.5, written policies and procedures regarding the following:~~

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

~~(2) Labeling of the sterile injectable product compounded drug preparations based on the intended route of administration and recommended rate of administration.~~

~~(3) Equipment and supplies.~~

~~(4) Training of staff in the preparation of sterile injectable products.~~

~~(5) Procedures for handling cytotoxic agents.~~

~~(6) Quality assurance program.~~

~~(7) Record keeping requirements.~~

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

~~(c) Pharmacies compounding sterile injectable drug products preparations shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic hazardous residues. The written policies and procedures shall describe the pharmacy~~

~~protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

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

(1) Use of master formula documents and compounding logs.

(2) Appropriate documentation.

(3) Appropriate sterility and potency testing.

~~(I)~~(c) For non-sterile-to-sterile batch compounding, the pharmacy shall maintain written policies and procedures for compounding that includes, in addition to the elements required by section 1735.5, 1751.3(a), and 1751.7(e), written policies and procedures regarding the following: ~~must be established for the use of master formulas and work sheets and for appropriate documentation.~~

~~(J)~~(1) Process validation for chosen ~~S~~ sterilization methods.

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

~~Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or materials containing cytotoxic residues. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.~~

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

~~(d)(2)~~(e) All personnel involved must read the policies and procedures before compounding sterile ~~injectable products~~ drug preparations.~~, and any~~ All personnel involved must read all additions, revisions, and deletions to the written policies and procedures ~~must be communicated to all personnel involved in sterile compounding~~. Each review must be documented by a signature and date.

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

~~(A) Competency evaluation.~~

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

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

~~(D) Process validation.~~

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

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

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

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

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

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

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

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

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

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

(1) All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor shall be

cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent shall occur on all ISO Class 5 surfaces, work table surfaces, carts, and counters.

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

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

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

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

(1) At the beginning of each shift;

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

(3) After each spill; and

(4) When surface contamination is known or suspected.

~~(d) Exterior workbench surfaces and other hard surfaces in the designated area, such as walls, floors, ceilings, shelves, tables, and stools, must be disinfected weekly and after any unanticipated event that could increase the risk of contamination.~~

(f) Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality. Certification and testing of primary and secondary engineering controls shall be performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed that would impact the device or area. Certification must be completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. Certification records must be retained for at least 3 years. Unidirectional compounding aseptic isolators or compounding aseptic containment isolators may be used outside of an ISO Class 7 cleanroom if the isolator is certified to meet the following

criteria:

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

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

(3) Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom may only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

(g) Pharmacies preparing ~~parenteral cytotoxic~~ sterile hazardous agents shall do so in accordance with Section 505.~~12~~5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a ~~laminar air flow hood~~ negative pressure PEC. Additionally, each PEC used to compound hazardous agents shall be externally vented. The ~~hood~~ negative pressure PEC must be certified ~~annually~~ every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015), which is hereby incorporated by reference. ~~the methods and procedures for certifying laminar air flow hoods and cleanroom requirements, in accordance with National Sanitation Foundation Standard 49 for Class II (Laminar Flow) Biohazard Cabinetry, as revised May, 1983 (available from the National Sanitation Foundation, 3475 Plymouth Road, P.O. Box 1468, Ann Arbor, Michigan 48106, phone number (313) 769-8010) or manufacturer's specifications. Certification records must be retained for at least 3 years.~~ Any drug preparation that is compounded in a PEC where hazardous drugs are prepared must be labeled as hazardous, regardless of whether the drug ingredients are considered hazardous.

(1) During the hazardous drug compounding that is performed in a compounding aseptic containment isolator, full hand hygiene and garbing must occur. Garbing shall include hair

cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves.

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

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

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

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

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

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

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

1751.5. Sterile ~~Injectable~~ Compounding Attire.

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

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

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

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

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

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

~~sterile glove.~~

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

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

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

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

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

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

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

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

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

supplies furnished by the pharmacy.

(b) The pharmacist-in-charge shall ~~be responsible to~~ ensure that all pharmacy personnel engaging in compounding sterile ~~injectable~~ drug ~~products~~ preparations ~~shall~~ have training and demonstrated competence in the safe handling and compounding of sterile ~~injectable~~ drug ~~products~~ preparations, including ~~cytotoxic~~ hazardous agents if the pharmacy compounds products with ~~cytotoxic~~ hazardous agents.

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

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

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

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

(A) Aseptic technique.

(B) Pharmaceutical calculations and terminology.

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

(D) Quality assurance procedures.

(E) Aseptic preparation procedures.

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

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

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

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

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

(2) Each person ~~assigned to the controlled area~~ engaged in sterile compounding must successfully complete practical skills training in aseptic technique and aseptic area practices

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

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

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

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

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

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

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

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

~~(4)~~(3) ~~Written justification of~~ Documentation justifying the chosen ~~expiration~~ beyond use dates

for compounded sterile ~~injectable~~ drug ~~products~~ preparations.

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

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

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

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

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

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

~~Each individual involved in the preparation of sterile injectable products must first successfully~~

~~complete a validation process on technique before being allowed to prepare sterile injectable drug products. The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation. The validation process shall be representative of all types of manipulations, products and batch sizes the individual is expected to prepare. The same personnel, procedures, equipment, and materials must be involved. Completed medium media samples must be incubated. If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken and documented, and the validation process repeated. Personnel competency must be revalidated at least every twelve months whenever the quality assurance program yields an unacceptable result, when the compounding process changes, equipment used in the compounding of sterile injectable drug products preparations is repaired or replaced, the facility is modified in a manner that affects airflow or traffic patterns, or whenever improper aseptic techniques are observed. Revalidation must be documented.~~

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

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

~~(c)~~ (e)(1) Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), shall be subject to documented end product testing for sterility and pyrogens and shall be quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing shall be USP chapter 71 compliant and pyrogens testing shall confirm acceptable levels of pyrogens per USP chapter 85 limits,

before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing shall apply regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients that were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparations.

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

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

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

~~Batch-produced sterile injectable drug products compounded from one or more non-sterile ingredients shall be subject to documented end-product testing for sterility and pyrogens and shall be quarantined until the end-product testing confirms sterility and acceptable levels of pyrogens.~~

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

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

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

1751.8. Beyond Use Dating for Sterile Compounded Drug Preparations.

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

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

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

(2) The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; and

(3) Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package

containers of other sterile preparations, and containers for storage dispensing.

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

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

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

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

(c) The beyond use date shall specify that storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile ingredients, regardless of intervening sterilization of that ingredient and the following applies:

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

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

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

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

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

(e) Where any sterile compounded drug preparation was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (d), the sterile compounded drug preparation shall be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process. Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time. If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded. This provision does not preclude the use of a PEC to compound an "immediate use" preparation. A PEC used solely to compound 'immediate use' preparations need not be placed within an ISO Class 7 cleanroom, with an ante-area. Such "immediate use" preparations shall be compounded only in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO class 5 environment and where failure to administer could result in loss of life or intense suffering. Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Article 7.5 Furnishing for Home Administration

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

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

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

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

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

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

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

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

(1) furnished by a registered pharmacist;

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

(3) under the effective control of a registered nurse, pharmacist or delivery person at all times when not in the pharmacy;

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

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

(b) The portable container may contain up to:

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

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

(3) two vials of urokinase 5000 units;

(4) Each of the following items shall be in sealed, unused containers; the furnishing pharmacy

may select any or all of these dangerous drugs in up to five dosage units for inclusion in the sealed, portable container:

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

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

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

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

(E) diphenhydramine HCl 50mg/mL;

(F) methylprednisolone 125mg/2mL;

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

(H) naloxone 1mg/mL 2 mL;

(I) droperidol 5mg/2mL;

(J) prochlorperazine 10mg/2mL;

(K) promethazine 25mg/mL;

(L) dextrose 25gms/50mL;

(M) glucagon 1mg/mL;

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

(O) bumetamide 0.5mg/2mL;

(P) furosemide 10mg/mL;

(Q) EMLA Cream 5 gm tube;

(R) Lidocaine 1 percent 30mL vials.

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

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

(1) implement and maintain policies and procedures for:

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

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

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

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

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

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

(f) The pharmacy shall ensure that within seven days (168 hours) after the seal has been broken on the portable container, the home health agency's director of nursing service or a registered nurse employed by the home health agency or licensed hospice returns the container to the furnishing pharmacy. The furnishing pharmacy shall then perform an inventory of the drugs used from the container, and if the container will be reused, must restock and reseal the container before it is again furnished to the home health agency or licensed hospice.

(g) The furnishing pharmacy shall have written policies and procedures for the contents, packaging, inventory monitoring, labeling and storage instructions of the portable container.

(h) The furnishing pharmacy shall ensure that the home health agency or licensed hospice returns the portable containers to the furnishing pharmacy at least every 60 days for verification of product quality, quantity, integrity and expiration dates, or within seven days (168 hours) after the seal has been broken.

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

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

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

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

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

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

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

Virginia Herold
Executive Officer
California State Board of Pharmacy

Adobe Connect - Q&A Pod Content from Meeting New Requirements for Sterile Compounding Webinar

Answered Questions (0)

Open Questions (66)
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1. Shari Lyons: Are there current requirements for sterile technique competencies for nursing staff?

2. denise.cummings@mchcares.com: Talk about nurse compounding on the unit, outside of the pharmacy

3. Shideh Ataii 2: regarding the BOP waiver process, should Pharmacies wait till the process is finalized before they submit the waiver?

4. Terry Lerma: If a site applies for a waiver for physical modification of a Clean Room Suite, is the expectation that the site uses 12 hour BUD until the physical space is compliant with new Regs?

5. Jerry Gonzales: For BUD dating, one slide mentioned using the shorter of the package insert or USP BUD. Many package inserts state for immediate use only. However, a 3rd party publciation such as TRissell'

6. Christine Low: If the Manufacturer's BUD is < USP 797, will sterility testing allow use of 797 BUD?

7. denise.cummings@mchcares.com: Please define "hazardous" drugs vs non-"hazardous'

8. Tommy Mai: Can you further clarify the requirements for the physician office sites?

9. Bob Shmaeff: What is hazardous sterrle compounding?

10. shahina shaikh: WE HAVE A SEGREGATED COMPOUNDING AREA WITH A CAI (ISO CLASS 5) - WHAT WILL OUR BUD 11. Linda Tran: For a temporary compounding space, is direct venting to the exterior required?

12. Cheryl Daniels: Is the NIOSH list what we should look to for identifying a hazzardous medication.

13. Carol Taketomo: Could you please comment on the humidity monitoring requirements for clean rooms. Children's Hospital Los Angeles

14. Ryan Stice: Page 22, references single vent per negative pressure hood. Does this mean that the venting needs to be seperate all the way outside of the building, or can two ents join to one exerior vent?

15. Nancy Zepeda 2: Will the exemption for HD sterile compounding go away in 1/2017? Will we beable to apply for a waiver?

16. Brandi Acevedo: The venting of the Chemotherapy hood does it need a ten foot stack? Also does the vent need a two hour fire wall?

17. Jerry Gonzales: Trissll's states longer BUD than pckg insert but shorter than USP. This would essentially mean we can't use anything but USP or pkg insert?

18. James Fung: Question for BOP. What is the CA BOP plan on inspecting for renewal of LSC (hospital)? If existing LSC expires prior to Jan 1, 2017, what type of inspections should be expect?

19. Sheetal Shah: need to know what definition of engaged from page 13 is?

20. Ramon Sanchez: With the increased use of TICE BCG, labeled a biohazardous substance but on the NIOSH group 1 list, what are your recommendations with reconstitution practices of the product? In a negative pressure room? In a separate designated hood for only that product? Or a cleaned hood that can be returned to service for other products?

21. Kwan Liou: We have an infusion clinic with negitive pressure buffer room, BSC and small Laminar FLow Hood (LFH) . We compound some antibotics and chemo premeds in the LFH. We were told that all products comming out of the LFH hood also has to have biohazardous warning lables. Is this true?

22. Kimberly Botwin: What is required for the designated area for immediate use sterile compounding outside of the pharmacy, such as a nurse preparing an IVPB in a critical situation?

23. Jose Lopez: what does CA BOP use as a reference for hazardous drugs? NISOH? what can be used as a guideline 24. shahina shaikh: THANKS - QUESTION HAS BEEN ANSWERED 25. Carol Taketomo: What is the current community standard of practice recommendations for the monitoring of mean kinetic tempertures (MKT)?

26. Grace Magedman: For non-hazardous compounding, if a satellite pharmacy is ISO-7 in the entire room, meets all the pressure/airflow requirements and has a demarcation between the buffer area where the ISO-5 PEC exists, will it still be eligible for Category 2 BUDs? Or does there need to be an additional/separate room with walls & door inside the ISO-7 satellite?

27. Gina Yam: we have a ISO-5 hood in a ISO-7 clean room in the new building. There is no buffer area. Should we target for Iso 7 or Iso 8 in the ante area?

28. Elizabeth DiGiacomo-Geffers: You mentioned compounding involves nursing. Can you delinieate expamples when a nurse compounds medication(s). Also what education and training is applicable.

29. Grace Magedman: It appears that the BOP BUD still overrides the USP 797/800, so even though the USP dating for cold temp is more restrictive than BOP's, the BOP dates will still override it? (9 vs 14 days) 30. Ross Domke: For clarification ..we currently have an isolator with segregated room ..what is the minimum we need to do to keep our current BUD's? Clean room with ante room?

31. Michael Sillman 4: What are the garbing requirements when using barrier isolators?

32. Thomas Jacobsen: USP 800 states that receiving and unpacking must occur in a negative or neutral pressure area. I believe Ca BOP requirements say that a pharmacy must be positive in pressure to the area outside of the pharmacy. So what are the recommendations of the presenters to deal with this issue?

33. Yoon Hee Kim: If we are undergoing construction, does the isolator hood need to be located the the pharmacy department, or can it be located in another area of the hospital?

34. Helen Kuo 2: Can you address NIOSH drugs in USP800?

35. Ranna Shamiya: A CAI in a segregated area can have 48h room temp/14 day refrigeration if the CAI meets criteria?

36. Kerry Rinato 2: Can you clarify for us when a waiver is required? What specific regulations must be met by the physical environment. Does this only apply to 797 or 800 as well?

37. Terry Lerma: Does a CACI that recirculates 70/30 prior to external exhaust meet the regulations?

38. Christine Low: thank you Lynn!

39. Gregory Prouty: During rescontruction period, we may need to rent a clean room trailer, can that waiver form be used to obtain a permit for trailer use or we need to apply for a seperate sterile compounding license for the trailer?

40. Ross Domke: never mind ...found the answer 41. Sheetal Shah: it said each person engaged in sterile compounding must complete competencies. what is the level of engagement required?

42. Thomas Jacobsen: Does the BOP support the use of mobile compounding facilities and will it license those for use?

43. denise.cummings@mchcares.com: Can nurses compound hazardous drugs on the unit, outside of the pharmacy?

44. Mark Minnie: Willl hazardous medication preparation have to cease pending waiver approval example being preparation of methotrexate for ectopic pregnancies 45. Shideh Ataii: Does BOP recommend any solid plan for moving infusion pharmcies to an interim area ? do we need to get licensure for the interim area?

46. Anup Patel: Is it required to have a dedicated HVAC?

47. Grace Magedman: Will recirculating BSCs no longer be allowed then, even though they vent to the outside? The hoods can contribute to the negative pressure differential and often times the CFM drawn from a BSC that vents 100% externally can cause problems with the pressure differential.

48. Shideh Ataii: the above was for during construction work in preparation of USP800 49. shahina shaikh: With the new prposed 797 - do we have to do humidity testing for a segregated compounding area and what will the BUD be with a CAI in a segregated area with the new proposed 797 50. Jane Hodding: Will pharmacies be held to the requirement for storing hazarduous substances in negative pressure rooms?

51. Shideh Ataii: we are due for IV recertification in November, do we need to have submitted our waiver before then?

52. Frank Cantelmi: We have a hazardus chem room and a iv prep room. Do we need a buffer room and a ante room? If so, what pressure differential do we need between the buffer and ante room?

53. Terry Lerma: Just an FYI we were recently surveyed regarding the definition of those engaged in sterile compounding and were informed that thks applies to all Pharmacy staff involved in checking or preparing CSP. In fact we just provided finger glove tip testing and media fills for 40+ Rx staff.. We could use some consistency with this survey point as we have a great number of staff involved and this requirement is 6-12 months 54. Shideh Ataii: To the BOP: what is the position of BOP when there is a conflict between 1735 and USP797 or USP800?

55. Gina Yam: question answered, thank you 56. Ross Domke: What specifically needs to be in place construction wise to be compliant with BOP by 1/1/17? I'm feeling a little confused :) 57. Chris Marking: The grid on Physical Plant Requirements - Hazardous states that a A2 and B2 cabinet are approved. Is this correct?

58. Fred Hom: Do we need to open chemo drugs from our wholesaler in a negative buffer room?

59. Shideh Ataii: for organizations without 24 hr pharmacy, is nursing allowed to compound and immediately use the med (within an hour)?

60. shahina shaikh: With the new prposed 797 - do we have to do humidity testing for a segregated compounding area and what will the BUD be with a CAI in a segregated area with the new proposed 797 61. Ramon Sanchez: With the increased use of TICE BCG,

labeled a biohazardous substance but on the NIOSH group 1 list, what are your recommendations with reconstitution practices of the product? In a negative pressure room? In a separate designated hood for only that product? Or a cleaned hood that can be returned to service for other products?

62. Kerry Rinato 2: Kerry Rinato 2: Can you clarify for us when a waiver is required? What specific regulations must be met by the physical environment. Does this only apply to 797 or 800 as well 63. Ramon Sanchez: what is the scientific/regulatory basis for the CA BOP regulation requiring separate external exhaust rather than co-mingled.

64. Dawn Rethmeier: what are the required training documentation for nursing when they perform compounding for immediate use
65. Joy Lai: Does prepackaged hazardous product need to be kept in hazardous compounding room?

66. Kethen So: What is the proper channel to submit questions about the compounding grid after the call? Kethen So, CSHP, UCSF Medical Center.

****Correction from Speaker Michael Ignacio (DCA)** During the Q&A, I spoke regarding recirculating or Class II Type A2 BSCs. I incorrectly stated the board would not permit the use of such BSCs. Provided the A2 BSCs are externally vented, the board will allow such BSCs. Sorry for the confusion.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

FROM: Alicia Munoz, MAS, FACHE, CPQH, CPPS
VP Quality and Patient Safety, HASIC, HQI

RE: Revision of Respiratory Monitoring of Patients Outside the ICU, Guidelines of Care Toolkit

SUMMARY

Medtronic is providing an unrestricted grant for HQI and CHA Medication Safety Committee to revise and validate the 2014 Respiratory Monitoring of Patients Outside the ICU: Guidelines of Care Toolkit.

The agenda, letter of interest and the signed grant are included. The budget is being revised to reflect the grant amount awarded.

Julie Morath will create a formal communication for CHA news and will reach out to you.

Next steps include the following:
Establishing workgroups
Facilitator recruited
Scribe recruited.

More to come. Thank you for your support—and looking forward to supporting the work.

ACTION REQUESTED

- *Informational Only/ Discussion*

DISCUSSION QUESTIONS

1. What does the Med/Safety Committee need to do to support the work?

Hospital Quality Institute
Leadership in quality and patient safety

June 3, 2016

TO: Clinical Education Grant Application Reviewer

RE: Letter of Interest for support to review, revise and revalidate the following:

Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Toolkit, June 2014

Health care practitioners and leaders involved in care for adult and pediatric patients in hospital procedural and non-procedural areas have approached Hospital Quality Institute (HQI) to engage in review and validation of Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Toolkit, June 2014.

Original work based in San Diego, California included multidisciplinary practitioners from several hospitals and healthcare systems. The toolkit gained wide adoption in California and has been a model across the United States and has international following.

The work will be state-wide, engaging clinicians' expert in obstructive sleep apnea, post-procedural and postoperative care, opioids and sedatives, and cost-benefit analyses. The scope of work is outlined in the Agenda and includes a final review and validation by the California Hospital Association's Committee on Medication Safety.

Hospital Quality Institute was established through a collaboration of the California Hospital Association (CHA) Hospital Council of Northern and Central California, Hospital Association of Southern California and Hospital Association of San Diego and Imperial Counties. HQI leads on statewide strategy and alignment efforts, educating and convening, spearheading and connecting hospitals to healthcare initiatives and collaboratives; and shaping quality improvement policy, measures and initiatives.

HQI appreciates industry support from Medtronic to help sustain the value of the respiratory tool kit and look forward to working with you on this project.

Thank you for your consideration.

Sincerely,

Julie Morath, RN, MS, CPPS
President/CEO
Hospital Quality Institute

Alicia Muñoz, FACHE, CQA, CPHQ
Regional Vice President
Quality Improvement and Patient Safety
Hospital Quality Institute

Agenda:

Hospital Quality Institute aims to review, update, and re-validate the following toolkit:

Respiratory Monitoring of Patients Outside the ICU. Guidelines of Care Tool Kit, 2014

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

Step one: Establish workgroups

Three workgroups will be recruited from California Hospital Association member hospitals across California State, one in each of the hospital association regions. The workgroups may be convened more than once. (one in person and conference calls as needed). Workgroups will include multidisciplinary clinicians focusing on obstructive sleep apnea, post-procedural and postoperative care, opioids and sedatives, and cost-benefit analysis.

Subject Matter Expert will be recruited as facilitator.
Scribe will be recruited.
Literature Search to be conducted.

Step two: Discuss Findings / Meetings held

Tool Kit will be distributed in advance for workgroup members to review literature; compare in house practices, protocols, order sets, and tools; and assemble reported issues/barriers, and recommendations.

Workgroups will convene with facilitator and scribe. Follow-up conference calls will be held.

Step three: Document recommendations

Member's collective experience, literature review, and shared practices and recommendations will be documented. A report will be submitted to California Hospital Association's Medication Safety Committee for final review and validation.

Step four: Dissemination, training and education

Publishing, distributing, creation of webinars, training seminars and workshops to share recommended practices will be created.

Timeline: 1 year.

1215 K Street, Suite 930 | Sacramento, CA 95814
(916) 552-7688 | fax (916) 554-2271 | www.hqinstitute.org

LETTER OF AGREEMENT (LOA) – Grant 6956_____

Regarding the Terms, Conditions and Purposes in Support of Medical Education

Section 1.

Between Hospital Quality Institute and Medtronic, 6135 Gunbarrel Drive, Boulder, CO 80301.

The Federal Tax I.D. Number for the Recipient is: _____ The title of the Activity/Program is: _Respiratory Monitoring of Patients Outside the ICU Guidelines of Care Tool Kit_____ ___

Program Location: __Sacremento, CA_____ Program Date: __September 1, 2016_____

Is this CME Accredited Yes/No YES __ If yes, check the box identifying the Accrediting Body below:

- X Accreditation for Continuing Medical Education
- ☐ American Osteopathic Association
- ☐ American Medical Association
- ☐ American Academy of Family Physicians
- ☐ American Dental Association's Continuing Education Recognition Program
- ☐ Other (please identify): _____

Supporter Contact Information: (Name and Email) _Alicia Munoz / __amunoz@hqinstitute.org_____

Section 2.

Medtronic wishes to provide support of the above-referenced program by means of the following:

1. Unrestricted educational grant (see paragraph #10 below): $_90,000.00_____
2. Restricted educational grant (to reimburse expenses for): $ _____
   a. Meeting Space
   b. Audio Visual
3. Sponsorship (see paragraph #10 below): $ _____
4. Disposable Product (total of product being provided): $ _____
5. Other (please describe): $ _____

TERMS AND CONDITIONS OF FUNDING GRANT:

1. **Statement of Purpose:** The Program is for scientific and educational purposes only and will not promote the Commercial Supporter's products, directly or indirectly.

2. **Control of Content & Selection of Presenters & Moderators:** Sponsor is ultimately responsible for control of content and selection of presenters and moderators. For Non-CME Events, Commercial Supporter, or its agents, will respond only to Sponsor-initiated requests for suggestions of presenters or sources of possible presenters. In response to such request, Commercial Supporter will suggest more than one name (whenever possible); will provide speaker qualifications; will disclose financial or other relationships between Commercial Supporter and speaker, and will provide this information in writing. Sponsor will record role of Commercial Supporter, or its agents, in suggesting presenter(s); will seek suggestions from other sources, and will make selection of presenter(s) balanced and independent.

3. **Disclosure of Financial Relationships:** Sponsor will ensure disclosure to the audience of (a) Commercial Supporter funding and (b) any significant relationship between the Sponsor and the Commercial Supporter (e.g., grant recipient) or between individual speakers or moderators and the Commercial Supporter.

4. **Involvement in Content:** There will be no "scripting", emphasis, or influence on content by the Commercial Supporter or its agents.

5. **Ancillary Promotional Activities:** No promotional activities will be permitted in the same room as the Program. No product advertisements will be permitted in the Program.

6. **Objectivity & Balance:** Sponsor will make every effort to ensure that any data presented regarding the Commercial Supporter's products (or any competing products) are objectively selected and presented, with favorable and unfavorable information and

balanced discussion of prevailing information on the product(s) and/or alternative treatments.

7. **Limitations of Data:** Sponsor will ensure, to the extent possible, disclosure of any limitations of data; e.g., ongoing research, interim analyses, preliminary data, or unsupported opinion.

8. **Discussion of Unapproved Uses:** Sponsor will require that presenters disclose when a product discussed as part of the Program is not approved in the United States for the use under discussion.

9. **Opportunities for Debate:** Sponsor will ensure opportunities for questioning or scientific debate.

10. **Use of Unrestricted Sponsorship/Grant Funds:**

    (a) Commercial Supporter agrees to provide unrestricted funds directly to the Sponsor for the sole purpose of offsetting some or all of Sponsor's costs of producing the Program, and thereby reducing the cost of registration for all Program attendees. Funds provided under this Agreement may be used solely to:

        (i) Obtain and compensate Program faculty;
        (ii) Subsidize Program attendee registration fees;
        (iii) Produce the Program;
        (iv) Rent Program facility space;
        (v) Provide large-scale buffet meals, snacks, or other refreshments to all Program attendees; and/or
        (vi) Pay for other costs incurred directly in connection with producing Program educational activities.

    (b) Notwithstanding the foregoing, Sponsor shall not, and agrees not to, use the funds provided under this agreement for any other purpose including, but not limited to:

        (i) Program attendee entertainment;
        (ii) Provide meals to select individual Program attendees;
        (iii) Provide reimbursement for travel and hotel costs to attendees
        (iv) Gifts; and/or
        (v) Raffle items.

