Medication Safety Committee Meeting

April 3, 2019

10 am - 12 pm

ZOOM Meeting

https://calhospital.zoom.us/j/9165527616

Conference Call Option:

720-707-2699 Meeting ID: 916 552 7616

Meeting Book - Medication Safety Committee Meeting

Medication Safety Committee Meeting Agenda - April 3, 2019

10:00 I. CALL TO ORDER/INTRODUCTIONS
Hanni

10:05/Hanni II. OLD BUSINESS

11:15 III. LEGISLATION

IV. INFORMATION

V. NEXT MEETING

A. Wednesday, July 17, 2019 - 10 am - 2 pm -In Person Meeting - Sacramento

12:00 VI. ADJOURNMENT
Hanni

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 3, 2019

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services
Candace Fong, Pharm D, System Director, Dignity Health

SUBJECT: Inventory Reconciliation from Automatic Dispensing Units

SUMMARY

During our last meeting, the board of pharmacy confirmed that a drug dispensing system is not a considered a satellite pharmacy and was in the process of developing FAQ's, see attached, Inventory Reconciliation Regulation – Summary and FAQ's.

DISCUSSION

1) Any further concerns with ADU's?

ACTION REQUESTED

- Information and follow up.

Attachments: Inventory Reconciliation Regulation – Summary and FAQs

BJB:br

Inventory Reconciliation Regulation – Summary and FAQs

California Code of Regulations, title 16, section 1715.65, Inventory Reconciliation Report of Controlled Substances took effect April 1, 2018.

Each subsection of CCR section 1716.65 is summarized in the table printed here. Below the table are answers to frequently asked questions (FAQs) about the regulation.

Section 1715.65. Inventory Reconciliation Report of Controlled Substances

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances.	Subsection (a) requires all pharmacies, and all clinics licensed under Business and Professions Code section 4180 or 4190 ("clinics"), to perform periodic inventory and reconciliation functions for all controlled drugs. (Note: No frequency of these duties is specified in the regulation except for Schedule II drugs, which are discussed below.)
(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.	Subsection (b) requires the pharmacist-in-charge (PIC) or the clinic's consultant pharmacist to: (1) Establish and maintain secure methods to prevent losses of controlled drugs. (2) Establish written policies and procedures for performing reconciliation reports. (3) Review all inventory and reconciliation reports.
(c) A pharmacy or clinic shall compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: *(1) A physical count, not an estimate, of all quantities of federal 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*	Subsection (c) requires each pharmacy or clinic to prepare at least a **quarterly** inventory reconciliation report of all federal Schedule II medications, which is based on: (1) A physical count of all federal Schedule II medications at the time of each inventory. (2) A review of all acquisition and disposition records since the last inventory.

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 federal Schedule II controlled substances since the last inventory reconciliation report;* *(3) A comparison of (1) and (2) to determine if there are any variances;* *(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; and* *(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.*	(3) A comparison of 1 and 2 to identify any differences (losses or overages). Collection and retention of records to compile each inventory report. The report must identify the possible causes of overages.
(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.	Subsection (d) requires a pharmacy or clinic to file a report of losses and known causes to the board within 30 days of discovery or within 14 days if theft, self-use or diversion by a board licensee is the cause. If the cause is unknown, this section requires the pharmacy or clinic to further investigate to identify the causes and to take corrective action to prevent additional losses.
(e) The inventory reconciliation report shall be dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be readily retrievable in the pharmacy or clinic for three years. A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.	Subsection (e) requires the inventory reconciliation report to be signed and dated by the individual(s) performing the inventory and countersigned by the PIC or professional director (for a clinic).

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).	Subsection (f) requires a new PIC to complete an inventory reconciliation report within 30 days of becoming PIC. Encourages the outgoing PIC to do a reconciliation report before leaving.
(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location.	Subsection (g) requires INPATIENT HOSPITAL PHARMACIES to complete a separate quarterly inventory reconciliation report for federal Schedule II drugs stored within the pharmacy and for each of the pharmacy's satellite locations.
(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; and* *(4) Confirmed losses of controlled substances are reported to the board.*	Subsection (h) requires the PIC of any pharmacy servicing an AUTOMATED DRUG DELIVERY SYSTEM (regardless of location) to: (1) Ensure that all controlled substances added to any automated drug delivery system are accounted for. (2) Ensure that access to any automated drug delivery system is limited to authorized facility personnel only. (3) Ensure that any discrepancy or unusual access to the controlled substances in the automated drug delivery system is evaluated. (4) Ensure that confirmed losses are reported to the board timely.