11. **Compliance with Laws, Regulations and Standards:** The parties agree to comply with all applicable federal, state and local laws, regulations, ordinances, government agency interpretation of laws or regulations and orders ("Laws and Regulations") with respect to the performance of all provisions of this agreement. The parties intend for this agreement to comply with the federal anti-kickback statute, 42 USC 1320 a-7b (b) and its regulations, the Foreign Corrupt Practices Act ("FCPA"), and the provisions of the AdvaMed Code of Ethics on Interactions with Healthcare Providers ("AdvaMed Code"), and believe in good faith that this agreement complies with these Laws and Regulations and the AdvaMed Code. In addition, the parties agree to abide by all requirements of the ACCME *Standards for Commercial Support of Continuing Medical Education*.

12. **Acknowledgment of Funding; Reporting:** The Sponsor agrees to: 1) acknowledge educational support from the Commercial Supporter in Program brochures, syllabi, and other Program materials; and 2) upon completion of the Program, furnish the Commercial Supporter a report concerning the expenditure of the funds provided. **Any portion of the funds utilized for payment or other transfer of value to a physician must be reported in accordance with the Physician Payment Sunshine Act. By accepting these funds, the Sponsor accepts responsibility of providing the Commercial Supporter with the following data for each physician receiving payment or other transfer of value: full name, primary business address, specialty, state of licensure, value, date of the transfer of value, and the nature of the payment (e.g. meal, speaking fee, etc.) by email within thirty (30) days of the event date:** PACE@covidien.com

Section 3.

Medtronic Representative (name) Rebekah Cavanagh

Signature Rebekah Cavanagh Date 8/18/16

Program Director (name) Julianne Morath Dept. Hospital Quality Institute (HQI)

Signature Julianne Morath Date August 17, 2016

CME Department Director or Designee (name): _____

Signature _____	Date _____

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

FROM: Alicia Munoz, MAS, FACHE, CPQH, CPPS
VP Quality and Patient Safety, HASIC, HQI

RE: Inventory of Opioid Work from Hospitals/Health Systems

SUMMARY

CHA Medication Safety Committee members voted to establish a registry to inventory efforts statewide in hospitals and healthcare systems to address the opioid epidemic. The intent is to speak on behalf of our hospitals and health systems as part of the solution to this epidemic of harm. San Diego is a trend setter and credit goes to the San Diego Medical Society Prescription Drug Abuse Medical Task Force for work in the ED and safe pain prescribing guidelines/practices.

ACTION REQUESTED

- ***What efforts are in place or currently underway at your facility or system? If you know of aligned work at other professional associations or groups please let me know.***

DISCUSSION QUESTIONS

1. Is there outcome information relative to the work that has been in place across varying regions of the state?

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

FROM: Candace Fong
Co-Chair, CHA Medication Safety Committee

RE: Board of Pharmacy Drug Reconciliation and Inventory Regulations

SUMMARY

The proposed text for the Board of Pharmacy Drug Reconciliation and Inventory Regulations is enclosed. Comments are due by October 31, 2016. One area of concern is the interpretation of "g." and what the definition of "pharmacy satellite location" is.

> g. For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.

ACTION REQUESTED

- *Comments on the above definition and any other areas of concern*

DISCUSSION QUESTIONS

1. How does this compare with the original language we responded to last November?
2. Are there other issues that need to be addressed?

Title 16. Board of Pharmacy
Proposed Text

Adopt section 1715.65 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1715.65. Inventory Reconciliation Report of Controlled Substances

a) Every pharmacy, and every clinic licensed under sections 4180 or 4190, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.
b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports taken, and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.
c) A pharmacy or clinic shall compile an Inventory Reconciliation Report of all Schedule II controlled substances at least every three months. This compilation shall require:
    1) A physical count, not an estimate, of all quantities of Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;
    2) A review of all acquisitions and dispositions of Schedule II controlled substances since the last Inventory Reconciliation Report;
    3) A comparison of (1) and (2) to determine if there are any variances; and
    4) All records used to compile each Inventory Reconciliation Report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form.
d) Losses shall be identified in writing and reported to the board and, when appropriate, to the Drug Enforcement Administration. Likely causes of overages shall be identified in writing and incorporated into the Inventory Reconciliation Report.
e) The Inventory Reconciliation Report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge, and be readily retrievable in the pharmacy or clinic for three years.
f) A new pharmacist-in-charge of a pharmacy shall complete an inventory within 30 days of becoming pharmacist-in-charge as identified in subdivision (c). Whenever possible an outgoing pharmacist-in-charge should complete an inventory as required in subdivision (c).
g) For inpatient hospital pharmacies, a separate Inventory Reconciliation Report shall be required for Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.
h) The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:
    1) All controlled substances added to an automated drug delivery system are accounted for;
    2) Access to automated drug delivery systems is limited to authorized facility personnel;

3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
4) Confirmed losses of controlled substances are reported to the board; and
5) A pharmacy or clinic identifying losses of controlled drugs but unable to identify the cause within 30 days shall take additional steps to identify the origin of the losses and improve security of controlled substance access to prevent losses.

Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4104 and 4332, Business and Professions Code.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

July 18, 2016

Robert M. Califf, MD
Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane, Rm.1061
Rockville, MD 20852

Subject: FDA Draft Compounding Guidances – Hospital and Health System Compounding Under the Federal Food, Drug and Cosmetic Act, FDA-2016-D-0271; Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act, FDA-2016-D-0269 and Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act, FDA-2016-D-0238

Dear Commissioner Califf,

On behalf of more than 400 member hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to comment on three proposed FDA draft compounding guidance documents released on April 15, 2016. CHA believes the FDA — along with state regulators, including boards of pharmacy — plays an important role in ensuring high quality, safe and timely medications are provided to patients in all settings, including the hospital and health system setting. In addition, we believe development of a federal regulatory framework that compliments state efforts is essential to ensuring that all hospitals have access to essential sterile and non-sterile compounded medications. FDA is an important partner in this process, and we look forward to collaborating with other stakeholders to ensure that a federal framework balances patient safety with the need for timely access to medication, without creating inappropriate regulatory barriers to providing care.

California has a longstanding history of exceptional pharmaceutical practices driven by a proactive, multidisciplinary, evidenced-based approach between hospitals and health systems and the California State Board of Pharmacy (BoP). There are 485 licensed hospital pharmacies, many of them also licensed for sterile compounding, and eight licensed centralized hospital packaging pharmacies (CHPP), which provide compounded drug products to multiple sites from a central hospital location; an additional nine hospitals/health systems are actively applying for central hospital packaging licensing. The state has long embraced a three-pronged framework for purchasing and processing of sterile and non-sterile compounded products through hospital pharmacies, central fill pharmacies and 503B manufacturers.

Patients are requiring more frequent use of compounded medications which, if not manufactured correctly, increases risk of medication error and patient harm. Health care reform and recent catastrophic events involving national and regional sterile compounding pharmacies have caused hospitals to reconsider their available options. Many struggle to balance the costs associated with purchasing products versus preparing them. Many hospitals and health systems have smaller, less suitable pharmaceutical physical plant space to compound the needed quantities of sterile products rapidly in an effective manner; purchasing from 503B manufacturers, while an important component, can only provide a portion of compounded drugs.

California hospital/health system pharmacies recognized the benefits of hospital pharmacy compounding and established CHPP's as an adjunct to their existing hospital compounding framework. In 2012, the

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

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

state passed AB 377[1], enabling hospitals and health systems to obtain a CHPP) license so they may prepare and compound unit dose drugs to inpatients for one or more hospitals provided the hospitals are under common ownership and located within a 75-mile radius of each other. The CHPP legislation was enacted with the support of the California BoP along with hospitals and health systems, when many across the state were proactively addressing strategic opportunities to improve their pharmaceutical operations' efficiency and effectiveness. The BoP supported this licensing process, which emphasized the highest quality and safety standards in compounding management and distribution. Together, hospitals and health systems and the BoP play a significant role in ensuring the safest and highest quality supply of sterile and non-sterile compounded medications and do so with a comprehensive framework composed of hospital compounding pharmacies, CHPP's and 503B manufacturers

California hospitals are positioning themselves to provide state of the art hospital pharmacy compounding services as a means to ensure the production of accurate and safe sterile compounded medications. This service's numerous benefits including:

- Minimizing the impact of drug shortages through batching as unit dose products
- Standardizing production to improve medication safety efficiently
- Minimizing the use of manually-applied auxiliary labels
- Decreasing outsourcing and dependence upon third party vendors
- Deploying quality assurance principles of USP 797 and USP 800
- Staffing with consistent and well-trained individuals whose primary focus is pharmacy compounding and production

The compounding pharmacies, particularly the CHPP's achieve higher production consistency and reliability than multiple smaller pharmacies in different locations with different facility accommodations and equipment. Automation can be more easily accommodated in a standalone space, along with easier shipping and receiving processes than those that serve an entire hospital system. Similar medication packaging and processes across the individual hospital facilities within a health system ensure medication administration accuracy and consistency by providers at the bedside.

Hospital/health system compounding pharmacies are vital to California hospitals and health systems now and in the future. CHA and its hospitals, health systems and pharmacists, agree with the FDA's intent to provide guidance with essential parameters for quality and safety. However, CHA offers specific guidance below to uphold these elements and enhance quality and patient safety standards for compounded drug administration.

I. Hospital and Health System Compounding Under the Federal Food, Drug, a Cosmetic Act, Guidance for Industry, FDA-2016-D0271

CHA urges FDA to delete the 1-mile radius requirement as criteria for medication distribution by a hospital or health system. California's expansive land mass and advanced health care reform measures have incentivized hospitals towards mergers and consolidation activity among multiple facilities across extensive local, regional and statewide territory. The proposed 1-mile radius is irrational. Determining that any health system distributing outside the 1-mile radius is automatically a large manufacturer is restrictive, arbitrary and an unreasonable distinction between a hospital-based compounding pharmacy and a large manufacturing distributor that does not manufacture per specific

[1] Added Article 7.6, commencing with 4128 to chapter 9 of Division 2 of the California Business and Professions Code.

patient prescription. Rather, the key criteria that should be used in the FDA guidelines for 503A facilities are facility, patient prescription and evidence-based — not mileage-based.

Further, there is no supporting evidence for a specific mileage requirement for hospital/ health system compounding subject to 503A compounding. While California CHPP regulations established a 75-mile radius, this distance was based on an approximate distance of a proposed CHPP several years ago — not on any evidence-based rationale or foreseeable future California CHPP model. California's present CHPPs have distribution distances varying between fewer than 5 miles to more than 70 miles. In addition, many of California hospital/health system campuses extend beyond a one mile radius and, as with the CHPP, the 1-mile radius restriction would have a negative impact on quality of care, forcing hospitals/health systems back to older less sophisticated systems, compromising patient care.

More importantly, the 1-mile limit will significantly affect hospitals that utilize health system compounding resources to support themselves, limiting access and increasing potential for sterile compounding being performed in less than optimal facilities. This practice would increase the risk of medication errors and contamination of sterile products only to patients within its own system facilities under common ownership, — that distribution is driven by patient-specific prescription or order, not geographic mileage boundaries.

CHA recommends FDA retain its facility and patient-specific prescriptions requirements and consider an alternative to replace the 1-mile geographic requirement —specifically, evidence-based criteria found in USP 797, USP 800, and USP 71. CHA recommends the use of safety and quality requirements in lieu of the 1-mile radius requirement, including USP 797, 800 and 71 as evidence-based practice requirements for processing and handling of non-hazardous and hazardous sterile compounding medications. USP 797 and USP 800 ensure compounding pharmacies provide the conditions and practices to prevent harm to patients and staff. Limiting non-patient specific compounding in hospitals and health systems based on USP 797 and USP 800 would address two of FDA's concerns with non-patient specific compounding in a hospital/health system 503A facility, by limiting the amount of product that could be created and used within a timely manner. State boards of pharmacy would retain responsibility for oversight of hospital/health system compliance, along with augmented oversight by Joint Commission accreditation and CMS conditions of participation which focus heavily on USP compliance, freeing FDA to focus on the 503B program oversight.

USP 71 refers to the specific practices that prevent harm to the patient from microbial, chemical or physical contamination; excessive bacterial endotoxins; and variations in product strength or poor quality ingredients. These evidence-based practices assure quality and patient safety regardless of geographic distances.

In addition, the FDA proposed facility component ("healthcare facilities that are owned and controlled by the same entity that owns and controls the hospital pharmacy") and the patient prescription requirement ("the drug products are only administered within the healthcare facilities to patients within the healthcare facilities, pursuant to a patient specific prescription or order"[2]) explicitly differ from 503B facilities that manufacture non- patient specific prescriptions. More importantly, these two factors imply patient responsibility and distinguish hospital and health system pharmacies from community and 503B pharmacies in that the hospital/health system retains authority for patient care outcomes and traceability of the compounded drug. FDA's terminology related to "common control" in its proposed facility component may need further definition, as multiple types of ownership configurations occur in

[2] Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, April 2016, page 5

hospital/health systems and alternative care settings. These sites can include assistance to smaller rural and critical access hospitals, along with support of ambulatory and surgical care settings, which may imply variable definitions of "common control." CHA supports a definition of "common control" that reflects the various relationships but maintains that compounded medications distributed to alternative settings of care are obtained and administered only pursuant to a physician's specific prescription or order.

CHA suggests that FDA adopt an expanded version of the definition of health system used in section 506F of the Federal Food, Drug and Cosmetic Act. Section 506F defines a health system as "a collection of hospitals that are owned and operated by the same entity and that share access to data bases with drug order information for their patients." However, because health systems often include other types of health care facilities that could benefit from access to high quality and safety sterile compounded drugs prepared by a system's centralized compounding pharmacy, we suggest a more expansive definition that includes not only hospitals but also other health system facilities, such as provider-based infusion centers, ambulatory surgical centers and other health care facilities that are owned and operated by the same entity.

While FDA suggests 503B manufacturers may fill the void should compounding services be needed outside a 1-mile radius, CHA is concerned that, while providing essential services, 503B facilities do not presently have the capacity to meet hospital compounding needs. Outsourcing facilities make larger batches of compounded drugs and are not equipped to provide specific products to hospitals and health systems. They also are limited in what they can provide and often times experience delays and shortages. As a result, hospitals compound products to meet their own unique needs in quantities significantly below 503B manufacturers' volume capabilities.

Using the outlined safety and quality standards would ensure standardization and consistency with other state and federal standards and regulations, including California compounding and CHPP regulations, and would prevent disruption to the present highly successful CHPP pharmacy configurations with advanced centralized compounding operations staffed by the most experienced pharmacy personnel. Reverting to antiquated systems for today's compounding in less sophisticated spaces would be resource intensive and would increase the risk of adverse drug events and patient injury. The 1-mile radius requirement could actually compromise patient health and safety as hospital pharmacies move towards increasing safeguards and updated facilities.

II. Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, FDA-2016-D-0269

California hospital and health system licensed compounding pharmacies are staffed with dedicated, fully trained personnel that provide sterile, non-sterile and repackaged unit dose medications for their hospitals/health systems. All of the medications are dispensed or administered with an appropriately licensed prescriber's order or prescription. Compounded medication that is prepared in batches and stocked for anticipatory compounding are assigned appropriate beyond-use-dates based on reliable, published stability studies and end-product testing that includes sterility, potency, endotoxin, pH and particulate matter tests. All sterile batched –prepared compounded medications that have extended use dating beyond USP 797 are quarantined and tested according to USP 797 and USP 71 standards before release for dispensing and administration. All compounding and repackaging activities are thoroughly documented and standardized, and include a review by staff to provide consistency and improve safety. All compounded preparations and repackaged medications are only dispensed to patients within the respective hospital/health system in quantities and timing parameters under USP 797 and USP 71.

Although the turn-over for batch prepared (anticipatory) compounded preparation is usually within 30 days, some preparations may have a longer shelf life because they are emergent drugs — including hydralazine a vasodilator used to prevent stroke secondary to hypertension, and norepinephrine, a cardiovascular support agent used for sepsis — that need to be stocked and ready for immediate use 24 hours a day, seven days a week, but may only be used once or twice in a six-month period. The supply is usually only enough for one to two patients and is tested according to USP 797 and USP 71 standards, assuring sterility and potency throughout the beyond-use -date and storage.

The 30-day limit is an understandable goal, but should not be a mandate because of the need for anticipatory compounding for acutely ill or injured patients who should not wait for the administration of medications, as outlined in CMS[3] and TJC guidelines[4]. Aligning compounding beyond-use dates with USP 797 and USP 71 valid sterility requirements is a more appropriate requirement that aligns with existing hospital and health system regulations for safe and effective care of acutely ill patients.

III. Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act, FDA-2016-D-0238

CHA believes the three-pronged framework for purchasing and processing of sterile and non-sterile compounded products through hospital pharmacies, CHPPs and 503B manufacturers is critical to successful administration and distribution of compounded medications and essential to realizing DSQA's goals[5]. All agree that 503B manufacturers are vital to the process; however, with continued sophistication of many of the CHPP's pharmacies, some are considering registering as outsourcing facilities.

To encourage participation in 503B programmatic development, CHA urges FDA to provide more clarity of the term "facility." FDA draft Facility Definition Guidance defines "facility," for the purposes of 503B, to include "all activities, equipment, appurtenances, and materials part of such a facility if they are related to human drug compounding under the supervision of the facility's management at the same street address, or in the same building, or in buildings located in close proximity to one another." It is unclear whether FDA would consider buildings that are on a hospital campus to be the same geographic location or in "close proximity" to one another. Hospitals and health systems must use 503A facilities to meet

[3] **CMS** Interpretive guidelines, Compounding includes: "Preparation of drugs or devices **in anticipation of prescription drug orders** based on routine, regularly observed prescribing patterns"; **"Medications must be available for administration to patients** when needed, including when the pharmacy is not open. Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following: automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc."; [The medication distribution system may include] Use of a **"floor stock system (i.e.; storage of pharmaceutical and over-the-counter drugs on the patient care unit),**" as long as the drugs are secured and controlled [emphasis added]

[4] **TJC,** "Hospital leaders, in conjunction with members of the medical staff and licensed independent practitioners, decide which emergency medications and their associated supplies **will be readily accessible in patient care areas based on the population served**; **Emergency medications and their associated supplies are readily accessible in patient care areas.** (See also PC.03.01.01, EP 8); Whenever possible, emergency medications are available in **unit-dose, age-specific, and ready-to-administer forms" [emphasis added].**

[5] **DQSA-The Drug Quality and Security Act (H.R. 3204)** creates a uniform, national standard for tracing pharmaceuticals through the supply chain. The bill ensures the safety of drugs for patients and the immediate preemption provision eliminates the burdensome patchwork of state pedigree laws. Wholesale distributors can start conducting business the same way in all 50 states.

urgent patient care and clinician needs, since some 503A compounded medications cannot be compounded in accordance with 503B Current Good Manufacturing Practices' requirements. If this definition is read to mean that anything produced on the same campus as a 503B facility would need to meet 503B standards, then 503A compounding would be prohibited — which would be contraindicated and prevent potential 503B development. CHA suggests that the FDA rethink its expansive definition of "facility." Hospitals and health systems cannot be expected to abandon existing facilities to qualify for 503B status. 503B "facility" requirements should be flexible enough to work within the existing three-pronged framework.

In conclusion, California hospitals and the California BoP work collaboratively to uphold continuous quality improvement measures to assure the highest standards of quality care and patient safety. Hospitals and health systems are deploying centralized packaging pharmacies due to more reliable production and distribution capability with highly educated pharmacists and staff as well as centralized, standardized practices that will enhance compounded medication safety measures. CHA appreciates the opportunity to respond and looks forward to working with FDA to ensure that final guidance provides workable solutions to meet our patients' needs. If you have additional questions, please contact me at akeefe@calhospital.org or (202) 488-4688 or BJ Bartleson, vice president, nursing and clinical services, at bbartleson@calhospital.org or (916) 552-7537.

Sincerely:

/s/
Alyssa Keefe
Vice President, Federal Regulatory Affairs

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

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

SUBJECT: BoP Request for a Construction Waiver

SUMMARY

The Board of Pharmacy has finalized the Sterile Compounding Regulations which includes the ability to make a request for delays in meeting structural compliance requirements. OSPHD and Board of Pharmacy representatives will discuss the requirements necessary for the waiver application.

ACTION REQUESTED

- *Discussion on process requirements for the waiver*

DISCUSSION QUESTIONS

1. What elements are necessary to present in the waiver?
2. Will there be a specific form that all hospitals will use for the waiver?
3. How will OSHPD work with the Board of Pharmacy and hospitals to facilitate waiver review?

Making a Request for a Construction Waiver to Comply with CA's Compounding Regs

Draft Procedures

August 31, 2016

16 CA Code of Regulations

As proposed in the regulation (as subdivision 1735.6(f) and in 1751.4(l)), the waiver request shall:

1. be made in writing;

2. identify the provision(s) requiring physical construction, alteration, or improvement; *and*

3. contain a timeline for any such change.

Additional Requirements

- The board or its designee may grant the waiver for construction when, in its discretion, good cause is demonstrated for the waiver.

- The waiver provision is not an exemption from compliance with the compounding structural requirements, but a delay in required compliance.

Status of the Compounding Regulation Provisions

Once the compounding regulations have been approved (the expected decision date is about September 13), the board will begin accepting waiver requests. Information will be added to the website announcing the option and how to submit a waiver request.

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Regulation Status

However, if the regulation is not approved by the Office of Administrative Law and returned to the board for correction and future resubmittal, waiver requests will not be accepted until the regulation is approved.

Process

The board expects to see in the pharmacy's or facility's written request for a waiver to permit construction the following items:

1. The name of the pharmacy, name of the individual submitting the request, title and contact information (address, email and phone number),
2. The reason for submitting the request, including the specific sections of California's compounding requirements requiring physical construction, alteration or improvement that are the reason for the waiver request,

Process

3. A description of the status of the construction process in the pharmacy:
   - Is there an architect, if so who?
   - Is this a structural modification, describe
   - Have building plans been developed?
   - Has a building permit been secured?
   - Time frame for completion of construction.

Remaining Components

4. If review by OSHPD is required, provide a copy of “Project Completion Timeline” and the “General OSHPD Project Number.”

5. A written description of how the pharmacy will perform compounding while the construction waiver is in effect.

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
Fax: (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

Guidance on Applying for Compliance Delays During Construction In Pharmacies that Compound

Title 16 of the California Code of Regulations (CCR) section 1735.6 (f) states where compliance with California's compounding regulations requires physical construction or alteration to a facility or physical environment, the board may grant a waiver of such compliance for a period of time to permit the required physical changes. See also related provisions in CCR section 1751.4.

Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For hospitals, please see Guidance on Applying for Compliance Delays During Construction in Hospital Pharmacies that Compound, to request an exemption.

Please submit your request to:

Compounding Construction Waiver Request
CA State Board of Pharmacy
1625 N Market Boulevard, Suite N-219
Sacramento, CA 95834
Or
Email to: Compounding.waivers@dca.ca.gov

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This document and form are available at www.pharmacy.ca.gov.

Pharmacy Name:

License Number: PHY/PHE

Please provide sterile compounding licenses associated with the above license: LSC/LSE

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

The provisions of the regulation for which a compliance delay for construction is needed:
(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request)

A description of the physical changes that must be made for compliance *(Attach additional page if necessary)*:

Please provide the timeframe for construction to completion:

Have building plans been developed? Yes ☐ No ☐

Has a building permit been secured? If yes, please provide number:

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

Reviewed by:

Pharmacy Pharmacist-in-Charge _____

Please Print

Signature: _____Date:_____

Please do not send architectural drawings or structural plans as they will not be reviewed.

California State Board of Pharmacy
1625 N. Market Blvd, N219, Sacramento, CA 95834
Phone: (916) 574-7900
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Application for any waiver must be made in writing, identify the provisions requiring physical construction or alteration, and provide a timeline for any such changes. The board may grant the waiver for a specified period when, in its discretion, good cause is demonstrated for such waiver.

For non-hospitals, please see Guidance on Applying for Compliance Delays During Construction in Pharmacies that Compound, to request an exemption.

Please submit your request to:

Compounding Construction Waiver Request
CA State Board of Pharmacy
1625 N Market Boulevard, Suite N-219
Sacramento, CA 95834
Or
Email to: Compounding.waivers@dca.ca.gov

Below is an example of the requested information in a format that you may submit to the board to request a waiver. It is in a fillable PDF format that you can complete online, printout, have signed and then return to the board along with any attachments. This form is available at www.pharmacy.ca.gov.

Hospital Pharmacy Name:

License Number: HSP/HPE

Provide all sterile compounding license numbers associated with the above license that require modification as part of this request:
LSC LSC LSC LSC LSC LSC

Name of the Individual Submitting this Request:

Title:

Email:

Phone Number:

General OSHPD Project Number for this modification:

Please attach a copy of the Project Completion Timeline, including a specific timeline for construction for EACH compounding pharmacy location that needs modification and is included under this OSHPD Project Number.

The provisions of the regulation for which a compliance delay for construction is needed:
(Note: CA Code of Regulations section 1735.6(f) requires the identification of code sections requiring physical construction, alteration or improvement that are the reason for the waiver request.)

A description of the physical changes that must be made for compliance *(Attach additional page if necessary)*:

Have building plans been developed? Yes ☐ No ☐

Has a building permit been secured? If yes, please provide number:

Please provide a written description of how the pharmacy will perform compounding while the compliance delay is in effect.

Reviewed by:

Hospital Chief Operating Officer _____

Please Print

Signature: _____Date:_____

Please do not send architectural drawings or structural plans as they will not be reviewed.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

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

SUBJECT: Medication Reconciliation and the Electronic Health Record

SUMMARY

Safety concerns around the use of medications, particularly with allergies, continues to be problematic for California hospitals. At the 7/6/16 CHA Medication Safety Committee it was determined that a future topic for committee consideration be the electronic health record, allergies and the need for effective medication reconciliation. The committee requested that Rita Shane represent her information on medication reconciliation and head up a subcommittee to address medication reconciliation issues. The workgroup members are: Rita Shane, Lori Nolan, Diane Schultz, Christine Low, Kevin Dorsey

ACTION REQUESTED

- ***Discussion on the work of the medication reconciliation sub-group moving forward***

DISCUSSION QUESTIONS

1. What are the driving issues and factors and how can the workgroup effect change?
2. Are there other groups we need to partner with?
3. What is the overall goal of the workgroup?

Recommendations to Improve Medication Safety:

Risks Associated with Medication Reconciliation and Transitions of Care

Rita Shane, Pharm.D., FASHP, FCSHP
Chief Pharmacy Officer
Cedars-Sinai Medical Center, Los Angeles
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy

OBJECTIVES

- Cite evidence regarding the frequency of medication errors in medication histories
- Describe the role of pharmacists in reducing readmissions through safe medication transition programs
- Describe the rationale behind using trained pharmacy technicians to obtain medication histories

BACKGROUND

- Medication reconciliation (med rec) is required by The Joint Commission and the Center for Medicare/Medicaid Services as part of Meaningful Use
- The process is intended to ensure the accuracy of the medication list at each patient encounter
- Medication lists are entered into electronic health records (EHR) by a variety of individuals (both licensed and unlicensed) across different healthcare settings
- The medications entered are not always accurate
- These lists are used to create hospital medication orders resulting in continuation of inaccurate and/or incorrect medications

BACKGROUND

- Clinicians rely on the information and prescribe medications that are listed even though the information may be inaccurate
- The requirement for med rec and adoption of the EHR has increased the potential for harmful medication errors with the unintended consequence of creating “med wreck”
- A medication order is a sentence
  - If any element: drug, dose, dosage form, route, frequency, duration are incorrect, incomplete or unclear, patient harm can result
- Evidence supports the need to improve current processes to prevent medication errors and patient harm

EVIDENCE

Risks at Admission

- Up to 67% of patients have discrepancies or error on their medication list upon admission to the hospital.[1]
- 39% of these errors or discrepancies have the potential to cause moderate to severe harm.[2]
- Reported rates of inpatient medication errors range from 45% to 76% due to inaccuracies in medication histories and reconciliation with most errors occurring on admission.[3]

EVIDENCE

Risks at Discharge

- 19-80% of patients experienced at least 1 medication discrepancy or error post-discharge.[4-7]
- 11% of patients experienced an adverse drug event within 24 days post-discharge; 27% were preventable and 33% were ameliorable.[8]
  - 13% were serious (temporary or permanent disability) and 16% were life-threatening
- Patients with medication discrepancies had a 30 day hospital readmission rate of 14.3% vs 6.1% for pts without a medication discrepancy[4]

Sources of Medication Lists

Errors introduced in any of these settings can become "hardwired" into the pt record

Home

- Pt
- Family members
- Caregivers
- Home Health nurses

Outpatient Settings

- Certified medical assistants
- Physicians
- Community pharmacies
- Patients

ED/Hospital

- Nurses
- Physicians
- Pharmacists
- Pharmacy technicians
- Pharmacy residents, students

Skilled Nursing Facility

- Nurses
- Physicians

CMS 2012-Meaningful Use

- Any licensed healthcare professional and *credentialed medical assistants*, can enter orders into the medical record
- Credentialed medical assistants are:
  - Certified medical assistants-graduates of an accredited medical assisting program
    - Training requirements: 2-6 units of pharmacology training. (based on evaluation of 4 California programs)
  - Medical assistants (who are not certified) who have completed a required order entry course

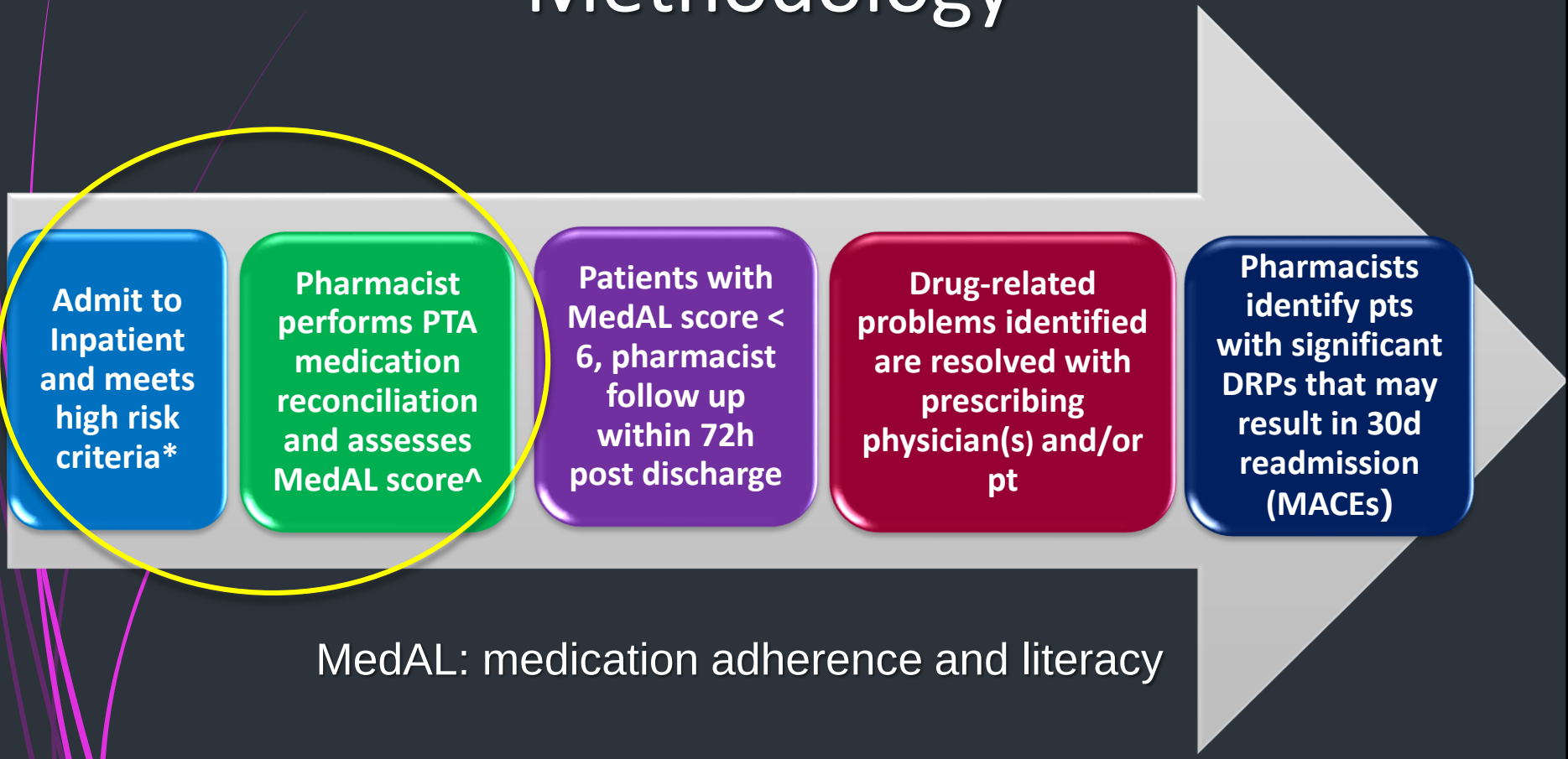
- https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/downloads/Stage2_EPCore_1_CPOE_MedicationOrders.pdf,accessed 9/20/16
- http://aama-ntl.org/docs/default-source/default-document-library/how-medical-assistants-meet-cms-requirement.pdf?sfvrsn=2, accessed 9/29/16

Medical Assistants
Requirements for Order Entry into Electronic Health Records

- 2 yr recent experience in a health care facility under the supervision of a licensed health care provider (LHP)
- Application signed by supervising LHP attesting proficiency in areas including pharmacology
- Completion of Assessment-Based Recognition in Order Entry (ABR-OE) Qualifying Courses-5 courses
  - Foundation of order entry in health care
  - How Medical Assistants can meet CMS meaningful use requirements
  - Medical Records: The Legal Document
  - Clinical Laboratory: Keeping up with CLIA
  - Anatomy, Physiology and Disease Screenings

https://learning.aama-ntl.org/Public/Catalog/Home.aspx, accessed 9/29/16

CSMC Safe Medication Transitions Methodology



MedAL: medication adherence and literacy

*High risk criteria: > 10 chronic meds, on anticoagulant, diagnosis of CHF w/ EF< 40%, pneumonia
^MedAL score: CSMC algorithm to assess patient's medication adherence and medication literacy

Errors on Admission Medication Lists

Minimizing Errors in Medication Histories Obtained at Hospital Admission

Randomized Controlled Trial

- **Usual Care: MD or RN**
- **Pharmacist**
- **Trained Technician**

- **High Risk Patients* admitted via Emergency Dept**
- **300 pt enrolled; 283 in final analysis**
- **Median age: ~76 (range: 50-83)**
- **Median # of meds" 14 (range; 10-19)**

****High risk:≥ 10 chronic meds, Acute MI, CHF, admitted from SNF, on anticoagulants, insulin, narrow therapeutic drugs, history of transplant***

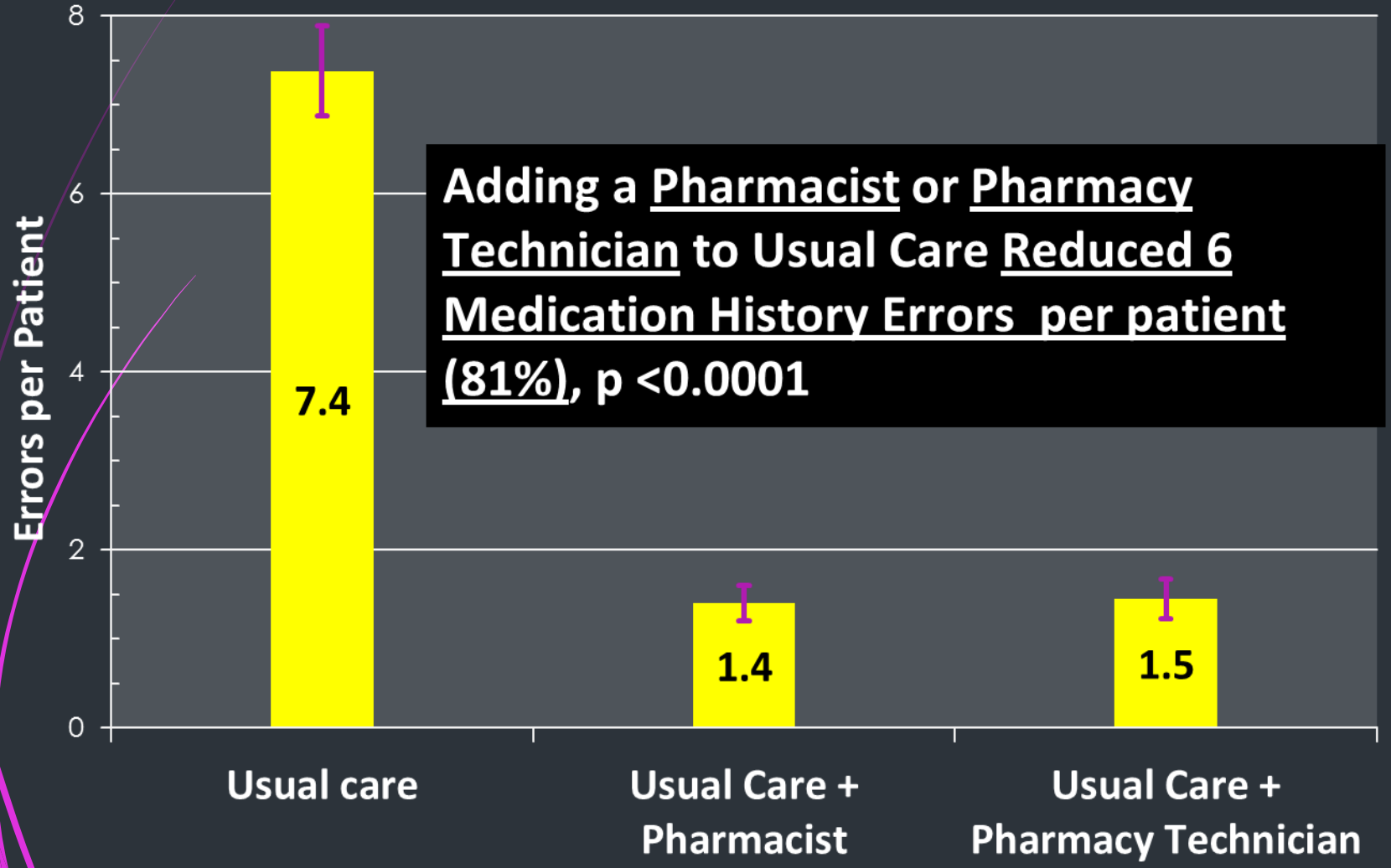
Pevnick JM NC, Jackevicius CA, Palmer KA, Shane R, Bresee C, Bear ME, Zaitseva O, Seki D, Desai A, Doyle B, Bell DS. Minimizing Medication Histories Errors for Patients Admitted to the Hospital Through the Emergency Department: A Three Arm Pragmatic Randomized Controlled Trial of Adding Admission Medication History Interviews by Pharmacists or Pharmacist-Supervised Pharmacy Technicians to Usual Care. J Patient-Centered Res Rev 2015;2:93.Research was supported by NIH/National Center for Advancing Translational Science UCLA CTSI Grant Number KL2TR000122. The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH. The investigators retained full independence in the conduct of this research.

Minimizing Errors in Medication Histories Obtained at Hospital Admission

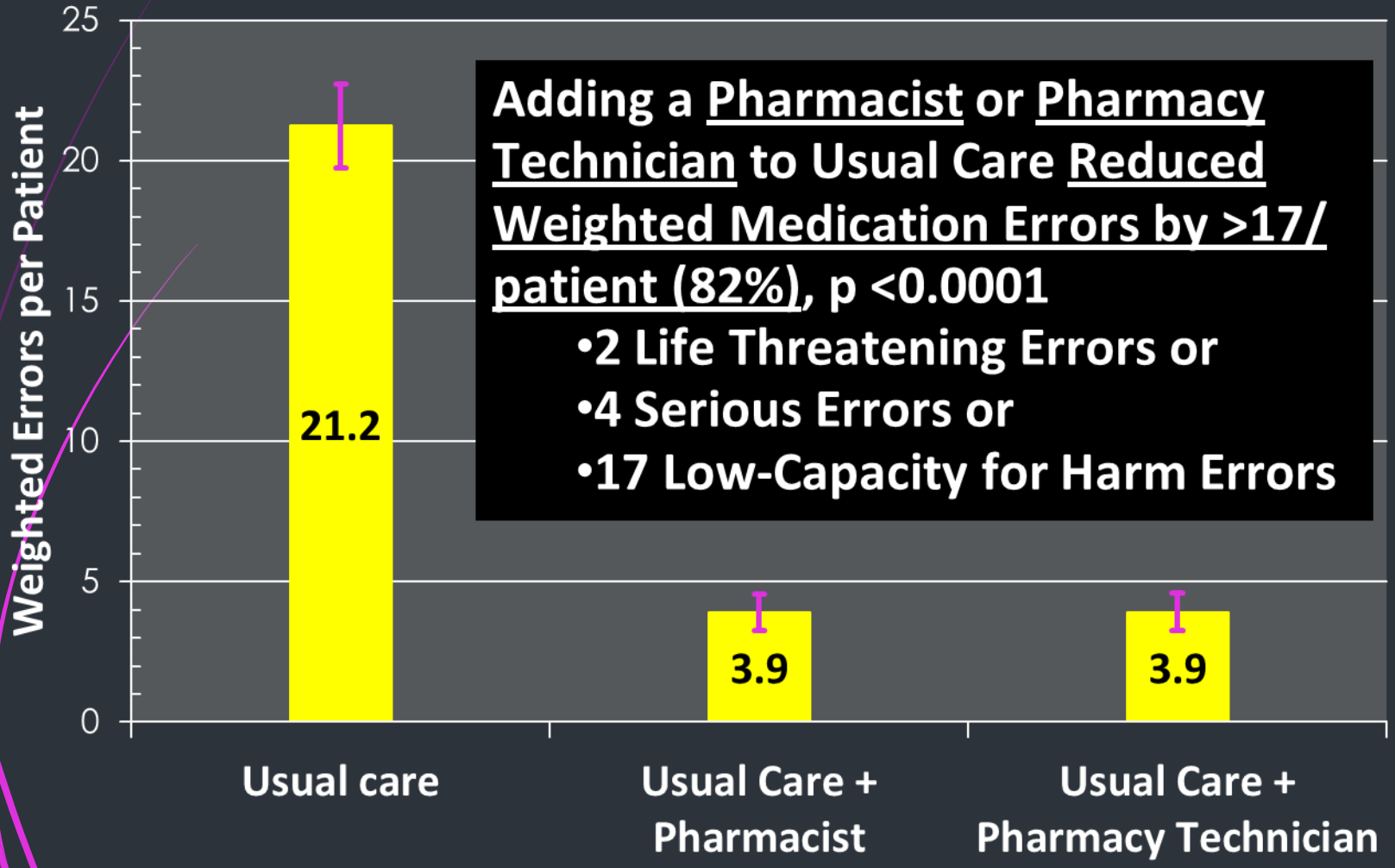
Randomized Controlled Trial

- Pt histories independently evaluated within 24 hr by gold standard pharmacist (proven study methodology)
- Gold standard pharmacist took patient history, compared with history taken, determined # errors and severity of errors:
  - Low capacity for harm: vitamin, laxative
  - Serious: beta blocker for hypertension
  - Life Threatening: transplant drug

Results: Number of Errors



Results: Severity of Errors

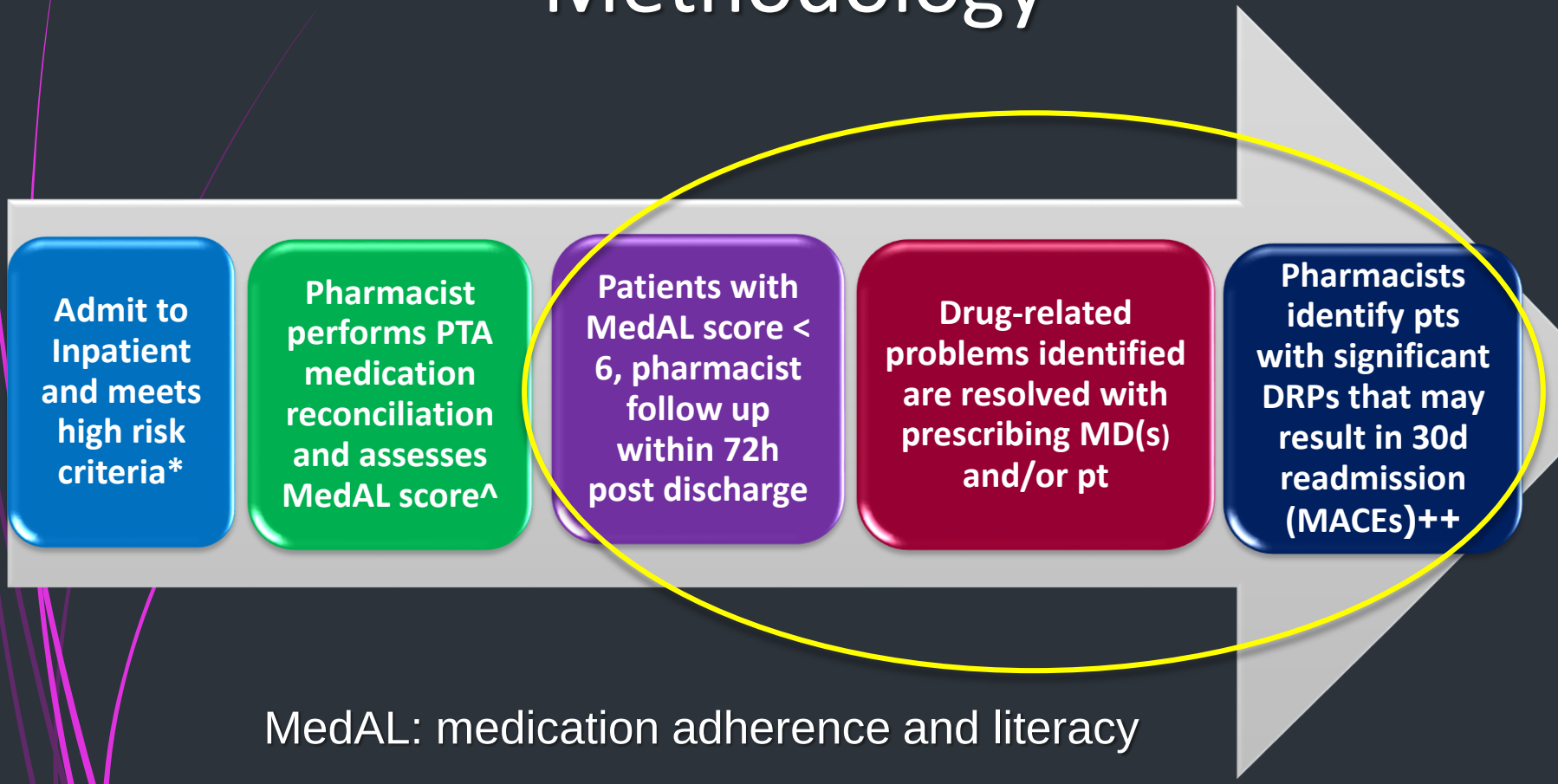


Examples of PTA Drug-Related Problems (DRPs) Resolved

PTA Med List	Drug-Related Problem Identified	DRP Type	Capacity for Harm
Insulin regular	PTA List: Insulin 300 units DRP: ordered as daily; 300 units is used to refill monthly insulin pump	Wrong route	Life-Threatening hypoglycemia
Albuterol	PTA List: albuterol 2.5mg/0.5ml nebulizer vials #30 Finding: ordered as 30 vials q4h.	Wrong dose	Serious/ Significant tachycardia
Keppra®	PTA List: 100mg po BID Finding: ordered as 100mg po BID (liquid). Pt reports taking 1000mg mg BID. Order changed.	Wrong Dose	Serious/ Significant Seizures
Amlodipine	PTA List: amlodipine 10mg daily Finding: MD reordered. Family indicated pt stopped taking due to swelling allergic reaction	Allergy	Serious/ Significant anaphylaxis

Errors Post-Discharge

Safe Medication Transitions Methodology



MedAL: medication adherence and literacy

*High risk criteria: > 10 chronic meds, on anticoagulant, diagnosis of CHF w/ EF< 40%, pneumonia
^MedAL score: CSMC algorithm to assess patient's medication adherence and medication literacy
++Physician validation of likelihood of readmission

High Risk Patients and MedAL Assessment

HIGH RISK CRITERIA

- **Chronic medications > 10 (excluding vitamins, supplements)**
- **Therapeutic anticoagulants**
- **CHF with EF < 40%**
- **Pneumonia on admission**

ADHERENCE

1. Do you ever forget to take your medicine?
2. Do you ever have problems remembering to take your medicines?
3. When you feel better do you sometimes stop taking your medicine?
4. Sometimes if you feel worse when you take the medicine, do you stop taking it?

LITERACY

1. Name of medicine?
2. Indication of medicine?
3. Strength of medicine?
4. Frequency/directions of medicine?

MedAL Score

Medication Adherence and Literacy Score

Medication Adherence (Scale 0-4)	Medication Literacy (Scale 0-4): High Literacy (4 points)	Medication Literacy (Scale 0-4): Intermediate (2-3 points)	Medication Literacy (Scale 0-4): Low Literacy (0-1 point)
High Adherence (4 points)	No Post DC Follow-up	No Post DC Follow-up	Perform Post DC Follow-up
Intermediate (2-3 points)	No Post DC Follow-up	Score 6: No Post DC Follow-Up Score <6: Perform Post DC Follow-Up	Perform Post DC Follow-up
Low Adherence (0-1 point)	Perform Post DC Follow-up	Perform Post DC Follow-up	Perform Post DC Follow-up

1. Impact of Pharmacist Post-discharge Phone Calls on Hospital Readmission and Patient Medication Literacy and Adherence. http://clinicaltrials.gov/show/NCT02031406
2. Medication Adherence and Literacy as Predictors of Hospital Readmission. American **Geriatrics Society Meeting 2014**
3. Transitions trifecta: calibrating the severity of drug related problems, medication adherence, and literacy in a high risk population. [Abstract]. Presented at ASHP The Midyear on December 10, 2013.

DC= Discharge from hospital

CSMC Modified Severity Scale for Identified DRPs

Adapted from the NCC MERP (National Coordinating Council for Medication Error Reporting and Prevention)

Post-Discharge Follow Up Results Jan-June 2016

	Jan 16	Feb 16	Mar 16	Apr 16	May 16	Jun 16
Number of patients evaluated	172	183	191	160	142	131
% significant/life-threatening DRPs/DRPs total	69.6%	72.7%	81.4%	71.0%	73.9%	68.3%
DRPs/pt	4.9	3.9	4.5	4.8	4.3	3.5
% readmissions prevented validated by MDs*	80.0%	79.4%	85.2%	76.7%	82.6%	64.3%

Criteria for readmission determination:
Category A >50% likelihood
Category B: 20-49% likelihood

Examples of Post Discharge (Drug-Related Problems) DRPs Identified and Resolved

Case	DRPs Identified and Pharmacists Actions	Avoidable MACE
77 yo M w/ PMH of CHF due to ICM s/p CABG, afib, severe MR, ESRD on HD, presenting w/ weakness	1) QTc 591 ms, pt taking amiodarone 200 mg PO daily. 2) eplerenone: C/I in ESRD (potential for hyperK, hypoNa, hypertriglyceridemia). 3) Isosorbide dinitrate/hydralazine: Pt taking old supply of BiDil TID (not prescribed), BP 80s/50s since discharge. **Recommendations:** 1) Decrease amiodarone to 100 mg PO daily. 2) Discontinue eplerenone and BiDil.	Readmission due to QTc prolongation, electrolyte imbalance, hypotension/fall
65 yo F w/ PMH of HFrEF (31%), DM, HTN, HLD, morbid obesity, presenting w/ CHF exacerbation	1) Problems filling D/C meds: did not pick up ivabradine (Corlanor®), doxycycline, furosemide, steroids for COPD exacerbation. 2) Advair: Not prescribed at discharge for possible COPD dx 3) Furosemide dose: duplicate prescription for 20mg and 40mg daily on AVS **Recommendations:** 1) Called pt's pharmacy to fill DC meds and Advair. 2) Recommend continuing hospital dose of furosemide 40mg	Readmission for acute decompensated CHF due to lack of diuretic; worsening COPD

Examples of Post Discharge (Drug-Related Problems) DRPs Identified and Resolved

Case	DRPs Identified and Pharmacists Actions	Avoidable MACE
CC: 91 yo F w/ PMH of CVA, afib on rivaroxaban, aortic stenosis, seizure, presenting w/ UTI	1) Bradycardia: metoprolol increased to 50mg BID (but AVS listed as 25mg BID (PTA dose). Pt also started on digoxin. Family reports HR in the 40s. 2) Levofloxacin: patient on 5-day course based on dirty UA. Denies symptoms; culture results suggests colonization. 3) Rivaroxaban: Pt prescribed rivaroxaban 20 mg daily. Recommended dose for pt w/ CrCL 29ml/min is 15 mg. **Recommendations:** 1) Recommend hold metoprolol, and D/C digoxin or check level. 2) Recommend D/C levofloxacin 3) Recommend rivaroxaban dose change to 15mg daily.	Readmission due to bradycardia, bleeding
77 yo F w/ PMH of DM2, CAD, HTN, presenting with w/ hyperglycemia (BG 649 on admission)	1) Insulin: pt was not using insulin glargine 10 units or checking BG after discharge. Pt reports no insulin or supplies at home. 2) Simvastatin: pt was not taking. **Recommendations:** 1) Found the most affordable insulin. Educated pt about compliance. 2) Case manager notified about pt's difficulty to pay. 3) Called in prescription for simvastatin, test strips and lancets.	Readmission with hyperglycemia due to med non-compliance

Health-System Pharmacist's Role in Evaluating Medications

Medications

Prior to Admit Medication List

As well as new orders

Drug

Indication

Dose

Route

Frequency

Dosage form

Duration

Patient Characteristics

Age

-Pediatrics

-Geriatrics

Gender

Height/Weight

Allergies

Kidney/Liver Function

Current labs

Previous admissions

Current Medication List

Drug-drug interactions

Drug-disease interactions

Drug-food interactions

Duplicate therapy

Contraindications

Medications needed but not prescribed

Monitoring requirements

Special Considerations

High risk patients or therapies such as:

Chemotherapy

Blood thinners

Antibiotics

Drugs with narrow therapeutic index

ICU

CSMC Safe Medication Transitions Results

- 7.4 medication history errors/high risk pt on admission
- 4.3 Drug Related Problems/pt post-discharge
  - Approximately 50% of problems are pt. related and 50% are prescriber-related
- Significant number of patients would have likely been readmitted without pharmacist follow up (based on physician validation)
  - >20% avoided Category A (>50% likelihood)
  - 60% avoided Category B (20-40% likelihood)
- >5% reduction in readmission in high risk pts with low literacy and adherence

Recommendations to Ensure Patient Safety

Patient Safety Imperatives

- Medication lists are frequently inaccurate and can lead to harm
- Ensuring the accuracy of the medication list at each transition of care is essential, especially when patients are admitted to and discharged from the hospital setting

Recommendations to Ensure Patient Safety

- Hospital pharmacies should be responsible for ensuring the medication list is accurate upon admission, especially for high risk patients
- Hospital pharmacies should ensure that high risk pts have a post-discharge follow up to prevent harm (adverse drug events and admissions)

Appendix

References

1. Tam VC, Knowles SR, Cornish PL, Fine N, Marchesano R, Etchells EE. Frequency, type and clinical importance of medication history errors at admission to hospital: a systematic review. *CMAJ.* 2005;173(5):510-515.
2. Cornish PL, Knowles SR, Marchesano R, et al. Unintended medication discrepancies at the time of hospital admission. *Arch Intern Med*. 2005;165(4):424-429.
3. Sen S; Siemianowski, L. Implementation of a pharmacy technician–centered medication reconciliation program at an urban teaching medical center. *Am J Health-Syst Pharm***.** 2014; 71:51-6.
4. Coleman EA, Smith JD, Raha D, Min SJ. Posthospital medication discrepancies: prevalence and contributing factors. *Arch Intern Med.* 2005; 165:1842-7
5. Vira T, Colquhoun M, Etchells E. Reconcilable differences: correcting medication errors at hospital admission and discharge. *Qual Saf Health Care*. 2006;15(2):122-126. doi:10.1136/qshc.2005.015347.
6. Wong JD, Bajcar JM, Wong GG, et al. Medication Reconciliation at Hospital Discharge: Evaluating Discrepancies. *The Annals of Pharmacotherapy*. 2008;42(10):1373-1379.
7. Kilcup M, Schultz D, Carlson J, et al. Postdischarge pharmacist medication reconciliation: Impact on readmission rates and financial savings. *J Am Pharm Assoc.* 2003; 53:78-84.
8. Forster AJ, Murff HJ, Peterson JF, Gandhi TK, Bates DW. Adverse events occurring after discharge. J Gen Intern Med. 2005: 20(4):317-23.

Severity Rating of Drug-Related Problems Resolved

(adapted from NCC-MERP)

Low Capacity for Harm

- **Category A**: Circumstances or events that have the capacity to cause error
- **Category B**: An error could have occurred but the error would not reach the patient
- **Category C**: An error could have reached the patient but would not cause patient harm

Serious/Significant

- **Category D**: The identified and intercepted error could have reached the patient and would have required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm
- **Category E:** The identified and intercepted error may have contributed to or resulted in temporary harm to the patient and required intervention
- **Category F:** The identified and intercepted error may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization

Life Threatening

- **Category G:** The identified and intercepted error may have contributed to or resulted in permanent patient harm
- **Category H**: The identified and intercepted error may have required intervention necessary to sustain life
- **Category I**: The identified and intercepted error may have contributed to or resulted in the patient's death

Use of the Medication Adherence and Literacy Algorithm to Identify Pts At Risk for 30-Day Readmission

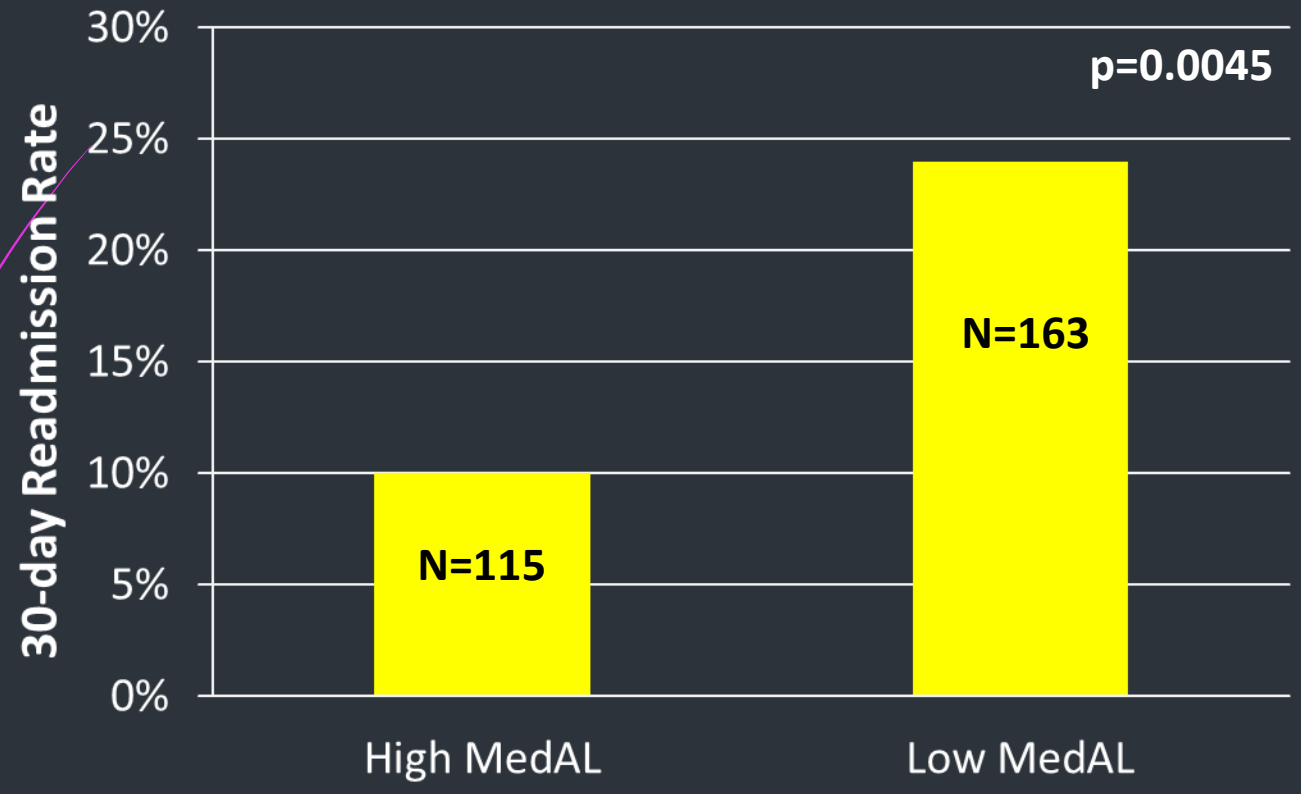
Value as Predictive Indicator

The odds of readmission for the group identified as needing post-discharge follow-up was 2.8 times greater than for the group identified as not needed post-discharge follow-up (95% CI 0.172 - 0.710, p=0.0045)

Conclusion: The MedAL algorithm can serve as a tool to identify patients that are at risk for readmission within 30 days. Post-discharge follow-up of patients identified by the MedAL algorithm may reduce 30-day admission rates.

Use of the MedAL Algorithm to Identify Patients at Risk for 30-day Readmissions

Odds of readmission for pts with low MedAL were 2.8x greater than high MedAL



Retrospective Cohort Study N=278 pts

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

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

SUBJECT: FDA Guidance on Insanitary Conditions for Sterile Compounding

SUMMARY

The Food and Drug Administration today issued draft guidance for pharmacies, physician offices and outsourcing facilities that compound or repackage drugs or mix, dilute or repackage biological products. The guidance provides examples of insanitary conditions under the Federal Food, Drug and Cosmetic Act, and recommended procedures to avoid or correct insanitary conditions in compounding facilities.

CHA was made aware that the Board of Pharmacy would be submitting comments and therefore will not be submitting comments

ACTION REQUESTED

- ***Informational Only/Discussion***

DICUSSION QUESTIONS

1. Are there any specific areas of concern?
2. Will the Board of Pharmacy share their response?

Insanitary Conditions at Compounding Facilities

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Sara Rothman (CDER) at 301-796-3110.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

August 2016
Compounding and Related Documents

Insanitary Conditions at Compounding Facilities

Guidance for Industry

Additional copies are available from:
Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

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Compounding and Related Documents

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Guidance for Industry[1]

Insanitary Conditions at Compounding Facilities

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or the Agency) on this topic. It does not create any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act or the Act), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health."[2] Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act, compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section 503A nor section 503B provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs prepared, packed, or held (hereinafter referred to as "produced") under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the Act.[3] Any drug that is produced under insanitary conditions is adulterated under the Act, including compounded human and animal drugs; repackaged drug products; compounded or repackaged radiopharmaceuticals; and mixed, diluted, or repackaged biological products. The policies described in this guidance document specifically address pharmacies, Federal facilities, physicians' offices (including veterinarians' offices), and outsourcing facilities that compound or repackage human or animal drugs (including radiopharmaceuticals); or that mix, dilute, or repackage biological products. For purposes of this guidance, we refer to such entities as "compounding facilities."

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs and the Center for Veterinary Medicine at the Food and Drug Administration.

[2] Insanitary conditions are conditions that could cause a drug to become contaminated with filth or rendered injurious to health; the drug need not be actually contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substance is deemed to be adulterated under section 501(a)(1) of the FD&C Act.

FDA is issuing this guidance to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions. This guidance is also intended to assist State regulatory agencies in understanding some examples of what FDA considers to be insanitary conditions that could cause a drug to become contaminated or rendered injurious to health.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Public Health Risk of Insanitary Conditions

FDA has investigated numerous outbreaks of infections and deaths found to be the result of drug products that were contaminated because they were produced under insanitary conditions. Most notably, in 2012, injectable drug products produced by a compounding facility and shipped across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection. FDA has investigated numerous other serious adverse events, including deaths, associated with contaminated drug products produced by compounding facilities, and it is likely that such adverse events are underreported.

Since the 2012 fungal meningitis outbreak, FDA has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations as a result of those findings. However, FDA does not inspect the vast majority of compounding facilities in the United States because they generally do not register with FDA unless they elect to become outsourcing facilities.[4] Therefore, FDA is often not aware of these facilities and potential problems with their drug products, or conditions and practices, unless it receives a complaint, such as a report of a serious adverse event or visible contamination. It is critical that compounding facilities avoid the presence of insanitary conditions and identify and remediate any insanitary conditions at their facilities before the conditions result in drug contamination and patient injury.

In addition, to protect the public health, it is critical that both FDA and State regulatory agencies take appropriate action when compounders produce drugs under insanitary conditions. Based on its inspections, FDA determines whether compounding facilities produce drugs under insanitary conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may initiate regulatory action. However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the States and, as explained above, generally are not routinely inspected by FDA. Therefore, FDA encourages State regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices,

[4] *See* section 503B of the FD&C Act.

including those described below, and if so, to take action, as appropriate, consistent with State laws and regulations, and to contact FDA.

III. POLICY

Section III.A of this guidance describes examples of conditions that would be considered insanitary conditions under section 501(a)(2)(A) of the FD&C Act. FDA has observed each of these conditions in one or more of the compounding facilities it has inspected. **These are only examples and are not an exhaustive list. Other conditions not described in this guidance may be considered insanitary**.

Section III.B of this guidance describes procedures that compounding facilities should employ to ensure that they do not have insanitary conditions and that they are capable of producing sterile drug products, and section III.C describes actions that compounding facilities should take if they identify insanitary conditions at their facilities. Finally, section III.D of this guidance describes potential FDA regulatory actions if insanitary conditions are not adequately corrected.

FDA intends to consider the entire set of conditions at the facility, including whether the facility engages in the procedures described in section III.B, when prioritizing regulatory action against a compounding facility for producing drugs under insanitary conditions.

A. Examples of Insanitary Conditions[5]

1. Insanitary Conditions Applicable to the Production of Sterile and/or Non-Sterile Drugs

Although maintaining sterility is not a requirement for non-sterile drugs, non-sterile drugs can become contaminated with microorganisms of a type or at a level that can cause patient harm. Non-sterile aqueous solutions are particularly susceptible to microbial growth if contaminated. Contamination may also include non-viable filth and the presence of unintended drug components. The following are examples of insanitary conditions that are applicable to both sterile and non-sterile drug production.

- Vermin (e.g., insects, rodents) observed in production areas or areas immediately adjacent to production.
- Visible microbial contamination (e.g., bacteria, mold) in the production area.
- Non-microbial contamination in the production area (e.g., rust, glass shavings, hairs).
- Handling beta-lactam, hazardous, or highly potent drugs (e.g., hormones) without providing adequate containment, segregation, and cleaning of work surfaces, utensils, and personnel to prevent cross-contamination.
- Production of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.

[5] For definitions of some of the terms used in this section, refer to United States Pharmacopeia (USP) Chapter <797>.

2. Insanitary Conditions in a Sterile Operation

a. Aseptic Practices

- Putting on gowning apparel improperly, in a way that may cause the gowning apparel to become contaminated. This includes, for example, gowning in non-classified areas, gowning apparel touching the floor, or putting on sterile gloves improperly (e.g., touching the outside of a glove with bare hands).
- Failing to disinfect or change gloves frequently enough given the nature of the operations to prevent contamination.
- Engaging in aseptic processing wearing non-sterile gloves. This could contaminate the critical area.[6]
- Engaging in aseptic manipulations with exposed hands, wrists, legs, hair, or mouth, for example.
- Performing aseptic manipulations outside of an International Organization for Standardization Class 5 (ISO 5) area.
- Exposing unprotected sterile product, including stock solutions, to lower than ISO 5 quality air (e.g., removing it from the ISO 5 area without a robust and intact container closure system).
- Engaging in aseptic processing after leaving the cleanroom and re-entering from a non-classified area without first replacing gowning apparel (e.g., sterile gloves, gowns, mask, foot covers). Movement of personnel in and out of the cleanroom without regowning may bring contaminants from the non-classified areas into the cleanroom.
- Moving quickly in the vicinity of open containers or instruments (e.g., needles). While conducting aseptic manipulations, ISO 5 airflow must be unidirectional to protect the product from contaminating particles. Quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area.
- Conducting aseptic manipulations or placing equipment/supplies in an area that blocks the movement of first pass air around an open container, whether before or after it is filled with sterile product. If unidirectional air over the critical surface is blocked, the area is no longer protected. If it is blocked by personnel conducting aseptic manipulations, contamination on personnel, particularly on exposed skin, could be introduced to the critical area.
- Using a non-sterile tool or manually contacting the inner surface of the container or closure. For example, during manual stoppering (e.g., hand stoppering), personnel touching the top of open containers, or the lower side or bottom of closures. This could contaminate the drug in the vials.
- Touching equipment or other surfaces (e.g., walls, telephone, floors) located outside of the ISO 5 area with gloved hands and then proceeding with aseptic manipulations without changing or sanitizing gloves.

[6] A *critical area* is an area designed to maintain sterility of sterilized materials. Sterilized product, containers or closures, and equipment may be exposed in critical areas. The ISO 5 area is the critical area, and the terms are used interchangeably throughout this guidance.

- Storing open sterile vials within the critical area without protective cover longer than needed for the process of filling drug product. The longer a vial is open to the environment, the greater the risk of contamination.
- Failure to disinfect container closure systems of sterile drug components immediately prior to opening for use.

b. Equipment/ Facilities

- Actionable microbial contamination of the ISO 5 area or in adjacent areas.
- Cleanroom with unsealed, loose ceiling tiles.
- ISO classified areas with difficult to clean (e.g., porous), particle-generating, or visibly dirty (e.g., rusty) equipment or surfaces such as shelving, floors, walls, doors, window sills, and ceilings. For example, wood is both difficult to clean and particle-generating.
- Classified areas and segregated production areas surrounding the ISO 5 area that contain dust-collecting overhangs (e.g., utility pipes or ledges, such as windowsills).
- ISO 5 area open to the surrounding cleanroom with minimal or no physical barriers separating it from non-aseptic activities (e.g., non-aseptic weighing materials, gowning, container labeling).
- ISO 5 area open to non-classified rooms (segregated production area). Lower quality air from the surrounding room entering the ISO 5 area increases the risk of introducing microbial contamination into drug products being manipulated.
- A facility designed and/or operated in a way that permits poor flow of personnel or materials, or allows the influx of poor quality air into a higher classified area. Examples include:
  - materials flow into the ISO 7 area directly from an unclassified area;
  - air return located next to the high efficiency particulate arrestance (HEPA) filter rather than near the floor;
  - an air vent between classified and unclassified areas;
  - a door opened between the unclassified area and the ISO 8 anteroom while the door between the ISO 7 and ISO 8 areas is also open;
  - inadequate pressure differentials between areas of higher quality air and lower quality air.
- A lack of HEPA-filtered air, or inadequate HEPA filter coverage or airflow, over the area to which sterile product is exposed.
- HEPA filters that are not sealed around each perimeter to the support frame. The air entering the cleanroom must be HEPA filtered to remove airborne particles. If HEPA filters are not sealed, air that is not HEPA filtered could enter the cleanroom.
- The presence of sinks or drains in the cleanroom where the ISO 5 area is located. Sinks and drains are sources of microbial contamination.
- Use of non-sterilized or non-depyrogenated equipment (e.g., transfer tubing, temporary bulk containers). Use of such equipment can introduce or increase bioburden and endotoxins.
- Use of non-sterilized or non-depyrogenated final containers/closures. Use of such container/closures could contaminate the drug product after it has been sterilized.

c. Sterilization

- The "sterilizing filter" is not adequate to accomplish sterilization and is not pharmaceutical grade.
- Temperature and time conditions used for heat sterilization are not lethal to heat-resistant microorganisms.

d. Cleaning and Disinfecting

- Non-sterile disinfecting agents and cleaning pads or wipes are used in the aseptic processing areas, especially the ISO 5 area. Non-sterile cleaning and disinfecting items could spread microbial spores.
- No, improper, or infrequent, use of a sporicidal agent in the facility's cleanrooms and ISO 5 area.
- No disinfection of equipment and/or supplies entering the aseptic processing areas. Disinfection should occur at each transition from areas of lower quality air to areas of higher quality (e.g., from non-classified to first classified room, from anteroom to buffer room, from buffer room to ISO 5 area).
- Disinfectant contact time (also known as "dwell time") and coverage of the item being disinfected are insufficient to achieve adequate levels of disinfection. The use, including contact time, of commercially-obtained disinfectants should follow the manufacturer's instructions.

B. Identifying Insanitary Conditions

Certain procedures are critical to ensuring that compounding facilities do not have insanitary conditions that could compromise drug sterility and that they are capable of producing sterile drug products. FDA recommends that compounding facilities that produce drugs that are intended to be sterile routinely employ these procedures to help ensure that they can produce sterile products. A non-exhaustive list of such procedures follows.

1. Conduct routine[7] environmental monitoring, including a) nonviable airborne particulate sampling; b) viable airborne particulate sampling; c) personnel sampling (including glove fingertip sampling); and d) surface sampling, including but not limited to equipment, work surfaces, and room surfaces. Environmental monitoring provides information on the quality of the aseptic processing environment and, if problematic, the compounding

[7] For compounding facilities that are not registered with FDA as outsourcing facilities, see USP Chapter <797>. For outsourcing facilities, see FDA's draft guidance, *Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* ("interim CGMP draft guidance"). Once final, this guidance will represent FDA's current thinking regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until FDA promulgates CGMP regulations that are more specific to outsourcing facilities.

This interim CGMP draft guidance states that outsourcing facilities should conduct environmental monitoring of the ISO 5 area at least daily. FDA recommends that compounding facilities that are not registered as outsourcing facilities also conduct daily environmental monoitoring during operations.

facility should promptly identify potential routes of contamination and perform corrective actions.

2. Certify the ISO 5 area every six months. If the ISO 5 area is not certified every six months or does not pass all certification requirements, there is no assurance that the ISO 5 area is working properly (e.g., generating unidirectional ISO 5 airflow). Smoke studies should be conducted as part of the certification to assess the airflow patterns necessary to maintain unidirectional flow from areas of higher air quality (e.g., ISO 5) to areas of lower air quality (e.g., ISO 7) to prevent microbial contamination of the sterile drug products during processing. Conducting smoke studies under dynamic conditions helps to ensure that unidirectional airflow is maintained while personnel are working in the ISO 5 area.

3. Measure pressure differentials during operations to help ensure proper airflow (i.e., from areas of higher quality air to adjacent areas with lower quality air).

4. Conduct media fill studies to closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

C. Corrective Actions

A compounding facility should immediately assess the impact of insanitary conditions on drug products produced, which should include an evaluation of how widespread the insanitary conditions are and over what period of time the conditions existed.

The compounding facility also should determine whether to cease production of drug products until the conditions have been corrected and initiate a recall of all potentially affected lots on the market.

For example, FDA considers the following insanitary conditions to be particularly serious, and if any one of these conditions exists, FDA strongly recommends that a compounding facility immediately initiate a recall of purportedly sterile drugs and cease sterile operations until the condition(s) have been corrected:

- Vermin (e.g., insects, rodents) observed in ISO 5 areas or in immediately adjacent areas.
- Visible microbial contamination (e.g., bacteria, mold) in the ISO 5 area or in immediately adjacent areas.
- Non-microbial contamination in the ISO 5 area (e.g., rust, glass shavings, hairs).
- Performing aseptic manipulations outside of the ISO 5 area.
- Exposing unprotected sterile product, including stock solutions, to lower than ISO 5 quality air (e.g., removing it from the ISO 5 area without a robust and intact container closure system).
- Cleanroom areas with unsealed, loose ceiling tiles.

- Production of drugs while construction is underway in an adjacent area without adequate controls to prevent contamination of the production environment and product.
- Consistent and frequent pressure reversals from areas of less clean air to areas of higher cleanliness.
- The "sterilizing filter" is not adequate to accomplish sterilization and is not pharmaceutical grade.
- Temperature and time conditions used for heat sterilization are not lethal to heat-resistant microorganisms.

If a compounding facility decides to initiate a recall, it should notify its local FDA District recall coordinator as soon as the decision to recall is made.[8] The compounding facility should also notify the applicable State regulatory body in the State(s) to which the facility ships drugs, consistent with State laws and guidance.

In addition to the immediate actions recommended above, if a compounding facility has insanitary conditions, it should undertake a comprehensive assessment of its operations, including, as applicable, facility design, procedures, personnel, processes, materials, and systems, and should consider consulting a third party with relevant drug production expertise to conduct this comprehensive evaluation and to assist in implementing appropriate corrective actions.

Compounding facilities producing purportedly sterile drug products under insanitary conditions should not rely on a passing sterility test as an indication of sterility assurance because microbial contamination, when present, is not uniformly distributed within a batch and may not be identified by a sterility test. Furthermore, compounding facilities must correct all insanitary conditions at their facility,[9] regardless of whether the drugs pass a sterility test.[10]

D. Regulatory Action

If a compounding facility produces drugs under insanitary conditions, the facility and responsible individuals may be subject to Federal regulatory actions including, but not limited to, a warning letter, seizure of product, and/or injunction. FDA may also recommend that the facility initiate a recall of some or all of its drugs and cease operations until the insanitary conditions have been adequately addressed. In addition, the applicable State regulatory agency may pursue regulatory action against the facility under applicable State authorities.

[8] *See* the FDA guidance, *Product Recalls, Including Removals and Corrections*.

[9] *See* section 501(a)(2)(A) of the FD&C Act.

[10] USP Chapter <71> concerning sterility testing states, "these Pharmacopeial procedures are not by themselves designed to ensure that a batch of product is sterile or has been sterilized. This is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures."

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2268]

Insanitary Conditions at Compounding Facilities; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Insanitary Conditions at Compounding Facilities." Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events in patients, including death. FDA is issuing this draft guidance to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions, and to assist State regulatory agencies in understanding some examples of what FDA considers to be insanitary conditions.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-2268 for "Insanitary Conditions at Compounding Facilities." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5197, Silver Spring, MD 20993, 301-796-3110.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Insanitary Conditions at Compounding Facilities." Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is deemed to be adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. Drug products compounded under insanitary conditions could become contaminated and cause serious adverse events in patients, including death. Although sections 503A and 503B of the FD&C Act

(21 U.S.C. 353a and 353b) provide exemptions for compounded drugs from specified provisions of the FD&C Act if certain conditions are met, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Any drug that is prepared, packed, or held under insanitary conditions is deemed to be adulterated under the FD&C Act, including drugs produced by a compounding facility.

Since the 2012 fungal meningitis outbreak associated with injectable drug products that a compounding facility produced and shipped across the country, FDA has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations as a result of these findings. However, FDA does not inspect the vast majority of compounding facilities in the United States because they generally do not register with FDA unless they elect to become outsourcing facilities. Therefore, FDA is often not aware of these facilities and potential problems with their drug products, or conditions and practices, unless it receives a complaint such as a report of a serious adverse event or visible contamination. It is critical that compounding facilities avoid the presence of insanitary conditions and identify and remediate any insanitary conditions at their facilities before the conditions result in drug contamination and patient injury.

FDA is issuing this draft guidance to assist compounding facilities in identifying insanitary conditions so that they can implement appropriate corrective actions, and to assist State regulatory agencies in understanding some examples of what FDA considers to be insanitary conditions.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current

thinking of FDA on insanitary conditions at compounding facilities. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm or http://www.regulations.gov.

Dated: July 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-18461 Filed: 8/3/2016 8:45 am; Publication Date: 8/4/2016]

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

October 5, 2016

TO: CHA Medication Safety Committee

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

RE: ACA Federal Upper Limit (FUL) Drug Pricing

SUMMARY

ACA changes included adjustments to the Federal Upper Limit (FUL) Drug Pricing. Historically FUL pricing was based on the estimated acquisition cost or the provider's usual and customary charge to the public for the drug. This was changed to the average price paid to the manufacturer for the drug in the United States by wholesalers for drug distribution to retail community pharmacies. The State of California adopted the new Federal FUL pricing on April 15, 2016 for Fee-For-Service Medi-Cal. We have heard that this has caused the reimbursement level of many drugs to fall below acquisition cost and that some hospital outpatient pharmacies have seen an increase in clients seeking to fill scripts that previously were filled by community pharmacies.

ACTION REQUESTED

- *CHA is checking to see if those of you with hospital outpatient pharmacies are experiencing any increases in number of Medi-Cal clients seeking filling of scripts or losses on scripts that are causing your hospital difficulty? If you are unsure, can you ask someone at your facility to review ?*

DISCUSSION QUESTIONS

1. Are there other drug pricing issues occurring in your facilities?

Medication Safety Toolkit Manual

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

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

MEDICATION GUIDELINE ACTIVITY MATRIX

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

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

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

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

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

	principles: 1. For items coming from a hospital something like this: "This is example shows how YYY hospital addresses X, and is intended for hospital and health care providers for their consideration as they evaluate their approach." 2. Try to use objective third-party materials that are freely available whenever possible (e.g., IHI, Joint Commission, peer reviewed publications). 3. For internally developed documents, develop a review process and include information about the review process when distributing it.	
2/6/14	Edited document forwarded to CHA legal counsel for feedback and disclaimer verbiage	
2/7/14	Menet suggested tweaking the intro to emphasize medication management and safety as opposed to medication error reduction.	
2/11/14	CHA legal counsel suggested “Any disclaimer should be in terms of providing something to "assist" hospitals develop (or prepare, or evaluate, etc.) whatever it is that they are working on. It should also include a statement that this 'tool' or 'guideline' is informational only, any questions or issues of a legal nature should be reviewed by hospital counsel.”	
3/4/14	Emailed back to the workgroup for final review prior to committee vote on April 9	
3/15/14	Final revisions received; document updated.	
3/18/14	Document sent back to committee for final approval.	
3/27/14	All votes received: 8 “Yes” votes; 0 “no” votes	
4/9/14	Finalized document presented to committee at quarterly meeting.	Pending publications approval for posting to CHA website
April 2014	Posted to CHA MSC Webpage	

OPIOID SAFE USE GUIDELINES (Cleo Mutebi: High Risk/High Alert Subcommittee)		
DATE	**ACTIVITY**	**STATUS**
October 2012	First Draft	
January 2013	Posted to CHPSO Website	
April 2013	Version 1.0	
June 2013	Pulled from CHA website for revision and reformat.	
August 2013	Reformatted by Jonathan Nelson and Eddie Avedikian	
October 2013	Under re-review by BJ Bartleson and Rory Jaffe.	Pending addt’l word-smithing and final reformat by Rory and BJ.
July 2014	Added Fentanyl wording	Final review needed

SB 1036 IMPLEMENTATION		
DATE	**ACTIVITY**	**RESULT/STATUS**

STERILE COMPOUNDING		
DATE	**ACTIVITY**	**RESULT /STATUS**

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

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

Insulin	12/9/13	Dan Ross	Page 6: I just had one change, really a question or request for clarity – near the bottom of page 6 – shows in purple and I bolded it. Actual copy and paste is below so you can easily find it.	
Med-ER	11/20/13	Jonathan N.	Draft deliverable submitted with the following notes: Attached are the following: • Draft Med-ER deliverable which contains a cover sheet and the grid. • Draft cover sheet in word for ease in editing • Draft grid in excel for ease in editing. Our to-do was to finalize this and send to you to forward to the MSC committee for their vote. Perhaps BJ and Rory want to take a look first before sending it out? Let me know if anyone has any questions or edits that we could address.	*Revisions included in January's meeting packet. -ih*
Fentanyl	11/13/13	Pam R.	Requested guidelines template so she could convert from the old template and revise guidelines accordingly.	*Template sent -ih*
Opioid & Anticoag	11/10/13	Jonathan N.	Revised guidelines submitted with the following notes: • We utilized track changes and accepted most of your edits. We left a few edits as unaccepted where useful for explaining our edits. • At our last MSC meeting, there was discussion around the importance of indicating physician involvement in the development of the guidelines. The current guidelines include a list of the organizations which participated in the drafting process. Unfortunately, it looks like there were no physician groups represented. Perhaps a solution would be to simply state that the committee included "physician, pharmacist and nurse representatives" and leave it there without specifying the actual groups involved. • I spent some time trying to standardize the formatting for each specific document, but it would probably be advantageous for each guideline to get one final editorial/formatting pass before being republished.	*Revisions included in January's meeting packet. -ih*
Opioid & Anticoag	10/17/13	Rory J.	1. First round of edits submitted by Rory and BJ 2. Edits forwarded to Eddie A. and Jonathan N.	*Edits forwarded to JN and EA -ih*
All	10/14/13	Ingrid H.	Guidelines templates and instructions emailed to Med Safety Committee members	

Implementation of SB 1039 and Program Flex Requests

Enactment of SB 1039, on January 1, 2015, directly impacted pharmacy law (Business and Professions Code (B&PC)), and California Health and Safety Code (H&SC). As a result, several regulatory sections of California Code of Regulations (CCR), Title 22, primarily for general acute care hospitals (GACHs), are impacted as potential licensure requirement conflicts may arise. Before a licensed entity may implement those sections of SB 1039 conflicting with Title 22, program flex requests must be submitted and Departmental approval obtained. The following is provided as general guidance.

Implementation of …

Pharmacy Technician: B&PC Section 4115(a) through (h) requires no program flex. Modify policies and procedures as appropriate.

Pharmacy Technician: B&PC Section 4115(i)(1) through (3) affects CCR, Title 22 Section 70263(f)(2) **and** (3), as well as Section 70263(q)(10), and will require a program flex request at **each** affected section. As to performing “checks of drug supplies stored throughout the health care facility,” the new law reads "monthly." Section 70263(q)(10), which refers to drug storage area inspections in general, stipulates, “drugs maintained on the nursing unit” are to be “inspected at least **monthly**,” and by “a **pharmacist**.” However, Section 70263(f)(3), which is specific to nursing unit emergency drug supply inspections, stipulates these be done “**no less frequently than every 30 days**” (also by a **pharmacist**). So, along with your flex request to have a pharmacy technician package and seal emergency supplies and/or inspect drug storage areas, include a separate program flex request to permit inspection of emergency supplies “**monthly.**” This section is GACH specific.

Intern Pharmacist: B&PC Section 4119.6 requires no program flex. This bill does **not** change the scope of practice for an intern pharmacist (IP); i.e., IPs may continue to practice as they always have, under proper pharmacist supervision, in accordance with state law and regulation and facility policies and procedures. Policies and procedures are to address all intern pharmacist activities. This section is GACH specific.

Dangerous drugs, etc.: B&PC Section 4119.7(a) requires no program flex. This section does **not** change any regulatory expectation with regards to "standing orders," "order sets," and "protocols" established under the policies and procedures of the health care facility, etc. This section is GACH specific.

Drug storage: B&PC Section 4119.7(b) requires no program flex. The health care facility's policy and procedure **are** to specify medication storage parameters. While this section is GACH specific, all licensed health care facilities are otherwise expected to address medication storage requirements by regulation as reflected in their policy and procedure.

Intern Pharmacist: B&PC Section 4119.7(c) requires no program flex. This section is GACH specific.

Bulk cleaning agents, etc.: H&SC Section 1250.06 impacts CCR, Title 22, Section 70263(s) in a GACH and requires a program flex. Similarly, Section 71233(s) is so impacted in an acute psychiatric hospital (APH). Modify your policies and procedures and submit them with your program flex.

Write or issue a prescription: H&SC Section 11150 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Prescribing, furnishing or administering controlled substances: H&SC Section 11210 requires no program flex. Scope of practice modification – facility policy and procedure, etc., is to address any such activity as they would for any mid-level practitioner.

Guidance for Submitting a "Program Flexibility" Request

Use of form *CDPH 5000 Program Flexibility* is not required, but recommended. Use of facility letterhead is acceptable, as long as the same information as requested on form *CDPH 5000* is provided.

The following assumes use of form *CDPH 5000.*

Under "Subject" simply enter "see below" as space is otherwise limited.

In the box, under "proposed alternate method(s) for meeting the intent of the regulations is," enter the following:

1. The regulation and subparagraph you desire to flex; e.g., "Section 70263(f)(2)." Do not simply enter "Section 70263" as this implies **all** of 70263 *Pharmaceutical Services and General Requirements;* i.e., subparagraphs (a) through (t).
2. Straight forward language for **each** flex request is suggested. For example:

> B&PC Section 4115(i)(1) and (2) conflicts with CCR, Title 22 Section 70263(f)(2). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to restock and seal emergency medication supplies used throughout the facility.
>
> B&PC Section 4115(i)(3) conflicts with CCR, Title 22 Sections 70263(f)(3) and 70263(q)(10). ***Name of your hospital*** requests program flexibility to allow a pharmacy technician to: (1) Perform monthly inspections of emergency medication supplies instead of no less frequently than 30 days; and, (2) Perform monthly inspections of the drug supplies in nursing units and areas. Any identified irregularities are to be reported within 24-

hours to the pharmacist in charge and the director or chief executive officer of the health care facility in accordance with facility policy and procedure.

H&SC Section 1250.06 conflicts with CCR, Title 22, Section 70263(s). ***Name of your hospital*** requests program flexibility to adopt policies and procedures whereby a pharmacist is not required to consult on the proper methods of repackaging and labeling of bulk cleaning agents, solvents, chemicals, and nondrug hazardous substances used throughout the hospital, except for areas where sterile compounding is performed.

Note: For an acute psychiatric hospital, reference CCR, Title 22, 71233(s) to request a program flex at H&SC Section 1250.06.

3. Repeat the process as outlined in 1 and 2 for **each** regulatory section a program flex is desired.
4. Be sure to include the policy and procedure for **each** program flex request as it serves as your supporting documentation.

Please include a contact person's name and their contact information (email and phone number) should questions arise.

Submit the request form(s) and all pertinent policies and procedures to your assigned CDPH L&C District Office. You can expect a response within 60 days.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee

Anticoagulants Guidelines

1215 K Street, Suite 800, Sacramento, CA 95814 · *Telephone:* 916.443.7401 · *Facsimile:* 916.552.7596 · www.calhospital.org
Corporate Members: Hospital Council of Northern and Central California, Hospital Association of Southern California, and Hospital Association of San Diego and Imperial Counties

TABLE OF CONTENTS

REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0	2/12	Final draft approved by committee
3.0	8/13	Revised to CHA Med Safety guideline specifications
4.0		
5.0		
6.0		

INTRODUCTION

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

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

COMMITTEE REPRESENTATION

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

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

Anticoagulation is a high risk therapy involving complex dosing, monitoring, and ensuring patient adherence with outpatient therapy. Reports of adverse events related to the improper use of anticoagulant drugs have received significant attention[1-9]. The following guidelines focus on safety strategies for **unfractionated heparin, warfarin and enoxaparin**. A number of tools are listed in the 'Resource Tools' section to assist with an organizational self-assessment of practices relating to anticoagulant use[RJ1].

The following tool is intended to guide acute care facilities in the safe use of anticoagulation agents. Medication safety includes all aspects of medication use from the acquisition stage to ongoing monitoring.

Step	Actions to Consider ~~to Increase Medication Safety~~		
	Heparin	**Warfarin**	**Low Molecular Weight Heparin**
Pharmacy Purchasing, Storage and Product Labeling	• Purchase commercially available, standard concentrations of IV heparin infusions for use throughout the facility. • Restrict purchases and storage of premixed IV solutions to the pharmacy if feasible • Limit the variety of concentrations and sizes purchased both for large volume parenterals and vials of heparin. Consider eliminating 10,000 units/ml vials • Store away from other drugs in the pharmacy with look alike names or packaging. Use TALLman lettering on labels and bins to differentiate between HeSpan and hEParin • Clearly differentiate heparin products used for treatment from low concentration products such as flushes. • Purchase patient population specific strengths of prefilled heparin flush syringes (e.g. Peds) • Use Tallman lettering on labels, order screens, MARs and other documents when feasible	• Purchase from a single manufacturer to promote consistent bioavailability for this narrow therapeutic index drug	• Purchase commercially available doses in prefilled syringes
Patient Care	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**

Common considerations:

- If providing unit stock, do so in automated dispensing cabinets (ADCs)
- stock in automated dispensing cabinets that are interfaced with the pharmacy system to enable pharmacy review prior to removal (not available via override feature).
- Employ additional verification measures in procedure areas if ADCs are not interfaced with the pharmacy system
- Segregate vials of different concentrations in single access pockets ('cubies') in automated dispensing cabinets

Prescribing

Heparin	Warfarin	Low Molecular Weight Heparin
• Ensure patients are screened for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the perpetual medical record • Approved order sets are readily available and used for prescribing • Baseline labs are ordered for monitoring therapy - aPTT or factor Xa if available. • Institute a protocol for rounding of doses (e.g. to closest 500 units) for weight based dosing. Consider maximum dosing for obese patients • Use standard concentrations of heparin in a standardized base solution.	• Require a baseline INR result be available prior to initiation of warfarin therapy and that baseline liver function tests and albumin are ordered • Consider adoption of protocols to allow pharmacists to monitor and order labs and adjust therapy • Intiate therapy at doses of 2.5 to 5 mg for patients 65 years and older, or younger patients with co morbid conditions that may affect their response to warfarin (e.g. thyroid disease)	• Screen patients for known history of HIT and/or allergy to heparin prior to initiation of therapy. Positive responses are entered in the record • Institute a protocol for rounding of doses for weight based dosing

Common considerations for heparin, warfarin, LMWH.

- Obtain a baseline serum creatinine and a complete blood count that includes hemoglobin, hematocrit and platelet count, prior to initiating therapy.
- Include ongoing lab monitoring in preformatted orders and policies/protocols
- Usemetric units for weight-based dosing and specify use of ideal or actual body weight in orders and guidelines.
- Consider approved protocols to treat patients with known or suspected HIT with direct thrombin inhibitors if antithrombotic therapy is required
- Include reminders on protocols, order forms and CPOE system to avoid concomitant use of heparin products or to discontinue other anticoagulants as appropriate
- Maintain a list of error-prone abbreviations that are not permitted.. Commas should be used when expressing large doses (e.g. 10,000 units)
- Establish a procedure for 'hold' orders
- Reconcile anticoagulants upon admission, transfer and discharge
- Update guidelines/order sets to reflect current evidence based practice e.g. CHEST, ACC, AHA, etc.

Pharmacist Order Entry

Heparin	Warfarin	Low Molecular Weight Heparin
	• Implement a process to screen for drug/food/nutritional product interactions	• Implement a process to screen for the presence of an epidural catheter

		• Consider standard administration time such as 17:00 or 18:00	
	Common considerations: • Use height and weight in metric units in pharmacy computer systems • Create pharmacy system alerts for duplicate orders from the same drug class. Provide dose range alerts for over/under dosing as applicable • One time doses administered in the ED or procedure settings should be entered in the pharmacy system to prevent dose duplication • Pharmacist should validate baseline labs		
Pharmacy Dispensing	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Heparin orders are verified by pharmacy prior to dispensing	• Doses are provided in unit dose packaging. • Consider elimination of pill splitting on nursing units	
	Common considerations • If available, use machine readable bar coding for verification prior to dispensing from the pharmacy for refill of automated dispensing cabinets or for single patient use		
Administration	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Conduct an independent verification of 5 "rights", drug concentration, rate of infusion, pump channel selection, IV line labeling and attachment is conducted prior to administration and at change in therapy • Use infusion pumps, preferably smart pumps with error reduction software, for IV infusions • Use smart pumps to deliver bolus and continuous doses from the same container only when a bolus dose can be safely programmed (with hard limits on total dose and minimum infusion time), and the pump automatically converts to continuous infusion after bolus is delivered. Be mindful of the volume required for bolus doses delivered through the pump versus IV push dosing. • Use initial weight for weight based dosing. Do not adjust weight each day unless there is a significant weight change as determined by organizational policy	• Consider MAR documentation of pertinent lab values used to monitor therapy (e.g. INR) • Schedule warfarin administration for the same time each day after INR results are available (afternoon or early evening)	• Conduct an independent verification of 5 "Rights" and correct indication prior to administration • Rotate and document injection sites • Monitor injection sites for hematomas • Use initial weight for weight based dosing. Do not adjust weight each day • To avoid the loss of drug when using the 30 and 40 mg prefilled syringes, do not expel the air bubble from the syringe before the injection.

	• Label lines of IV heparin infusions to help prevent line mix ups • Routinely ensure IV heparin infusions are connected to the right lines. This includes at initiation, change-in-rate, new bag being hung and at shift handoff. ~~Trace back~~ and reconcile IV lines upon initiation, change in orders and at shift handoff[RJ2] • Do not administer IM		
	Common considerations • Make clearly labeled and approved protocols, pathways, nomograms, flow sheets and/or checklists readily accessible in print or electronic form • Consider requiring MAR documentation of pertinent lab values used to monitor therapy (e.g. aPTT,factor Xa levels, INR) when doses are administered • Incorporate screening questions in automated dispensing cabinets to identify adverse drug reactions when reversal agents (e.g. protamine, Vitamin K) are dispensed List specific interventions or treatments that are to be avoided (e.g. IM injections) on pharmacy and medication administration records		
Education	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Instruct patients diagnosed with HIT to communicate this to all healthcare providers	• Give patients and caregivers verbal and written information at 8th grade reading level or below, preferably in their language: o on proper dietary methods and their effect on therapy goals o how their therapy is monitored with changes in dose based on lab results and adherence to prescribed treatment o instructions on how to manage dose changes safely at home when existing tablet strength differs from a new dose o signs and symptoms of bleeding (e.g. bleeding gums) or thromboembolic complications o drug and herbal interactions. Ensure patients/caregivers understand that warfarin and Coumadin are the same drug o Ensure the patient	• Have patients/caregivers demonstrate proficiency if they are to self administer at home • Use videos, pamphlets, and other facility approved tools to complement one on one education • Instruct patients diagnosed with HIT to communicate this to all healthcare providers

		understands importance of adherence with anticoagulation dosing • Prior to discharge, stress the importance of follow up appointments. Facilitate a confirmed appointment with the lab, physician or anticoagulation clinic	
	Common considerations • Consider initial training and baseline competency evaluation for all practitioners who prescribe, dispense and/or monitor therapy (including physicians, nursing, pharmacy and dieticians) • Include anticoagulants on list of High Alert meds and educate staff on risk reduction strategies that are employed to improve safety • Share information about error-prone situations and errors within and outside the facility with practitioners on an ongoing basis • For inpatients, provide education about antithrombotics at initiation of therapy; aim to provide most of the information about after discharge therapy well before discharge		
Monitoring	**Heparin**	**Warfarin**	**Low Molecular Weight Heparin**
	• Monitor complete blood counts at routine intervals • Obtain an aPTT or factor Xa level between 6-8 hrs after initiation of heparin therapy (unless bleeding) • Modify dosing protocols and nomograms if lab changes are made that impact test values (e.g. reagents, testing methods). • Check and recalibrate point of care and monitoring devices when new lots of reagent are received	• Draw blood specimens at the same time each morning so results are available before warfarin doses are prescribed • If the patient is placed on NPO status, contact the prescriber for new anticoagulation orders as appropriate • Use a protocol to guide the reversal of supra therapeutic INR when indicated. **Oral** phytonadione preferred unless rapid reduction is required. • Ensure a process is in place to notify the food and nutrition department when patients are on warfarin therapy • If IV Vitamin K is required, dilute in at least 50 ml of solution, and administer over 30-60 min. Avoid IM administration of Vitamin K	• Obtain baseline serum creatinine, hemoglobin, hematocrit and platelet count are available prior to initiating therapy • Monitor platelet counts at routine intervals (e.g. every 3 days) for the first 2 weeks of therapy • Adjust dose for renal impairment and extremes of body weight as specified by approved protocols
	Common Considerations • Implement a protocol or guideline for monitoring and/or discontinuing therapy prior to invasive procedures • Include alerts on pharmacy order entry screens, automated dispensing cabinets, protocols/pathways to review medications the patient has received in the last 24hrs (including in ED) to ensure that an adequate time has lapsed between doses • Ensure that practitioners have easy access to inpatient (and preferably applicable outpatient) lab results to guide therapy		

	• Report critical values to the responsible caregiver within the facility identified time frame • If platelet counts decline to less than 100,000/mm3 or less than 50% of baseline, ensure there is a mechanism in place for heparin-induced thrombocytopenia (HIT) evaluation, and discontinue of all sources of heparin including flushes and heparin coated instruments • Enhance detection of potential adverse events by interfacing pharmacy and lab systems and incorporating alerts to the pharmacy system for selected values of lab tests (e.g. aPTT greater than 100 sec, platelet count less than 100,000/mm^3, facility defined value of elevated INR) • Monitor patients for fall risk and notify physician immediately post fall

Other	Heparin	Warfarin	Low Molecular Weight Heparin
	• Consider inpatient pharmacy managed anticoagulation services • Use saline flushes (not heparin flushes) for peripheral venous access catheters • When appropriate, discontinue heparin 4 hours before surgery	• Consider inpatient and outpatient pharmacy managed anticoagulation services • When appropriate 5 days prior to surgery or procedures. For patients at high risk for VTE, consider bridge therapy with low molecular weight ~~LMWH [RJ3] or~~ heparin (LMWH).	• Consider inpatient pharmacy managed anticoagulation services • Implement a protocol or guideline for safely managing the care and removal of epidural catheters placed during regional anesthesia when LMW heparin has been administered for surgical prophylaxis • When appropriate, administer last dose 24 hours prior to surgery and give ½ total daily dose for last pre-operative dose.

Transitional Care: Discharge Planning	Heparin	Warfarin	Low Molecular Weight Heparin
	Common Considerations 1. Provide education on the importance of vigilant adherence with anticoagulation therapy 2. Educate patients to be mindful of brand to brand variation resulting in differences in bioavailability when refilling prescriptions for warfarin 3. Facilitate a confirmed appointment with the lab, physician and/or anticoagulation clinic prior to discharge from the hospital. Stress the importance of making and keeping follow up appointments. 4. Prior to discharge, collaborate with case managers and social workers to identify and address barriers for adherence to medication therapy e.g. insurance coverage, prescription affordability, access and transportation for physician appointments, support in post discharge setting 5. Collaborate with long term care providers and community based organizations who can provide follow up visits or phone calls to encourage medication adherence 6. See Resource Tools section for **WARFARIN DOSE REMINDER CHART**		

References	1. The Joint Commission Accreditation Program: Hospital National Patient Safety Goals. http://www.jointcommission.org/PatientSafety/NationalPatientSafetyGoals 2. Fanikos J, et. al. Medication errors associated with anticoagulant therapy in the hospital. *Am J Cardiol* Aug 15 2004;94(4):532-5. 3. Winterstein AG, et. al. Identifying clinically significant preventable adverse drug events through a hospital's database of adverse drug reaction reports. *Am J Health Syst Pharm* Sep 15 2002;59(18):1742-9. 4. Errors Involving Drug Products Used to Treat Cardiovascular Diseases: Part III. USP *CAPSLink Newsletter*. May 2005. http://www.usp.org/pdf/EN/patientSafety/capsLink2005-05-01.pdf. 5. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report. A report on the relationship of drug names and medication errors in response to the Institute of Medicine's call for action. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia;2008. 6. Hicks RW, Becker SC, Cousins DD. MEDMARXR data report: A Chartbook of Medication Error Findings from the Perioperative Settings from 1998-2005. Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2006. 7. Santell JP, Hicks RW, Cousins DD. MEDMARXR data report: A Chartbook of 2000-2004 Findings from Intensive Care Units and Radiological Services.Rockville, MD: Center for the Advancement of Patient Safety, US Pharmacopeia; 2005. 8. Adverse events in Hospitals OIG report http://oig.hhs.gov/oei/reports/oei-06-09-00090.pdf
Resource tools	1. **ISMP Medication Safety Self Assessment for Antithrombotic Therapy in** Hospitals http://www.ismp.org/selfassessments/asa2006/Intro.asp 2. **ISMP - Failure Mode and Effects Analysis for Anticoagulants** http://www.ismp.org/Tools/FMEAofAnticoagulants.pdf 3. **The Joint Commission Sentinel Event Alert**, **Issue 41: Preventing errors relating to commonly used anticoagulants** http://www.jointcommission.org/ 4. **ASHP Anticoagulation Resource Center http://www.ashp.org/anticoagulation** 5. **Anticoagulant Toolkit Developed by Purdue University PharmaTAP in collaboration with the Indiana Patient Safety Center (IPSC), Indiana Hospital Association (IHA) and VHA Central, this toolkit aims to reduce adverse drug events associated with high-alert medications.** 6**. LA County - Best Practice Recommendations Guidelines for the Use of Concentrated Heparin** 7. **Warfarin Dose Reminder Chart** http://www.aafp.org/fpm/2005/0500/p77.html 8. **AHRQ Guide to Using Warfarin Safely**: http://www.ahrq.gov/consumer/btpills.htm#booklet

Reducing Controlled Substances Diversion in Hospitals

California Hospital Association Medication Safety Collaborative Committee
www.calhospital.org/medication-safety-committee

Introduction
The attached road map is intended for acute care settings as a plan to help navigate controlled substance diversion prevention goals. The document provides a recommended framework to coordinate the needed resources and technology for an optimal diversion prevention program. Actions taken pursuant to this framework should be reflected in a standardized set of processes within the organization to ensure that they are maintained.

Some actions are required by law or regulation (and marked with ►) while some may be good recommendations to have in place. Ultimately, each organization is responsible for developing a diversion prevention plan that protects patients from impaired care providers (i.e., to the extent it affects a provider's ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of controlled substances within the organization).

Credits
The committee thanks the Minnesota Department of Health and Minnesota Hospital Association and the Minnesota Drug Diversion Coalition[1] for developing the original document. With their permission, this document builds upon their work and includes California-specific guidance.

Committee Representation
The committee includes representatives from:

- Association of California Nurse Leaders
- California Association of Health Facilities
- California Board of Pharmacy
- California Department of Public Health
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization
- California Medical Association
- California Society of Health System Pharmacists

[1] Minnesota Coalition members are listed at www.health.state.mn.us/patientsafety/drugdiversion/.

CALIFORNIA HOSPITAL ASSOCIATION
Leadership in Health Policy and Advocacy

Road Map to Controlled Substance Diversion Prevention

Applies to health care professionals, patients, families, visitors, and others.

Component	Specific Action(s)	Self-Assessment Checklist
Safety Teams / Organizational Structure	1. Organization defines Controlled Substance (CS) Diversion Prevention Program.	1a. The organization has an interdisciplinary team involved in developing and overseeing the CS Diversion Prevention Program. 1b. The CS Diversion Prevention Program includes prevention, detection and investigation. 1c. The CS Diversion Prevention Program is reviewed by the team and updated at least annually. 1d. CS Diversion Prevention Program champions have been identified and have designated clear roles with expectations from the following areas: • Medical Staff • Pharmacy • Nursing • Security • Human Resources • Patient Safety/Risk Management/Compliance • Administration • Legal (as necessary) • Communications (as necessary)
	2. An organizational structure is in place that supports an effective CS Diversion Prevention Program.	2a. The organization has a designated coordinator(s) for the CS Diversion Prevention Program. 2b. The coordinator(s) has dedicated time to serve in this coordination function. 2c. The organization has a team prepared to respond to suspected CS diversion situations. 2d. The organization has and regularly reviews policies and procedures addressing all aspects of the CS use processes. 2e. The organization regularly reviews policies and procedures to assure compliance with state and federal laws.

	3. Organization proactively collaborates with local law enforcement.	3a. The organization (e.g. security) has engaged local law enforcement (e.g. county sheriff, chief of police) to discuss the CS Diversion Prevention Program and establish a communication strategy (including public) prior to CS diversion situations.
	4. Organization fulfills all reporting requirements for diversion or loss of CS.	4a. ►The owner reports to the California Board of Pharmacy within thirty days of discovery of any CS losses, including their amounts and strengths. 4b. ►The DEA registrant or their designee reports any CS theft or significant loss to the DEA within one business day of discovery. 4c. ►The organization follows other applicable requirements. For example, Medicare Conditions of Participation states: "Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate."
Access to Information / Accurate Reporting / Monitoring / Surveillance / Detection System	1. Organization reviews and audits relevant data that could indicate potential CS diversion.	1a. ►The organization has a process to generate controlled substance data on a minimum monthly basis such as controlled substance surveillance reports, high user report, CS use through reports/log-sheets and CS "Disposition and Inventory" sheets.
	2. Organization tracks and reviews measures recommended by Medication Safety Committee or other designated groups reporting directly to a Medical Staff Committee.	2a. ►The organization has a process in place to review and analyze CS data on a regular basis. 2b. ►The organization shares findings from the data analysis on a regular basis. 2c. ►There is a process in place to activate a response team that includes a patient care manager, pharmacy, Human Resources (HR) and security when diversion is suspected. 2d. ►The organization has a process in place to contact law enforcement when diversion or theft is suspected.
Facility Expectations	1. Organization communicates the expectation that staff "speak up" when they become aware of an issue related to CS diversion.	1a. ►Senior leadership has clearly communicated that all staff are to speak up and will be supported in speaking up when they become aware of possible diversion. 1b. ►The hospital treats such information as confidential and takes all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information.
	2. Organization establishes full disclosure policy.	2a. ►The organization has a clearly defined full disclosure policy and process to communicate to patients/families who are

		affected by CS prevention diversion.
	3. The organization's HR practices support an effective organization-wide CS Diversion Prevention Program.	3a. The organization has established and communicated ways for staff to speak up anonymously (e.g. hot line, paper or electronic submission). 3b. The organization has a process in place to remove an impaired caregiver from patient care. 3c. ►The organization conducts pre-employment background checks for Licensed Independent Practitioners (LIPs) and employees. 3d. A log of staff photographs and signatures are maintained as appropriate. 3e. The organization has a process to manage employee access to CS in a timely fashion when terminated or transferred. 3f. The organization has developed a "for cause" policy for drug testing.
	4. Organization does not allow sharing of pass codes.	4a. ►The organization establishes and enforces a policy of not sharing pass codes such as electronic medical record (EMR), Automated Distribution Machine[2] (ADM) and pharmacy door codes.
Education Staff (and Patients)	1. Organization has in place an effective and comprehensive training and education program for all staff on CS diversion prevention.	1a. The CS Diversion Prevention Program team has attended CS diversion prevention and statutory requirements training (e.g. National Association of Drug Diversion Investigators [NADDI], professional associations, licensing boards, state, local and federal law enforcement). 1b. Expectations and supporting education have been incorporated into training for all new staff and LIPs. 1c. Expectations and training include, at a minimum, providing awareness training to know the signs of diversion. 1d. Resources are available to support employees and LIPs, e.g. Employee Assistance Program (EAP) and Health Professional Services Program (HPSP). 1e. The facility requires training on CS policies and

[2] ADM is a robotic or computerized device in which the device components are designed to distribute drugs in a licensed health care facility. A pharmacist is responsible for the drug entry into the patient's profile, final review and distribution of the patient medications.

		procedures prior to authorizing staff to have CS access. 1f. The facility provides ongoing staff education at least annually to promote safe handling of CS and CS diversion awareness. 1g. The organization provides patient education on safe medication handling, including potential for diversion.
Storage and Security	1. Organization stores CS and other high-risk items securely, in all settings and circumstances.	1a. ►The organization has a process in place for securing CS (as described in section 2 below) for every setting and circumstance.
	2. Organization has a process in place for securing CS.	2a. Never leave CS unattended. 2b. CS are stored in a locked location (e.g., ADM, ℂ[3] vault or locked cabinet/drawer/box) at all times. 2c. ADM-managed CS are stored in a location with one CS-type access. For example, users cannot have access to a second type of CS when accessing the intended CS. 2d. Access to CS storage areas is limited to authorized staff. 2e. Non-ADM CS cabinets are secured with a locking device. 2f. ADM and non-ADM access is removed promptly for terminated employees. 2g. Patient-specific CS infusions (e.g., PCA[4], epidural, and continuous infusions) are enclosed in a locked box. 2h. Keys are controlled and accounted for. 2i. Prescription pads and paper are stored in ADM, locked location or under control of an LIP. 2j. Facility designates authorized individuals to order prescription pads/paper direct from the vendor for the operating unit or patient care area. 2k. Electronic and non-electronic prescriptions comply with state and federal requirements. 2l. CS brought in by a patient that cannot be returned home are inventoried by two authorized health care staff and stored in

[3] Schedule II controlled substance.
[4] Patient-controlled analgesia.

		a locked, limited access area. 2m. CS brought to the hospital for use by the patient (i.e., Patient's Own Medication) is securely stored and accounted for during the hospitalization as well as upon the patient's discharge. It is recommended to have a process in place where patients are contacted after discharge to pick up their CS in storage. CS remaining in the pharmacy and not picked up by the patient after discharge is to be destroyed per the hospital's policies. Preferably, the patient is contacted and asked to pick up their CS.
	3. Organization uses camera surveillance in high-risk areas as appropriate.	3a. Camera surveillance is used in primary CS pharmacy storage area (e.g. narcotics vault).
Procurement	1. Organization effectively and safely handles procurement in the hospital pharmacy.	The organization has a process in place for procuring CS that includes: 1a. ►If the hospital utilizes the controlled substance ordering system (CSOS)[5], then each user must have their own password. Passwords cannot be shared. 1b. ►Excluding radiopharmaceuticals[6], the hospital pharmacy procures all CS. 1c. ►Individuals authorized to order ©-© are limited to the DEA registrant and authorized individuals. DEA 222 forms are secured and accessible only to these individuals. 1d. ►Individuals other than the DEA registrant authorized to order CS must have a power of attorney on file to execute the DEA 222 forms as per 21CFR1305.05. 1e. The persons authorized to order CS are not the same persons who receive the CS. 1f. ►All invoices received are signed and have the date when the medications were received. 1g. ►Only a licensed pharmacist or authorized receiving person signs for the controlled substance delivery. 1h. ►If CS are delivered to hospital central receiving, an

[5] An electronic DEA 222 program. DEA's CSOS is an encrypted electronic controlled substance ordering system between a wholesaler and the DEA licensee's authorized user. The DEA's CSOS is the preferred method for © CS procurement.

[6] Currently, there is one © radiopharmaceutical: DaTscan™ (Iodine I-123 ioflupane), a cocaine analog indicated for striatal dopamine transporter visualization using SPECT brain imaging to assist in the evaluation of adult patients with suspected Parkinsonian syndromes.

		authorized receiving person signs for the delivery, central receiving transfers CS to the pharmacy within one working day following receipt by the hospital, and then the pharmacist immediately inventories the CS. 1i. ►If CS are delivered to the pharmacy when the pharmacy is closed and pharmacist unavailable, then storage of this delivery must comply with the requirements of California Business and Professions Code 4059.5(f).[7] 1j. ►Any discrepancy between the receipt and the type or quantity of CS actually received is reported to the delivering wholesaler or manufacturer by the next business day after delivery.
Prescribing	1. The organization's ordering/ prescribing practices minimize the risk of CS diversion.	1a. ►CS are prescribed only by licensed authorized prescribers with a DEA registration or institutionally assigned DEA suffix. 1b. ►A valid order from an authorized prescriber exists for all CS administered. 1c. ►CS are not prescribed by an authorized prescriber for him/herself or immediate family members. 1d. Patient-specific CS orders are generated by electronic systems with controlled access except in emergencies in accordance with applicable federal and state laws and rules. 1e. Range orders for CS are minimized.
Preparation & Dispensing	1. The organization's preparation and dispensing practices minimize the risk of CS diversion.	1a. ►Tamper-evident packaging is utilized for CS prepared by pharmacy.[8] 1b. ►CS transported via pneumatic tube are sent via secured transaction. 1c. ►There must be a co-signature for delivery of CS to non-ADM areas. Document chain of custody. 1d. CS are dispensed in single-unit-dose packaging.[9] 1e. Secure, locked, non-transparent medication delivery

[7] See appendix for B&P 4059.5(f) text.
[8] Tamper-evident packaging means a container within which a drug is sealed so that the contents cannot be opened without obvious destruction of the seal.
[9] Single-unit-dose packaging means a single-unit container for articles intended for administration as a single dose, direct from the container.

		carts/containers are used to deliver CS and accessible only by authorized individuals. 1f. ADMs are utilized in patient care areas for the distribution of CS and are interfaced with the electronic patient profile to limit access only to medications ordered for a specific patient. 1g. Reconciliation is performed on ADM CS dispense transactions for temporary patients to ensure that the CS went to an actual patient.[10] 1h. Bar code scanning is utilized when replenishing ADMs. 1i. A blind count process is used for narcotic vault and ADM distributed CS.[11] 1j. The number of CS on override status in profile ADMs is minimized (e.g. one-time injectables for emergencies only). 1k. Biometric-ID technology is used instead of passwords. If passwords are used, passwords expire on a regular interval.[12] 1l. ADM downtime procedures must be defined to maintain the control, documentation and accountability of CS.
Administration	1. The organization's CS administration practices minimize the risk of CS diversion.	1a. There is a defined time between CS retrieval from storage areas and time of administration and documentation (e.g. within 30 minutes of ADM removal or within 30 minutes of the end of the procedure). 1b. The CS retrieved for a patient is the package size equivalent to, or the closest available to, the dose to be administered. 1c. ►Only health care providers operating within the scope of their practice may administer CS. 1d. ►CS are removed for one patient at a time from ADMs and/or locked storage areas.

[10] For example, a temporary patient ID may have been used when CS are needed in an emergency and the admission information is not yet transferred to the ADM.

[11] Blind count is a process utilized with ADM when refilling a controlled substance into the drug's individual pocket. The ADM requests the person replenishing the controlled substance to the ADM to count the quantity in the machine before adding the refill. The count in the pocket is not presented to the person replenishing the CS. If the count entered by the person replenishing the ADM is correct, the ADM will allow the refill of the controlled substance.

[12] For example, the ISMP recommends changing passwords every 90 days or less if biometric authentication is not also in use (http://www.ismp.org/selfassessments/ADC/Survey.pdf).

		1e. ►The individual retrieving CS from ADM/locked storage area/box is also the person that administers the medication. The organization defines exceptions (e.g. emergencies) and has a policy/process in place to assure chain of custody. 1f. ►All CS are drawn up into syringes that, if not immediately administered, are labeled per institutional policy.
Handling Waste	1. The organization's "waste" handling practices maintain chain of custody to minimize the risk for CS diversion.	Pharmacy: 1a. CS waste from Compounded sterile Product (CSP) preparation in the Pharmacy is collected and randomly assayed. Areas outside Pharmacy: 1b. ►Unusable product[13] (UP) CS are to be immediately wasted and witnessed by health care professionals per specific hospital procedures. 1c. All Potentially Reusable Product[14] (PRP) drugs are returned to the pharmacy for evaluation of re-use/re-issue. 1d. The organization has identified the high-risk areas (e.g. surgical, anesthesia, procedural) where CS diversion occurs. 1e. The organization has identified specific high-risk CS medications (e.g., fentanyl) that are randomly assayed. 1f. The organization has a process to randomly obtain and assay UP CS. For random assays, the UP CS would not be subject to immediate witnessed waste.
	2. The organization's practices for handling unused CS, empty CS containers or CS returned to pharmacy minimize the risk of diversion.	**Wasting of UP CS:** 2a. ►Approved methods for wasting a CS are defined per federal, state and county laws and regulations. 2b. ►The wasting of all CS requires an independent licensed witness and must be documented in the ADM or via proof of use form, except when UP CS are returned to pharmacy for assay. 2c. ►An individual witnessing CS wasting verifies the volume/amount being wasted matches the documentation and physically watches the medication being wasted per policy.

[13] UP: Any medication that may not be used for a patient due to either the integrity no longer being intact or the medication has exceed its expiration/ beyond use date.

[14] PRP: Medications that have been issued to a patient, which have not been used, the integrity of such packaging remains intact and expiration/beyond use date allow the medication to be re-issued to another patient.

		2d. ►Empty containers of CS (e.g., vials) are discarded in limited access waste containers. 2e. ►Waste containers with trace UP CS are secured to prevent tampering. 2f. ►The pharmacy accounts for manufacturer overfill in injectable containers. All overfill amounts are captured, verified, documented, and wasted accordingly. Controlled substance overfill should be considered unusable product (UP). **PRP Returns:** 2g. PRP ADM managed CS are returned to a secure return bin/pocket and not to the original ADM pocket. 2h. ►All PRP CS returns to pharmacy require chain of custody documentation in the patient care area and in pharmacy **Waste or Reverse Distribution:** 2i. ►DEA registrant or their designee assists with all phases of transfer of CS to a reverse distributor and/or hazardous waste disposal company. 2j. Expired CS that are quarantined for reverse distribution are properly accounted by way of a log or inventory list. The items sent back via reverse distribution could be reconciled with the reverse distribution log of CS.
Monitoring of CS and Process if Diversion is Suspected	1. Organization removes access to CS if diversion is suspected.	1a. ►All personnel actions (e.g. suspension, terminations and resignations) are promptly communicated to pharmacy so access to CS can be removed. 1b. ►If the hospital becomes aware of an arrest of an employee for illicit use of CS, the hospital immediately conducts its own investigation. The organization assesses whether to suspend, transfer, terminate or take other action (e.g., remove access to CS) against the employee.
	2. Organization regularly monitors CS through inventory, reports and audits.	2a. CS purchase invoices are compared to CS orders and receipt into the pharmacy's perpetual inventory. Any CS purchases outside of the pharmacy department are tracked. Since the invoice-receipt pair may both be removed with CS diversion, invoices also are reconciled to statements or wholesale purchase history reports to detect missing invoices. 2b. Movement of CS throughout the hospital is tracked. For example, reports match narcotic vault transactions with receipt into ADM and/or paper inventory record with RN signature of

		receipt. 2c. ►CS within an ADM or narcotic vault are inventoried at least monthly. 2d. Non-automated CS storage areas are inventoried at each shift change. 2e. ADM reports are reviewed at least monthly by pharmacy or patient care managers as defined by the organization. Reports compare ADM activity with medication administration record. 2f. ADM CS activity is compared to peers with similar staffing responsibilities and FTE appointments. 2g. Transaction activity (e.g. inventory abnormalities, removal of quantities greater than prescribed dose, cancellations, returns and waste) is compared to peers. 2h. Patient MAR: amount and quantity administered, is compared to what other caregivers administer on subsequent shifts (without patient change in condition). 2i. Non-ADM CS storage area record of use is compared with MAR (e.g. anesthesia record, sedation record, eMAR) to assure appropriate documentation of waste.
	3. A process is in place to resolve CS discrepancies.	3a. ►CS discrepancies are resolved upon discovery, no later than end of shift. Discrepancies that cannot be resolved are jointly reviewed by pharmacy and patient care leadership with resolution within 24 hours (e.g. metric: unresolved nursing unit CS discrepancies > 24 hours/total nursing unit CS discrepancies should be ≤8 percent). 3b. It is recommended that a pharmacist reconcile CS discrepancies in the ADMs. ►A pharmacist has responsibility for the discrepancy even when a technician performs these duties.
	4. Organization creates standard process to investigate potential diversion cases.	4a. ►There is a standard process in place to investigate potential diversion cases.

Selected Legal References[15]

Federal

21 Code of Federal Regulations Chapter II: Drug Enforcement Administration

Sec. 1301.76 Other security controls for practitioners.

(a) The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause. For purposes of this subsection, the term "for cause" means a surrender in lieu of, or as a consequence of, any federal or state administrative, civil or criminal action resulting from an investigation of the individual's handling of controlled substances.

(b) The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant shall also complete, and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft. When determining whether a loss is significant, a registrant should consider, among others, the following factors:

(1) The actual quantity of controlled substances lost in relation to the type of business;
(2) The specific controlled substances lost;
(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
(4) A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,
(5) Whether the specific controlled substances are likely candidates for diversion;
(6) Local trends and other indicators of the diversion potential of the missing controlled substance.

Sec. 1301.90 Employee screening procedures.

It is the position of DEA that the obtaining of certain information by non-practitioners is vital to fairly assess the likelihood of an employee committing a drug security breach. The need to know this information is a matter of business necessity, essential to overall controlled substances security. In this regard, it is believed that conviction of crimes and unauthorized use of controlled substances are activities that are proper subjects for inquiry. It is, therefore, assumed that the following questions will become a part of an employer's comprehensive employee screening program:

Question. Within the past five years, have you been convicted of a felony, or within the past two years, of any misdemeanor or are you presently formally charged with committing a criminal offense? (Do not include any traffic violations, juvenile offenses or military convictions, except by general court-martial.) If the answer is yes, furnish details of conviction, offense, location, date and sentence.

Question. In the past three years, have you ever knowingly used any narcotics, amphetamines or barbiturates, other than those prescribed to you by a physician? If the answer is yes, furnish details.

Advice. An authorization, in writing, that allows inquiries to be made of courts and law enforcement agencies for possible pending charges or convictions must be executed by a person who is allowed to work in an area where access to controlled substances clearly exists. A person must be advised that any false information or omission

[15] This is not a comprehensive listing of applicable laws and regulations.

of information will jeopardize his or her position with respect to employment. The application for employment should inform a person that information furnished or recovered as a result of any inquiry will not necessarily preclude employment, but will be considered as part of an overall evaluation of the person's qualifications. The maintaining of fair employment practices, the protection of the person's right of privacy, and the assurance that the results of such inquiries will be treated by the employer in confidence will be explained to the employee.

Sec. 1301.91 Employee responsibility to report drug diversion.

Reports of drug diversion by fellow employees is not only a necessary part of an overall employee security program but also serves the public interest at large. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer. The employer shall treat such information as confidential and shall take all reasonable steps to protect the confidentiality of the information and the identity of the employee furnishing information. A failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area. The employer shall inform all employees concerning this policy.

Sec. 1301.92 Illicit activities by employees.

It is the position of DEA that employees who possess, sell, use or divert controlled substances will subject themselves not only to State or Federal prosecution for any illicit activity, but shall also immediately become the subject of independent action regarding their continued employment. The employer will assess the seriousness of the employee's violation, the position of responsibility held by the employee, past record of employment, etc., in determining whether to suspend, transfer, terminate or take other action against the employee.

Sec. 1301.93 Sources of information for employee checks.

DEA recommends that inquiries concerning employees' criminal records be made as follows:

Local inquiries. Inquiries should be made by name, date and place of birth, and other identifying information, to local courts and law enforcement agencies for records of pending charges and convictions. Local practice may require such inquiries to be made in person, rather than by mail, and a copy of an authorization from the employee may be required by certain law enforcement agencies.

DEA inquiries. Inquiries supplying identifying information should also be furnished to DEA Field Division Offices along with written consent from the concerned individual for a check of DEA files for records of convictions. The Regional check will result in a national check being made by the Field Division Office.

42 Code of Federal Regulations, State Operations Manual, Appendix A[16]

§482.25(a)(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs. A-0494

- Records of the receipt and disposition of all scheduled drugs must be current and must be accurate.
- The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and determination of the extent of loss or diversion.
- Facility policies and procedures should minimize scheduled drug diversion.

[16] Bulleted items are from the Interpretive Guidelines for that regulation.

§482.25(b) In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and State law. A-500

- Drugs and biologicals must be controlled and distributed in accordance with applicable Federal and State laws and regulations, and in accordance with applicable standards of practice. Applicable standards of practice include compliance with all Federal and State laws, regulations, and guidelines, as well as, standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals.
- The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970.

§482.25(b)(2)(i) All drugs and biologicals must be kept in a secure area and locked when appropriate. A-0502

- All controlled substances must be locked.

§482.25(b)(2)(ii) Drugs listed in Schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept within a secure area. A-0503

- All Schedule II, III, IV, and V drugs must be kept locked within a secure area. A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals.

§482.25(b)(2)(iii) Only authorized personnel may have access to locked areas. A-504

- The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.
- The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored.

§482.25(b)(7) Abuses and loss of controlled substances must be reported in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate. A-509

- Controlled drug losses are to be reported to appropriate authorities in accordance with State and Federal laws.

State of California

Business and Professions Code

4059.5

> (a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative shall sign for and receive the delivery.
>
> (b) A dangerous drug or dangerous device transferred, sold, or delivered to a person within this state shall be transferred, sold, or delivered only to an entity licensed by the board, to a manufacturer, or to an ultimate user or the ultimate user's agent.
>
> (c) Notwithstanding subdivisions (a) and (b), deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premises within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the dangerous drugs or dangerous devices.

(d) Notwithstanding any other provision of law, a dangerous drug or dangerous device may be ordered by and provided to a manufacturer, physician, dentist, podiatrist, optometrist, veterinarian, naturopathic doctor pursuant to Section 3640.7, or laboratory, or a physical therapist acting within the scope of his or her license. A person or entity receiving delivery of a dangerous drug or dangerous device, or a duly authorized representative of the person or entity, shall sign for the receipt of the dangerous drug or dangerous device.

(e) A dangerous drug or dangerous device shall not be transferred, sold, or delivered to a person outside this state, whether foreign or domestic, unless the transferor, seller, or deliverer does so in compliance with the laws of this state and of the United States and of the state or country to which the dangerous drugs or dangerous devices are to be transferred, sold, or delivered. Compliance with the laws of this state and the United States and of the state or country to which the dangerous drugs or dangerous devices are to be delivered shall include, but not be limited to, determining that the recipient of the dangerous drugs or dangerous devices is authorized by law to receive the dangerous drugs or dangerous devices.

(f) Notwithstanding subdivision (a), a pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met:

(1) The drugs are placed in a secure storage facility in the same building as the pharmacy.

(2) Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered.

(3) The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered.

(4) The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility.

(5) The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility.

The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility.

4081(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept …

4332 Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

Health and Safety Code

11209. (a) No person shall deliver Schedule II, III, or IV controlled substances to a pharmacy or pharmacy receiving area, nor shall any person receive controlled substances on behalf of a pharmacy unless, at the time of delivery, a pharmacist or authorized receiving personnel signs a receipt showing the type and quantity of the controlled substances received. Any discrepancy between the receipt and the type or quantity of controlled substances actually received shall be reported to the delivering wholesaler or manufacturer by the next business day after delivery to the pharmacy.

Title 16, Division 17, California State Board of Pharmacy

§1714 Operational Standards and Security

(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist.

§1715.6 Reporting Drug Loss

The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths.

Title 22, Division 5, Licensing & Certification of Health Facilities…, Chapter 1, General Acute Care Hospitals

§70263 Pharmaceutical Services General Requirements

(c)(1) The [pharmacy and therapeutics] committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures.

(l) Medications shall not be left at the patient's bedside unless the prescriber so orders. Such bedside medications shall be kept in a cabinet, drawer or in possession of the patient. Drugs shall not be left at the bedside which are listed in Schedules II, III and IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970 as amended. If the hospital permits bedside storage of medications, written policies and procedures shall be established for the dispensing, storage and records of use, of such medications.

(q)(10) Drugs maintained on the nursing unit shall be inspected at least monthly by a pharmacist. Any irregularities shall be reported to the director of nursing service and as required by hospital policy.

(q)(11)(A) Drugs listed in Schedules II, III, or IV of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, shall be destroyed in the presence of two pharmacists or a pharmacist and a registered nurse employed by the hospital. The name of the patient, the name and strength of the drug, the prescription number, the amount destroyed, the date of destruction and the signatures of the witnesses required above shall be in the patient's medical record or in a separate log. Such a log shall be retained for at least three years.

§ 70265 Pharmaceutical Service Staff

A pharmacist shall have overall responsibility for the pharmaceutical service. He shall be responsible for the procurement, storage and distribution of all drugs as well as the development, coordination, supervision and review of pharmaceutical services in the hospital.

§70269 Pharmaceutical Service Space

(b) All spaces and areas used for the storage of drugs shall be lockable and accessible to authorized personnel only.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Guidelines

Insulin Recommended Safe Practice Guidelines

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

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DRAFT DOCUMENT CHANGE LOG

VERSION	DATE	AUTHOR	CHANGES
0.1	8/20/14	Jillian Hacker	Updates and Revisions
1.0		Jillian Hacker	Final draft approved by committee

ANNUAL REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0		
3.0		
4.0		
5.0		
6.0		

INTRODUCTION

Insulin therapy is required in a substantial percentage of hospitalized patients. Insulin (all forms) is a high-alert medication that is commonly associated with adverse drug events in hospitalized patients.

The intent of these guidelines is to summarize the insulin safe practices that have been shown to reduce the risk of preventable harm when insulin is used to treat hospitalized patients. Hospitals should use these guidelines to perform a gap analysis to evaluate their current practices and then use the results to develop a plan to improve insulin safety in their organization. These guidelines 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. Working through the Pharmacy and Therapeutics Committee, each hospital should carefully review the guidelines and adopt and implement the safe practices in a manner that is appropriate for their institution.

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

COMMITTEE REPRESENTATION

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

- Association of California Nurse Leaders (ACNL)
- California Association of Health Facilities (CAHF)
- California Board of Pharmacy
- California Department of Public Health (CDPH)
- California Hospital Association member hospitals
- California Hospital Patient Safety Organization (CHPSO)
- California Medical Association
- California Society of Health-System Pharmacists (CSHP)

Actions to Consider to Increase Medication Safety

Pharmacy Purchasing 1.1

- Consider using visual clues, such as affixing a photo to the bin of the insulin that should be stored there, to help ensure the correct vial is returned to the correct bin.
- Do not store different insulin types, such as U-500 Insulin products, and brands in the same bin with a divider; instead, store different insulin types and brands in separate bins labeled accordingly.
- Use both brand and generic names on pharmacy bin labels.
- Use ISMP recommended Tall Man lettering on pharmacy bin labels – for example, HumaLOG, HumuLIN, NovoLIN, NovoLOG.

Unit Storage of Medications

In Pharmacy 2.1

- Consider using visual clues, such as affixing a photo to the bin of the insulin that should be stored there, to help ensure the correct vial is returned to the correct bin.
- Store different insulin types, strengths and brands in separate bins labeled accordingly.
- Do not keep insulin vials on top of counters or within pharmacy compounding hoods, as insulin could be confused with heparin, which is also measured in units. Put all insulin vials back in the appropriate storage area immediately after use2.
- Insulin syringes should be stored separately from tuberculin syringes.
- If U-500 insulin is used in a facility, then store in a locked box labeled U-500 CONCENTRATED Insulin to prevent mix-up.

Inpatient Care Area 2.2

- Consider If possible, inpatient pharmacy prepares patient-specific syringes.
- DO NOT use multi-dose vials for more than one patient as according to Center for Disease Control and Prevention (CDC) guidelines.
- All multi-dose insulin products should have proper patient labeling and corresponding expiration dates.
- If insulin products are stored in automatic dispensing cabinets (ADCs), they should be placed in individual pockets (single-medication access) to prevent errors in retrieval. All insulin types should be segregated (both ADC and medication room storage).
- Insulin should not be stored at the patient's bedside. When insulin is needed, the insulin should be obtained by a nurse and provided to the patient for observed administration, then returned to a secure area for proper storage.
- Insulin syringes should be stored separately from tuberculin syringes.

- Insulin used to refill insulin pumps should not be stored in the medication room or ADC. Instead, pharmacy should deliver directly to nurse any insulin used for the refilling of cartridges in an insulin pump.
- Pharmacy personnel should store all insulin medications in patient care areas without the original carton (remove packaging container from actual pen/vial).
- Utilize physical and/or electronic alerts to care providers that insulin pens should not be used for multiple patients. Utilize reminders that multiple dose vials are not to be used for multiple patients.

Prescribing

- Avoid complicated and error-prone insulin infusion protocols and limit the number of insulin protocols to minimize confusion.
- Ensure an alternate source of glucose is ordered when NPO/reduction or discontinuation of enteral/parenteral feeding is ordered, especially for patients on an insulin drip or a long-acting insulin to prevent hypoglycemia.
- Always review and evaluate preprinted insulin order sets and insulin infusion protocols by the Pharmacy and Therapeutics (P&T) committee at least annually.
- Nursing staff should provide feedback to ensure uniform understanding and accurate execution of orders/protocols.
- Set criteria for blood glucose levels with upper and lower limits upon which the physician should be notified.
- Ensure protocol for managing hypoglycemia is available which includes criteria for notifying physician.
- Encourage the use of scheduled subcutaneous insulin order sets with basal, nutritional, and correction components; this glycemic management is the preferred method for achieving and maintaining glucose control in non-critically ill patients3.
- Bedside capillary point of care (POC) testing should be ordered for patients receiving insulin. Schedules should be based on patient's nutritional status:
    - Before meals and at bedtime (AC&HS) for patients who are eating or receiving bolus enteral nutrition,
    - Every 4 to 6 hours for patients who are NPO or receiving continuous enteral/parenteral nutrition.
    - Consider periodic late night blood glucose (BG) testing (e.g. 0200) to monitor for nocturnal hypoglycemia.

Pharmacy Order Entry & Dispensing

- DO NOT use multi-dose vials for more than one patient as according to CDC guidelines.
- Ensure U-500 unit vials remain in the inpatient pharmacy.
- Pharmacy should dispense patient-specific individual doses of U-500, one dose at a time. As there are no U-500 insulin syringes, to avoid confusion, each dose should be dispensed in a tuberculin syringe with the total dose being expressed in both units and volume (i.e. , 200 units [0.4 ml]).4
- All insulin infusions should be standardized and prepared within the inpatient pharmacy when possible.
- Ensure pharmacist competency on differentiating between different insulin types and duration of action.
- If doses of insulin are included on the label, they should be listed as “units” or “units = ml”, but not “ml” alone.
- If patient’s own insulin is allowed, independent verification of the product by a pharmacist or prescriber must be performed and documented.
- Pharmacy information system should include appropriate alerts and decision support to reduce risk of input errors. This means the pharmacist should have real-time access to the laboratory information system.
- Pharmacy technicians involved in distribution and preparation of insulin products should be educated regarding the high-alert status of insulin, appropriate safety practices and consequences of error. Double checks will be utilized when possible.
- Pharmacy should establish standard safety-focused practice for pharmacist review of insulin orders, which includes all preparations of IV products for injection.
- Pharmacy-generated medical administration records (MARs) should include appropriate warnings and alerts related to insulin therapy. When a patient is prescribed more than one type of insulin, pharmacy-generated MARs should clearly discriminate between insulin types.
- Pharmacy-generated MARs should include specific administration times or time prior to or after meals

Nursing Administration

- **DO** Require a second independent check for all insulin administration, second independent check includes verification of blood glucose result upon which dosing is based.
- Single-use, auto-disabling fingerstick devices must be utilized in the hospital setting when obtaining blood sample. The glucometer should be cleaned and disinfected after every use, per manufacturer’s instructions, to prevent carry-over of blood and infectious agents3.
- Ensure an alternate source of glucose is ordered when NPO/reduction or discontinuation of enteral/parenteral feeding is ordered, especially for patients on an insulin drip or a long-acting insulin, to prevent hypoglycemia.

Monitoring

Blood Glucose Monitoring While on Non-Infusion Insulin 6:1

- All patients with diabetes should have an order for blood glucose monitoring, with the results available to all members of the healthcare team.
- Patients with known diabetes should have a hemoglobin A1c level drawn if a recent level is unavailable.
- All patients with high blood sugar values on admission, receiving enteral/parenteral nutrition, or receiving therapies associated with hyperglycemia (e.g. corticosteroids), should have their blood glucose monitored independent of diabetes history.
- Establish blood glucose goals for critically ill and non-critically ill patients using current recommended guidelines (e.g., American Association of Clinical Endocrinologists)
- Bedside capillary point of care (POC) testing schedules should be based on patient's nutritional status:
- Before meals and at bedtime (AC&HS) for patients who are eating or receiving bolus enteral nutrition.
- Every 4 to 6 hours for patients who are NPO or receiving continuous enteral/parenteral nutrition.
- Consider periodic late night BG testing (e.g. 0200) to monitor for nocturnal hypoglycemia.
- POC results should be documented in the medical record with corresponding insulin administration times.
- Monitor the patient's nutritional intake. If less than 100% of the meal is consumed, you may need to adjust the prandial insulin dose per institution's protocol.

Blood Glucose Monitoring Before Starting Insulin Infusion 6:2

- Ensure blood glucose assessment is done immediately prior to beginning insulin infusion.
- If the glucose measurement is above a predefined level, initiate the insulin protocol as ordered.

Prior to Initiation of Continuous Infusion Insulin 6:3

- Discontinue all previous insulin and any other oral hypoglycemics.
- Optimal glucose control should be achieved in patients who are NPO and receiving a continuous glucose source (continuous tube feeding, parenteral nutrition, or dextrose containing IV Fluids).
- Use with caution in patients receiving oral feedings or bolus tube feedings.
- Use with caution in patients who are pregnant. Consider an Endocrinology or Perinatology consult before instituting this protocol in pregnancy.

Monitoring Considerations While on Insulin Infusion 6:4

Call the physician when:

- Per hospital infusion protocols, patients blood glucose to be monitored routinely and as needed.
- Other orders for insulin (SubQ, IV or in parenteral nutrition) are received without discontinuing this order set.

- Tube feedings, dextrose containing IV Fluids, or parenteral nutrition are started, stopped, interrupted or changed.
- Notify physician when blood glucose levels fall outside predefined upper and lower limits.

Patients with diabetes or hyperglycemia who are eating should be on a consistent-carbohydrate diet, and glucose monitoring should be ordered before each meal and at bedtime. Typically, oral agents should be discontinued during acute illness unless it is a very brief hospitalization. Oral agents can be restarted as patients approach discharge or transfer to a non-acute setting[5].

It should be emphasized that using a correction scale insulin regimen, also known as "sliding scale insulin," alone is not appropriate to treat sustained hyperglycemia (> 140 mg/dl)[6].

Other Considerations

- Develop policies and procedures on safe and appropriate use of patient's own insulin pump (allow/disallow) and insulin and ensure they include risk assessment, proper communication and documentation on MAR of self-administered insulin doses.
- Ensure insulin protocol compliance by conducting periodic retrospective record review to assess adherence to insulin protocol and blood sugar monitoring requirements.
- QA program to track and trend hypoglycemic incidents (e.g. D50, glucagon, or oral glucose use) in patients receiving insulin to drive performance improvement efforts.

REFERENCES

1) Reports of insulin pen sharing between patients have continued despite numerous warnings by the ISMP, CDC, and FDA. ISMP has stated that the safe use of insulin pens in the inpatient setting can "only be assured through timely education and ongoing monitoring" (ISMP Medication Safety Alert Newsletter 2012; 17 (1): 1-4).
2) ISMP Med Safety Alert 2002 May 1, 2002
3) CDC Safe Injection Practice Guidelines http://oneandonlycampaign.org/content/what-are-they-why-follow-them Accessed July 2, 2014.
4) ISMP Medication Safety Alert Newsletter 2013; 18 (22): 1-2.
5) American Association of Clinical Endocrinologists' Comprehensive Diabetes Management Algorithm 2013 Consensus Statement. 2013; 19 (supp 2): 1-48
6) http://clinical.diabetesjournals.org/content/29/1/3.full / http://clinical.diabetesjournals.org/content/29/1/3.full#sec-7

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CALIFORNIA HOSPITAL ASSOCIATION

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Medication Safety Committee

Emergency Department Medication Management Safety Tool

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VERSION	DATE	AUTHOR	CHANGES
0.1	November 2013	Med-ER Workgroup	Initial Draft
1.0	April 2014	Med-ER Workgroup	Final draft approved by committee

INTRODUCTION

More and more, healthcare professionals and regulators are turning their focus to mitigating risk for medication management in the emergency department. Reducing opportunities for medication error and increasing the opportunities for a safe medication management environment represents a prime opportunity to improve the healthcare delivery system – and helping your organization do so is the goal of this tool.

When using this tool, consider using it as a gap analysis tool that sets out two benchmarks:

- **Recommended** which is considered a minimal level of care which all institutions should strive to meet as a baseline level of care, and

- **Ideal** which is an optimal level of care to strive toward, recognizing that it may or may not be fully attainable at a given hospital.

If your institution does not meet the "recommended" level, consider conducting analysis to determine pathways for meeting this benchmark. However, once the **recommended** level is obtained, consider ways to then move toward the **ideal** benchmark level of care. The **Medication Management Elements** are intended to assist with development of a formal plan to minimize medication related events described in Health and Safety Code Section 1339.63, and address elements routinely used in CDPH MERP surveys.

This tool has been reviewed by the California Hospital Association's Medication Safety Committee, and is intended for hospital and health care providers for consideration as they evaluate current practices and develop specific programs. **This tool is not to be viewed as fixed protocol that must be followed, nor is it entirely inclusive or exclusive of all methods of reasonable care that can obtain/produce the same results.** The CHA's Medication Safety Committee is a voluntary collaborative supported by the CHA, and is comprised of CHA member hospitals and non-hospital representatives.

Information contained in this tool should not be construed as legal advice or used to resolve legal problems by health care facilities or practitioners without first consulting legal counsel. It is important to note that facilities must adhere to all relevant state and federal regulations and statutes governing operations and practice.

COMMITTEE REPRESENTATION

The Medication Safety Committee includes nurse, physician, and pharmacist representatives.

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
PRESCRIBING	**Utilize:** • Order sets • Protocols • Guidelines **Verify:** • Allergy info	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts *(Includes clinical decision support tools)*	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts	**CPOE - Includes, But Not Limited To:** • Allergy verification hard stop • Weight-based dosing for pediatric populations • Standardized order sets, best practice drug information hyperlinks and best practice physician alerts *(Includes clinical decision support tools)*
RX ORDER COMMUNICATION	**Utilize:** • Order sets • Protocols • Guidelines **Verify:** • Allergy info	**CPOE:** • Allergy verification hard stop • Weight-based dosing for pediatric populations *(Includes clinical decision support tools)*	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE	**Emergent:** • Repeat-back **Non-Emergent:** • CPOE
LABELING	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings	**Incorporate:** • Tall Man Lettering • Look-alike/sound-alike warnings
PACKAGING	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV) :** • Unit Dose • Barcoded • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded	**Liquids (or Oral IV):** • Unit Dose • Barcoded **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)	**Liquids (or Oral IV):** • Smallest Size Possible • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)	**Liquids (or Oral IV):** • Unit Dose • Barcoded • Minimize # of IV Product Concentrations *(utilize manufacturer pre-made IV products when possible)* **Oral Solids:** • Unit Dose • Barcoded **Injectables:** -Unit Dose -Barcoded -• Minimize # of IV Product Concentrations (utilize manufacturer pre-made IV products when possible)

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
COMPOUNDING	**During Pharmacy Operating Hours:** • Utilize laminar flow hood • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **After Hours & Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours *(24 hours)*:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present	**During Pharmacy Operating Hours *(24 hours)*:** • USP 797 compliant area • Ensure Beyond-Use Dating matches USP 797 risk level **Emergency Situations:** • Utilize ER designated clean area • Appropriate sterile competencies present
Dispensing	**Utilize** automated dispensing machine **Prevent** after-hours use of pharmacy by stocking ADM with sufficient quantities of medications and enabling "non-profile" feature **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs **Enable** available alert features on ADM **Review** ADM content monthly for appropriateness *NOTE: See administration section for additional safeguards to use with these strategies*	**Utilize** automated dispensing machine **Enable** ADM "profile" feature, and allow for review of medication overrides **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs . **Review** ADM content monthly for appropriateness **Ensure** "on-call" pharmacist is available for emergency dispensing	**Utilize** automated dispensing machine **Enable** ADM "profile" feature, and allow for review of medication overrides **Enable** ADM "profile" feature, and allow for either concurrent or retrospective review of medication overrides if resources and manpower allow for it and in consideration of HR-HA population needs **Review** ADM content monthly for appropriateness **Ensure** "on-call" pharmacist is available for emergency dispensing **Enable** ADM "profile" feature if facility has ability to provide 24-hour order verification	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: see monitoring section for concurrent order* *NOTE: See monitoring section for pharmacist review guidelines*	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: See monitoring section for concurrent order verification*	**Utilize** automated dispensing machine **Review** ADM content monthly for appropriateness **Enable** ADM "profile" feature, and allow for review of medication overrides *NOTE: See monitoring section for concurrent order verification*

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
Distribution	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution (to the extent possible allowed for by operating hours) • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available • Delivers specialty items • Utilizes advanced technology with features for secure medication delivery	**Pharmacy:** • Controls or directs medication distribution • Distributes ER medications in most ready to use formulation available • Delivers specialty items • Utilizes advanced technology with features for secure medication delivery
Administration	**Implement** independent double checks for caregivers administering High Risk-High Alert medications	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system	**Implement** independent double checks for caregivers administering High Risk-High Alert medications **Employ** barcode medication administration using an EHR system
Education	**Current drug information resources** are available to practitioners in a form that is readily available **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education	**Current drug information resources** are available to practitioners in a form that is readily available **EHR System** contains decision support tools and best practice links **Pharmacy** takes an active role in medication education
Monitoring	**Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders	**Concurrent Review:** • ER patients being held for admission to an inpatient bed **Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders	**Concurrent Review:** • ER patients being held for admission to an inpatient bed **Retrospective Review:** • Review sample cohort representative of patient population (for example, at-risk patient populations such as pediatrics and/or geriatrics)	**Concurrent Review:** • Review orders

EMERGENCY DEPARTMENT MEDICATION MANAGEMENT SAFETY TOOL

Med Mgmt. Element	SMALL		MEDIUM		LARGE	
	Recommended	**Ideal**	**Recommended**	**Ideal**	**Recommended**	**Ideal**
Use	**Regularly evaluate medication use processes** and identify system vulnerabilities - e.g., including but not limited to, chart review, direct observations, etc.	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval **Regularly evaluate medication use processes** and identify system vulnerabilities - e.g., including but not limited to, chart review, direct observations, etc.	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider utilizing an ER pharmacist for at least 8 hours a day, 7 days a week *Note: Entities which do not utilize pharmacists in the ER should consider increasing the frequency of MUE's*	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider adding additional pharmacy resources beyond the 8 hour per-day minimum	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval Consider utilizing an ER pharmacist for at least 16 hours a day, 7 days a week	**Retrospective Medication Utilization Evaluation (MUE):** potential focus areas are at-risk populations in emergent situations quarterly or at a regularly defined interval For large-sized hospitals, consider utilizing an ER pharmacist 24/7

Instructions for Using the CHA/CSHP Compounding Grids 2016

WHAT

The California Hospital Association (CHA)/California Society of Health-System Pharmacists (CSHP) Compounding Grids identify the proposed Board of Pharmacy requirements that will take effect Jan. 1, 2017, as well as describe the upcoming USP 797 and USP 800 requirements that will likely be effective July 1, 2018. There are six compounding grids: Physical Plant Requirements for Non-Hazardous Compounding, Physical Plant Requirements for Hazardous Compounding, Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous and Hazardous Garbing.

These tools are intended for hospital and health care pharmacists in charge (PICs) and other hospital staff as they evaluate their current sterile compounding practices. The grids are based on the Board of Pharmacy's Feb. 24, 2016, "Order of Adoption- Sterile Compounding Regulations" and interpreted by CHA's and CSHP's Medication Safety senior pharmacy leaders. The grids are not a fixed compliance assessment that must be followed, and they should not be construed as legal advice or used to resolve legal problems.

WHEN

The Board of Pharmacy regulations take effect Jan. 1, 2017. If a facility is not able to meet the physical plant requirements, a waiver will be required prior to Jan. 1, 2017. The waiver requires a plan and a proposed timeline. *Note: There is no waiver for training, testing and cleaning requirements.*

USP 800 is in its final form with an effective date of July 1, 2018. USP 797 is undergoing review and is expected to be finalized for an effective date of July 1, 2018, but there may be some changes to the proposed language.

HOW

To use the grids:

1. The Compounding Frequency of Documentation, Temperature Requirements and Monitoring, Required Laboratory Testing, and Non-Hazardous/Hazardous Garbing grids are self-explanatory.

2. The physical plant grids for non-hazardous and hazardous sterile compounding should be used as follows:

Which room	Date requirements take effect	
	January 1, 2017	**July 1, 2018**
Hazardous	Board of Pharmacy	USP <800> (CDPH requirement)
Non-hazardous	Board of Pharmacy	USP <797> still draft (CDPH requirement)

1. Look at the negative pressure, Hazardous Compounding Grid, space, equipment and the Board of Pharmacy requirements.

   a. Find the type of room in the current space (the SEC = secondary engineering control).
   b. Second, determine if you can meet the minimum requirements.
      - If yes, congratulations. Next, be sure to review the USP 800 requirements.
      - The USP requirements go into effect in two years — July 2018.
   c. If the current set up does **not** meet the Board of Pharmacy requirements, a waiver will be required prior to Jan. 1, 2017. This will require a plan and a timeline.
   d. If structural changes are necessary, be sure to review the USP 800 planned requirements and proposed changes simultaneously, especially refrigeration and storage in negative pressure spaces.

2. Repeat the same process with the positive pressure, non-hazardous space compounding grid.

WHO

CHA and CSHP created a task force in the fall of 2014 to develop a series of grids to assist health system pharmacists understand the requirements as delineated by the California State Board of Pharmacy and the current and proposed USP chapters 797 and 800. The Sterile Compounding Task Force members are:

Christine Acosta, Board of Pharmacy
Elaine Beals, CSHP Southern California Chapter, Kaiser
Corbin Bennett, CSHP Sierra Chapter, Kaiser
Darrell R. Chan, CSHP Orange County Chapter, Prime Health Care
Lucinda Chan, CSHP Diablo Chapter, Touro University
Helen Chun, CSHP Southern California Chapter, Kaiser
Candace Fong, Past Chair, CHA Medication Safety Committee, Dignity Health
Ken Fukushima, CSHP Orange County Chapter, CPS Pharmacy
Jeannette Hanni, CSHP QuatraCounty Chapter, Sutter, CHA Medication Safety Committee Chair
Stephanie Holcomb, CSHP Sierra Chapter, Community Medical
Martin Iyoya, Diablo, CSHP Board Liaison, John Muir Health
Mervyn Kalman, CSHP San Fernando Valley Chapter, Consultant
Doug. C. O'Brien, CHA Medication Safety Committee, Kaiser
Lynn Paulsen, University of California, CHA Medication Safety Committee, Chair SCTF
Maria Serpa, CSHP Sacramento Valley Chapter, Sutter
Art Woo, California Department of Public Health, CHA Medication Safety Committee
Betty Yee, CSHP Diablo Chapter, Retired

TEMPERATURE REQUIREMENTS AND MONITORING

(CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797>(7/1/18) Requirements)

Temperature Description	Degrees Centigrade		Degrees Fahrenheit		Comments/Explanations Requires NIST Certified Temperature Monitoring Devices (USP <1118>	USP 39 NF 34 (2016) *(Used as a reference by the FDA for all package inserts)*	CDC Vaccine Storage (May 2014) USP <797> proposed	Board of Pharmacy January 1, 2018
	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	2º	8º	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)
Controlled Room Temperature	20º	25º	68º	77º	• Excursions allowed between 15 ºC to 30 ºC (59 ºF to 86 ºF) as long as the MKT is ≤ 25 ºC (77 ºF) • Spikes to 40 ºC (104 ºF) are permitted for less than 24 hours as long as the MKT is ≤ 25 ºC (77 ºF) • Check for specific drugs with narrow ranges	General Notices 10.30.60		No provision for excursions §1735.1 (j)
Clean Room Temperatures		20º or less		68º or less	In order to compensate for the additional layers of protective garb, this is the general recommendation.		USP <797> proposed for July 1, 2018	
	20º	25º	68º	77º				Or lower required

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

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

MONITORING REQUIREMENTS

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

This tool is intended for hospital and health care pharmacists in charge (PIC) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety Senior Pharmacy Leaders. 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.

PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed 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)**	**Beyond Use Dates**		**Comments**
		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**
• **Temp 20-24C (68-75F)** • **HEPA-filtered air**	• **ISO 5 with unidirectional flow** • **HEPA-filtered first air** • **Non-turbulent**			
>ISO Class 7 clean room with ISO 8 or better ante-area • No sink in clean room • Sink in ante • 0.02-0.05" w.c. positive pressure differential relative to all adjacent spaces OR • Displacement airflow method: requires air velocity of >40 feet per minute from the clean area across the line of demarcation into the ante area, from floor to ceiling and wall to wall CCR §1735.1(e)(m) & §1250.4 (1-4)	**Any ISO Class 5 PEC:** • Laminar Flow Hood OR • Biological Safety Cabinet with unidirectional flow OR • Compounding automated robots OR • Compounding Aseptic Isolators (CAI) with unidirectional flow. Air within the CAI shall not be recirculated or turbulent. CAI must meet requirements in 1751.4 (f) (1-3)	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State *** CCR §1751.8 (a)	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State*** CCR §1751.8 (b)	• Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Document **daily** pressure differential or air velocity, or use **continuous recording device**, between adjoining ISO rooms. 1751.1(a)(8)
Segregated sterile compounding area • Any preparation area that is not ISO classed, 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 • Biological Safety Cabinet with unidirectional flow • CAI where mfg not meeting requirements in 1751.4(f)(1-3)	12 hours CCR §1751.8 (d)	12 hours	• 12 hours BUD for low-risk, non-hazardous preparations only 1751.8(d)(2) • PEC requires certification at least every 6 months CCR 1751.4(f)
	• No PEC or outside ISO 5 PEC • Under conditions not meeting all requirements in any subdivision 1751.8 (a-d)	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
PROPOSED USP 797 - NON-HAZARDOUS DRUGS Effective July 1,2018				

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety senior pharmacy leaders. 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.

PHYSICAL PLANT REQUIREMENTS – NON-HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>SECONDARY ENGINEERING CONTROL
• Temp = or < 20 C
• Humidity < 60%
• Controlled through HVAC
• Air enters HEPA filter in the ceiling of buffer room and returns low on the wall</th><th>PRIMARY ENGINEERING CONTROL (PEC)
ISO 5 with unidirectional flow</th><th>BEYOND USE DATES</th><th></th></tr>
<tr><td colspan="3">Category 1</td><td>Comments</td></tr>
<tr><td>Segregated compounding area (SCA)
• Not ISO classified
• Buffer/ante not meeting ISO 7/8 respectively
• Buffer/ante fails surface sampling
• Away from significant traffic flow
• Away from unsealed doors/windows that connect to outdoor
• Perimeter must be defined
• Sink must be 1 meter from PEC (greater than the 3 ft. for the BOP requirements)
• Not adjacent to construction, warehouse or food prep</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI
• Isolator</td><td>• Less than or equal to 12 hours at Room Temp*
• Less than or equal to 24 hours at Cold Temp (Refrigerator)**</td><td>• Recertification every six months
• Endotoxin and sterility testing not required for products
• No shipping or external cartons allowed in SCA</td></tr>
<tr><td colspan="3">Category 2</td><td>Comments</td></tr>
<tr><td>PEC in ISO 7 buffer room
• With ISO 8 or better ante, separated from surrounding unclassified area
• Buffer and ante must be separate rooms with walls and doors, and controls to prevent low quality air into controlled areas
• Sink in ante
• Buffer and ante must have ACPH = or >30, at least 15 must be HEPA filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02” wc to separate each ISO classified area and from ante to general pharmacy area</td><td>ISO Class 5 PEC:
• Laminar Air Flow System (LAFS)
• Biological Safety Cabinet (BSC)
• Restricted Access Barrier System (RABS), can be CAI or CACI</td><td rowspan="2">Sterile to Sterile, No Preservatives, Aseptic Technique
<table><tr><th>Sterility Testing</th><th>Room Temp BUD</th><th>Refrigerated BUD</th><th>Freezer BUD</th></tr><tr><td>NO</td><td>6 days</td><td>9 days</td><td>45 days</td></tr><tr><td>YES</td><td>28 days</td><td>42 days</td><td>45 days</td></tr></table>BUD days start after the quarantine period for sterility testing

For: Terminal sterilization, preservatives, non-sterile to sterile compounding BUDs, please see the USP <797> document</td><td rowspan="2">• Recertification every six months
• No tacky mats in ISO classified areas
• Document pressure differential or velocity daily or use continuous recording device
• No shipping or external cartons allowed in buffer/ante
• Endotoxin testing required for CSP compounded from non-sterile ingredient(s)</td></tr>
<tr><td>PEC in ISO 8 area
• Sink can be in ISO 8 area 1 meter from PEC
• Must have ACPH = 15 ;must be HEPA-filtered fresh air vs. recirculated air
• Positive pressure differential at least 0.02”wc to separate each ISO classified area and to general unclassified area</td><td>• Isolator (must meet standards; see lines 505-511 in proposed USP <797>)</td></tr>
</table>

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy’s 2/24/2016 “Order of Adoption Sterile Compounding Regulations” and designed by CHA’s and CSHP’s Medication Safety senior pharmacy leaders. 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.

NON-HAZARDOUS GARBING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Compounding attire	Order of garbing in the anteroom	Specifications
Shoe covers	1	May be eliminated IF written documentation by CAI manufacturer
Head cover	2	
Facial hair covers (if applicable)	2	
Face mask	3 (followed by washing of hands to the elbows x 30 seconds with soap and water and drying)	May be eliminated IF written documentation by CAI mfr.
Non-shedding gown	4	
Sterile gloves Must wear sterile gloves over any CAI gauntlet gloves	5	Tested for compatibility with sterile 70% isopropyl alcohol (SIPA)
PROHIBITED ITEMS AND INDIVIDUALS		
Always prohibited • Wrist, hand, finger or visible jewelry • Piercing with jewelry • Headphones • Earbuds • Personal electronic devices (including cell phones) • Cosmetics • Nail polish • Artificial nails • False eyelashes		Eyelash extensions are permitted
Excluded from ISO 7 and ISO 5 spaces until resolved		
• Exposed rashes • Sunburn • Weeping sores • Conjunctivitis • Active respiratory infections • Communicable diseases		

HAZARDOUS GARBING: In addition to the above requirements (USP<800>)

Compounding attire	Specifications	Information
Double shoe covers		Don the second pair upon entering the buffer area. Remove upon leaving.
Sterile chemo gloves	Chemo gloves must meet ASTM standard 6978 (or its successor). NO powder.	Change every 30 minutes or when torn, punctured or contaminated.
Disposable chemo gowns made of polypropylene or other laminate materials (should be glossy)	Must be changed every 2-3 hours or per manufacturer guidance. NEVER worn outside the HD handling area.	Must close in the back, long-sleeved, closed cuffs that are knit or elastic. No seams or closures that HDs could pass through.
Face shields	Required when working outside a C-PEC	Surgeons, spill cleanup, etc.

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REQUIRED LABORATORY TESTING

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

<table>
<tr><th>Environmental Testing
Under Dynamic Conditions</th><th>USP <797></th><th>Board of Pharmacy (BOP)</th></tr>
<tr><td>Viable surface sampling</td><td rowspan="2">Every six months: Requires identification of every colony forming units (CFUs) to the genus level and action plan for CFUs exceeding USP thresholds
<table><tr><th>Location</th><th>Viable airborne</th><th>Viable surface</th></tr><tr><td>ISO-5 (PEC)</td><td>>1</td><td>>3</td></tr><tr><td>ISO-7 (Buffer)</td><td>>10</td><td>>5</td></tr><tr><td>ISO-8 (Anteroom)</td><td>>100</td><td>>100</td></tr></table>(highly pathogenic microorganisms [e.g., G(-) rods, coag (+) Staph, molds and yeasts] must be immediately remedied, regardless of CFU count)</td><td rowspan="2">• Every six months for low and medium risk California Code of Regulations (CCR) §1751.4 (j)
• Every six months for high risk CCR §1751.4 (j)
• Genus level identification of CFUs exceeding the threshold (facility determined) CCR §1751.4 (j)</td></tr>
<tr><td>Viable air sampling by volumetric impaction: (400-1,000 liters)</td></tr>
<tr><td>Volumetric air sampling by impaction: non-viable particle counts</td><td>Every six months: requires action plan for particle counts exceeding ISO class as required</td><td>• Every six months as part of hood re-certification for low and medium risk
• Weekly for high risk</td></tr>
<tr><td colspan="3">Process validation: The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used in place of the actual product used during sterile preparation.</td></tr>
</table>

Personnel	When Required	What Tests Are Required (BOP and USP)
Moderate and low risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing, then 1x annually thereafter. CCR §1735.1(u)
Moderate and low risk compounding – ongoing competency	Annually as part of the competency testing process	
High risk compounding – initial competency	Prior to the first compound prepared for a patient	Media fill tests that mirror the most complex compounding done by the individual and gloved fingertip testing - required 3x during initial testing then semi-annually thereafter. CCR §1735.1(u)
High risk compounding – ongoing competency	Every six months as part of the competency testing process	

Lot Compounding (More than one of the identical product)	USP <797> July 1, 2018 Proposed	Board of Pharmacy: Additional Policies Required
Sterile to sterile compounding	N/A	Written policies and procedures including (1) master formulae and compounding logs, (2) appropriate documentation and (3) appropriate sterility and potency testing CCR §1751.3 (b)(1-3)
Non-sterile to sterile		Written policies and procedures including: (1) process validation for chosen sterilization methods and (2) end-product evaluation, quantitative and qualitative testing CCR §1751.3 (c)(1-2)

End Product Testing: Requirement for Sterility and Potency Testing for Lots of Low/Med Risk CSPs	Comments	USP <797> July 1, 2018	BOP January 1, 2017
Beyond Use Date (BUD) is the lesser of the USP <797> or the manufacturer package insert/written communication	• Meets all PEC ISO 5 requirements • Low risk: 48 hour RT, 14 days refrigeration • Medium risk: 30 hour RT, 9 days refrigeration • USP <797> revisions have different BUD	• As long as the shorter of the manufacturer insert stability and the USP <797> BUD is met, there is no batch sterility testing requirement.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CR §1751.3 (d)
Extended BUD (USP <797>)	• The USP <797> BUDs are an exemption from the USP <71> sterility testing. • BUD can only be extended if sterility tests according USP <71> are performed. • USP <797> does not exempt extended BUDs from sterility testing.	• No exemption for sterility testing for extended BUD. • Every batch of extended BUD requires sterility testing and sequestering. • In the revised USP <797> there is no extended BUD option.	• "Appropriate sterility and bacterial endotoxin testing" • Facility policy should describe processes as determined by the PIC to assure sterility and accuracy of sterile compounding processes within the facility CCR §1735.2(i)(3-4)
Potency testing is the USP monograph described testing of potency	Products should have one of the following: • A manufacturer-sanctioned process • A published (refereed journal) method followed exactly • Lab data from testing of facility product	• No requirements in USP <797>	• Will require potency testing, schedule per the facility policy • Facility policy should describe processes as determined by the PIC to assure accuracy of sterile compounding processes within the facility CCR §1751.3 (d)(3)(3-4)

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety senior pharmacy leaders. 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.

PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

Hazardous Drugs - BOP				
		Beyond Use Dates		
SECONDARY ENGINEERING CONTROL • **Temp 20-24C (68-75F)** • **Externally vented** • **Negative pressure** • **Physically separate room**	**PRIMARY ENGINEERING CONTROL** • **PECs ISO class 5 negative pressure unidirectional flow** • **HEPA filtered airflow** • **Non-turbulent** • **HEPA filtered exhausted air** • **External venting dedicated to 1 BSC or Compounding Aseptic Isolators (CACI)**	**LOW RISK** • **Sterile to sterile** • **=< 3 commercial packages** • **=< 2 entries into 1 sterile container**	**MEDIUM RISK** • **Combine or pool sterile ingredients** • **For multiple patients or one patient multiple times** • **Complex manipulations** • **Long compounding process**	**Comments**
• **ISO Class 7 or better** • Sink in ante area • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 30 ACPH • Ante-area ISO 7 or better CCR §1735.6(e)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • CACI with unidirectional flow. Air within the CACI shall not be recirculated or turbulent.	48 hours at Room Temp* 14 days at Cold Temp** 45 days Solid Frozen State ***	30 hours at Room Temp* 9 days at Cold Temp** 45 days Solid Frozen State ***	• Document daily pressure differential or air velocity, or use continuous recording device, between adjoining ISO rooms. 1751.1(a)(8) • Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification at least every 6 months CCR §1751(b)(1), 1751.4(f) • Externally vented 1751.4(g), 1735.6(e); each hood must have a separate vent • All surfaces with the room shall be smooth, seamless, impervious and non-shedding 1735.6(e)(4) • No requirements for negative pressure drug storage
• **Segregated Compounding Area** • Sterile to sterile compounding only • Sink at least 3 ft. from PEC • Emergency eye wash station acceptable • At least 0.01”-0.03” w.c. negative relative to all adjacent space (rooms, above ceiling and corridors) • Minimum 12 ACPH 1735.6 (e) (1)	• Biological Safety Cabinet, Class II Type A2 • Biological Safety Cabinet, Class II Type B2 • CACI with unidirectional flow. CACI must meet requirements in 1751.4 (f) (1-3)	12 hours	12 hours	• Requires negative pressure ISO 5 PEC 1751.4(g) • Each ISO environment requires certification at least 6 months CCR §1751(b)(1), 1751.4(f)(g) • Externally vented 1751.4(g), 1735.6(e) • All surfaces with the room shall be smooth, seamless, impervious and non-shedding 1735.6(e)(4) • Sink can be within 3 ft. of CACI if CACI meets requirements in 1751.4 (f) (1-3) • No requirements for negative pressure drug storage
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				

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PHYSICAL PLANT REQUIREMENTS - HAZARDOUS

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and proposed USP<797> (7/1/18) Requirements

HAZARDOUS DRUGS - USP 797				
SECONDARY ENGINEERING CONTROL **Externally vented through HEPA filtration**	**PRIMARY ENGINEERING CONTROL** **C-PECs ISO class 5 negative pressure unidirectional flow** **C-PECs externally vented**	**BEYOND USE DATES (July 1, 2018)**		**Comments**
		Low Risk	**Medium Risk**	
• **HEPA filtered air in negative pressure physically separate room** • **ISO class 7 or better buffer room** • **0.01" to 0.03"w.c. negative pressure** • **Minimum 30 ACPH HEPA filtered air** • **Sink placed at least 1 meter from the entrance of buffer room (greater than the 3 feet required by BoP)**	• 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	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **48 hours Room Temp** **14 days Cold Temp** **45 days Solid Frozen State**	*USP <800> and <797> BUDs* *6 days at Room Temp** *9 days at Cold Temp*** *45 days Freezer Temp **** ***BUT will be overridden by the BOP BUDs unless there is a regulatory change*** **BOP BUDs** **30 hours Room Temp** **9 days Cold Temp** **45 days Solid Frozen State**	• Requires negative pressure ISO 5 C-PEC • C-PEC and C-SEC externally vented • Eyewash readily available • Drug storage MUST be in a negative pressure space; includes the refrigerator. • Receiving of hazardous drugs must be in a negative or neutral pressure space. • May use the negative pressure room for non-sterile hazardous compounding BUT not at the same time.
• **Containment Segregated Compounding Area (C-SCA)** • **Must be a negative pressure separate room** • **0.01" to 0.03"w.c. negative pressure** • **Unclassified room** • **Minimum 12 ACPH HEPA filtered air** • **Sink at least 1 meter from C-PEC (greater than the 3 feet required by the BOP)**	• ISO Class 5 Biological Safety Cabinet, Class II Type A2 • ISO Class 5 Biological Safety Cabinet, Class II Type B1, B2 • ISO Class 5 Biological Safety Cabinet, Class III • Containment Aseptic Compounding Isolators (CACI) with unidirectional flow	12 hours	12 hours	

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

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

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

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COMPOUNDING FREQUENCY OF DOCUMENTATION

CHA/CSHP Interpretation of California Board of Pharmacy (1/1/17), USP<800> (7/1/18) and Proposed USP<797> (7/1/18) Requirements

The most stringent requirement will be required. BOP regulations for BOP requirements, and BOP and USP 797 regulation for CDPH requirements		
DAILY	LOW AND MEDIUM RISK	HIGH RISK
Room Temperature	X	X
Refrigerator (Twice a day for vaccines)	X	X
Freezer (Twice a day for vaccines)	X	X
Air pressure differentials or air velocity between adjoining ISO rooms	X	X
MiniHelix differentials for CAI, CACIs	X	X
Cleaning with germicidal cleaners and disinfected with suitable agent (sterile IPA) Counters + Cleanable Surfaces + Floors+ Carts	X	X
Cleaning within the ISO 5 environment (before each shift, every 30 minutes and before and after each batch) Facilities with IV robots will be required to petition the BOP for exception with documentation and description of an alternative cleaning schedule	X	X
MONTHLY	LOW AND MEDIUM RISK	HIGH RISK
Cleaning with germicidal cleaners and disinfected with suitable agents (sterile IPA) Exterior workbench Walls Ceiling Shelves/Storage Tables Stools	X	X
Sporicidal agent used for cleaning, all sites	X	X
QUARTERLY	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	NA	X
BIANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Viable surface sampling, ALL CFUs identified to genus per USP <797>; facility-determined limits for BOP	X	X
Volumetric air sampling Particle count CFUs, identified to genus. ALL CFUs identified to genus per USP <797>, only facility-determined limits for BOP	X	NA
Hood certifications under dynamic conditions	X	X
Determination of CAI and CACI recovery times	X	X
Media fill for employees	NA	X
ANNUAL	LOW AND MEDIUM RISK	HIGH RISK
Media fill for employees	X	NA
Competency testing Observation Written	X	X

This tool is intended for hospital and health care pharmacists in charge (PICs) and senior staff as they evaluate their current sterile compounding practices. It is based on available Board of Pharmacy's 2/24/2016 "Order of Adoption Sterile Compounding Regulations" and designed by CHA's and CSHP's Medication Safety senior pharmacy leaders. 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.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

Medication Safety Committee Guidelines

Recommendations for Improving Safety of Opioid use

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

TABLE OF CONTENTS

DRAFT DOCUMENT CHANGE LOG

VERSION	DATE	AUTHOR	CHANGES
0.1	01/2013	Cleo Mutebi	Draft
1.0	04/2013	Cleo Mutebi	Final draft approved by committee
1.1	11/2013	Multiple	Edits: Hanni/Aveikian/Jaffe/Bartleson

ANNUAL REVISION LOG

VERSION	REVIEW DATE	REVISIONS/CHANGES
2.0	10/2013	Revised to CHA Med Safety guideline specifications
3.0	07/2014	Added Fentanyl guidelines
4.0		

INTRODUCTION

Opioid use is generally safe but is associated with serious adverse effects such as over sedation (0.5% incidence). The purpose of these recommendations is to reduce the risk of adverse drug events associated with use of opioids in perioperative settings. These recommendations focus on narcotic over-sedation in adult patients being treated for acute pain.

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

The attached recommendations/~~guide~~ is intended for acute care settings as a plan to help assess the safe use of opioids.

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

COMMITTEE REPRESENTATION

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

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

The following tool is intended to guide acute care facilities in the safe use of opioid agents. Medication safety includes all aspects of medication use, from the prescribing stage to ongoing monitoring.

Medication Use Step	Recommendation(s)
Prescribing	1) Consider using an acute pain management order set. *Rationale* i. A standardized order set will promote national best practices ii. Encourages multimodal techniques for pain management (e.g., including round the clock non-opioid therapy if not contraindicated). iii. Minimize opioid side effects a. Naloxone orders b. Bowel regimen orders c. Antiemetic orders d. Reduce variation from best practices 2) Improve provider awareness of patient's history of opioid use and other risk factors for over sedation. *Rationale* i. Opioid naïve patients are at the highest risk for experiencing over sedation. ii. Screening information (for patients at high risk for over sedation) should be available prescribers and other clinicians. iii. Design information support systems to identify patients who are at high risk (Sleep apnea, Morbid obesity, elderly >60 years old). 3) Improve use of patient controlled analgesia (PCA) *Rationale* i. Patient centered treatment ii. Minimizes adverse drug events such as over sedation 4) Consider development and implementation of an acute pain management service *Rationale* i. Prospective assessment of patients at high risk for respiratory depression/ over-sedation ii. Actively manages pain therapy iii. Addresses patient satisfaction

Dispensing / Distribution	Assess need for stocking multiple concentrations of narcotics *Rationale* i. High concentrations can be mistakenly administered resulting in over-sedation
Administration	1) Consider establishing standardized procedure for naloxone administration to ensure availability and consistency in the emergent management of over-sedation. *Rationale* i. Naloxone is not consistently ordered on patients that are on ~~opioid~~s, including naloxone orders during opioid prescribing provides healthcare professionals an approved order to act on in the event of an emergency. Each organization to develop policies and procedures that define parameters for when naxolone orders should begin being initiated. 2) Consider lower and upper limits for 'smart' infusion pumps by utilizing drug libraries intended to prompt users when settings reach above or below these pre-determined settings. For opioids, these limits should take into consideration all routes of administration. Furthermore, the drug library can delineate acuity and patient populations; including, but not limited to, neonatal, pediatric, adult, and geriatric patients *Rationale* i. Use of infusion pump drug libraries can help minimize and prevent errors with opioid overdose.
Clinical Education	1) Train staff to identify the patients at high risk for over-sedation and respiratory depression. a) No previous use of opioid history b) Sleep apnea c) Morbid obesity d) Elderly >60 years old *Rationale:* i. Clear guidance to staff in identifying risk areas.

Medication Use Step	Recommendation(s)
Clinical Education	2) Improve documentation and communication of risk factors for over-sedation to all care givers across the continuum of care a) Pain scale scores b) Sedation scale assessment c) Pain goals *Rationale:* i. Complete information should be readily available to prescribers for timely pain treatment care plan adjustments in response to an adverse drug event 3) Staff should be educated on equianalgesic potency (physician & nurse). a) Potency reference cards b) Talks on pain management therapies and alternatives c) Incorporate into order set *Rationale:* i. Staff competence on dose equivalencies. 4) Advise prescribers in the use of multimodal therapies a) Benefits of multimodal therapy alternatives based on best practices (Tylenol, Motrin, Neurontin®) b) Around the clock use of non-opioid analgesics therapy unless contraindicated *Rationale:* i. Medical staff education. 5) Educate clinicians on the recognition of advancing sedation a) Utilization of sedation scale assessment tools *Rationale:* i. Medical staff education.

Clinical Education	6) Nursing education, pain management a) Standardized process of pain goal setting b) Define frequency of patient/family pain management education *Rationale:* i. Medical staff education.
Patient Education	7) Standardized patient orientation/education to pain scale tool and use a) Educate patients on realistic pain goals and use of pain scale b) Educate patients/families on responding to adverse effects *Rationale:* ~~➢~~i. Medical staff and patient education.
Monitoring	~~1) Improve documentation and communication of risk factors for oversedation to all care givers across the continuum of care~~ ~~a) Pain scale scores~~ ~~b) Sedation scale assessment~~ ~~c) Pain goals~~ ~~*Rationale*~~ ~~i. Complete information should be readily available to prescribers for timely pain treatment care plan adjustments in response to an adverse drug event~~ 2) Implement appropriate physiologic monitoring practices a) Consider use of capnograpy to monitor ventilation in identified high risk patients b) Consider continuous pulse oximetry in identified high risk patients ~~b)~~ *Rationale* ii. Enables earlier recognition and intervention in advancing oversedation. ~~1)~~ 3) Consider implementing~~Implement~~ a stop (i.e., either a hard and/or soft stop) that engages prescribers to routinely review the use of opioids. a) Utilize an alert system to trigger an opioid therapy evaluation. This process to include a communication tool to notify the prescriber when the desired number of days has passed from the original order date. b) Consider using pharmacists ~~Pharmacists~~ to oversee these stops as it relates to disease management and ensure the prompt re-evaluation by the prescriber whether or not the opioid is continued or discontinued.

Policy and Procedure Documentation Tools	1) Revision of pain assessment and reassessment policy to include a) Sedation measurement and documentation
Quality Measures: Examples	1) Naloxone administration for the purposes of reversing Opioid therapy 2) Reported over-sedation events 3) Rapid Response Team calls related to over-sedation

*Note: Despite warnings from the FDA, manufacturers, and various patient safety agencies, transdermal fentaNYL patches continue to be prescribed inappropriately to treat patients with acute pain and patients who are not opioid tolerant. FentaNYL patches are only for patients who are **opioid-tolerant** for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration for an extended period of time AND cannot be managed by other means.*
*The patches are **NOT** to be used to treat sudden, occasional or mild pain, or pain after surgery.*

REFERENCES

American Pain Society, (2012). Current Understanding of Assessment, Management and Treatment.

American Society of Anesthesiologists (2012). Practice Guidelines for Acute Pain Management in the Perioperative Setting. Report from the ASA Task Force on Acute Pain Management. Anesthesiology, 2012 Feb; 116(2): 248-73.

Brant, J (2012). Personal Interview of September 28, 2012. Medication Safety Researcher, Billings Clinic, Billings, MT.

California Hospital Association (2011). Medication Safety Committee; High Alert Medication Guideline – Fentanyl Transdermal Patch.

Cohen, M. (2007). Medication Errors, *American Pharmacists Association*, Washington, D.C.

D'Arcy, Y. (2008). Meeting the Challenges of Acute Pain Management. Medscape.org.

Feroli, Bob (2012). Personal Interview of September 27, 2012. Medication Safety Officer, Johns Hopkins Hospital, Baltimore, MD.

Food & Drug Administration. "Smart" Infusion Pumps are Selectively Intelligent. By Kathleen Cummings, BSN, RN, and Ryan McGowan, BS (Article reprinted from *Nursing2011*, March issue, p.59.)

http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TipsandArticlesonDeviceSafety/ucm245160.htm

Jarzyna, D. et al (2011). American Society for Pain Management Nursing Guidelines on Monitoring for Opioid Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No 3 (September) 2011: pp 118-145.

The Joint Commission (2012) Sentinel Event Alert #49. Safe Use of Opioids in Hospitals.

Lucas, C. E., Vlahos, A. L., & Ledgerwood, A. M. (2007). Kindness Kills: The Negative Impact of Pain as the Fifth Vital Sign. *Journal Of The American College Of Surgeons*, *205*(1), 101-107. doi:10.1016/j.jamcollsurg.2007.01.062

McCarter, M. (2007). Capnography monitoring enhances safety of postoperative patient controlled analgesia. *American Health & Drug Benefits.* Accessed September 2012 http://www.ahdbonline.com/feature/capnography-monitoring-enhances-safety-postoperative-patient-controlled-analgesia

Meisel, M (2003). Process Improvement Reduces Post-Surgical Opioid Oversedation: Pain Team Pilot Achieves Four-Fold Reduction in Incidence. *Scope*, August 2003, Volume 8, Number 8.

Meisel, M (2012). Personal Interview of May, 2012. Medication Safety Officer, Fairview Health Services, Minneapolis, MN.

National Health Services, United Kingdom (2008). Reducing Harm from High Risk Medications.

San Diego Patient Safety Council (2009). Patient Controlled Analgesia (PCA) guidelines of Care for the Opioid Naïve Patient.

University of Michigan Health System (2011). Elevating Pain Management Strategies to Improve Patient Outcomes. A 2011 finalist in the Association of Health System Pharmacists Foundation Literature Awards.

Vermaire, D (2011). Quality Improvement Project to Reduce Perioperative Opioid Oversedation Events in a Pediatric Hospital. *BMJ Qual Saf* 2011; 20:895-902.

World Health Organization (2012). Pain Relief Ladder. Accessed September 28, 2012 at www.who.int/cancer/palliative/painladder/en/

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- Time Limitations for Approvals
- Documenting Compliance
- Fees
- Amended Construction Documents
- Incremental Design, Bidding, and Construction
- Construction Barriers
- Materially and *Non*-Materially Altered
- Temporary Construction
- Unauthorized Construction
- PINs & CANs: Discerning which and when to apply
- TIO— Testing · Inspection · Observation
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- And Much, Much More!

Wednesday, October 12th

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&

Tuesday, October 18th

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SEMINAR INFORMATION:

$150 per person ⇨ Continental breakfast + morning and afternoon refreshments + buffet lunch

8:30 am—4:00 pm ⇨ Registration & breakfast: 7:30 am— 8:30 am. (Schedule includes 1-hour lunch)

To Attend ⇨ Complete the attached registration form and return it with your payment, by mail, email, or fax.

Registered attendees will receive an email with a link to the seminar materials a week before the seminar. **Please note:** Hard copies/binders will **not** be provided at the seminar.

LESSONS LEARNED DURING CONSTRUCTION

SEMINAR REGISTRATION FORM

Clear Form

OSHPD

WHICH SEMINAR DO YOU PLAN TO ATTEND?

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Anaheim Marriott Suites
12015 Harbor Blvd., Garden Grove, CA 92840

☐ Sacramento—October 18, 2016
Crowne Plaza Hotel Sacramento
5321 Date Ave., Sacramento, CA 95841

Please type or print your name and organization as it should appear on your name tag

NAME: _____

FACILITY/FIRM NAME: _____

PHONE #: _____

EMAIL ADDRESS: _____

Please select which most closely describes you:

- ☐ Hospital Owner
- ☐ Architect
- ☐ Structural Engineer
- ☐ MEP Engineer
- ☐ Construction
- ☐ IOR
- ☐ Other _____

ADDITIONAL ATTENDEES: (Please enter each name as it should appear on name tag)

1. _____
2. _____
3. _____
4. _____

REGISTRATION FEE: $150 per person

TOTAL CHARGE/CHECK AMOUNT: $_____

METHOD OF PAYMENT: (Make Checks/Money Orders payable to: OSHPD)

☐ CHECK #_____ ☐ MONEY ORDER ☐ AMERICAN EXPRESS ☐ MASTERCARD ☐ VISA

CREDIT CARD NUMBER: _____ EXP DATE: _____

NAME (as it appears on card): _____

BILLING ADDRESS: _____

CITY: _____ STATE: _____ ZIP CODE: _____

SIGNATURE: _____

FDD

Please submit completed registration form, with your payment, to:
OSHPD — Hospital Building Safety Board
Attention: Krista Harrington
400 R Street, Ste. 200
Sacramento, CA 95811

Hospital Building Safety Board

Registration forms may be submitted by fax: (916) 324-9118 • by email: FDD.Seminar@oshpd.ca.gov
or by mail to the address listed above.
Seating is limited to the first 140 paid attendees. Registration fees will not be refunded for "No Shows."

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

September 27, 2016

TO: Medication Safety Committee Members

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

SUBJECT: Proposed 2017 Meeting Schedule

Following is the proposed meeting schedule for 2017 Medication Safety Committee meetings:

January 4, 2017	Sacramento, CHA Offices Board Room
April 5, 2017	Sacramento, CHA Offices Board Room
July 5, 2017	Sacramento, CHA Offices Board Room
October 11, 2017	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