FAQs about CCR section 1716.65

1. The regulation took effect April 1, 2018. Should I have performed my initial inventory beginning April 1, 2018?

No. The board expects pharmacies and clinics to transition to satisfy the inventory reconciliation requirements over a short period of time, but not necessarily by April 1. An initial physical count of the Schedule II medications is the first step.

2. Are there any drugs in addition to federal Schedule II controlled substances affected by the requirement to do a physical count and reconciliation each quarter?

No. The regulation requires a quarterly count and reconciliation of only federal Schedule II drugs. California and the federal government have separate controlled substances schedules, although there is much similarity between the two. Nevertheless, the board determined that the federal Schedule II drug list is more current and complete, and the federal list is the reference for reporting dispensing into the Controlled Substances Utilization Review and Evaluation System (CURES) in California. A pharmacy may on its own add additional drugs to its reconciliation program.

3. Can a pharmacy or clinic estimate (instead of physically counting) federal Schedule II medications for the quarterly inventory?

No. A physical count of every Schedule II medication is required for the quarterly inventory reconciliation report.

4. Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?

No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of controlled medications to identify and prevent losses of Schedule III, IV and V drugs. The regulation only specifies the frequency of reconciliation duties for federal Schedule II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard of practice in the community under the circumstances of the pharmacy.

5. Does a perpetual inventory system satisfy the requirements of this regulation?

No. The use of a perpetual inventory system does not satisfy the regulation. The regulation requires both a physical count and reconciliation with all acquisitions and dispositions be performed every 90 days.

6. If I use a perpetual inventory, can I use the physical counts made for the perpetual inventory instead of physically counting the drugs specifically for the inventory reconciliation report?

It depends. The regulation requires a physical count of each Schedule II medication every quarter, which is then used as part of the inventory reconciliation analysis and report. If, for example, the pharmacy or clinic physically counts the specific drug stock each time a Schedule II drug is dispensed or acquired, that count might be used to fulfill the physical count required by the inventory reconciliation regulation, but the PIC or consultant will need additional data. For any drug where there were no dispositions or acquisitions during the quarterly reconciliation period (and therefore no physical count through the perpetual inventory system), a physical

count of the Schedule II drug must be made because each drug must be physically counted at least quarterly.

7. I have a recent physical count for each Schedule II drug. What do I compare that to? What do I do with that information?

For each medication, the PIC or consultant would start with the physical count of the medication from the last inventory reconciliation report and:

1. Add all acquisitions and subtract all dispositions that occurred during the reconciliation period (no greater than 90 days) to identify the amount of drug stock that should be on hand (expected drug stock).
2. Compare the expected drug stock to the actual physical inventory count.
3. If there is a difference, attempt to identify the source of overage or shortage. **NOTE:** If there is a discrepancy and the recent physical count is from a perpetual inventory system, the board urges the facility to initiate a supplementary physical count of the medication. Determine if the facility needs to take corrective action, including modify its policies and procedures, conduct an investigation, institute additional security or modify its practices.
4. Whether or not there is a discrepancy, the results must be recorded in your inventory reconciliation report.

8. Does an inpatient hospital pharmacy or a pharmacy servicing onsite or offsite emergency kits (e-kits) have to complete an inventory reconciliation report for the Schedule II controlled substances contained within the e-kits?

There is no specific reconciliation report for the kits themselves, although a pharmacy's replenishment of Schedule II drugs removed from the emergency kits would be part of a pharmacy's disposition of medication.

9. An inventory reconciliation report of all Schedule II drugs shall be compiled at least every three months and, in order to complete the report, the inventory must be compared with a review of drugs that entered and left the pharmacy since the previous inventory reconciliation. Since no reconciliation report exists before April 1, 2018, does that mean that the first inventory reconciliation report will not be due before July 1, 2018?

To initiate the reconciliation process and establish a baseline for future inventory reconciliation reports, a physical count of all Schedule II medications must be undertaken. The board would generally expect a pharmacy to perform this count on or after April 1, 2018. To allow time to develop meaningful written policies and procedures for the inventory reconciliation process, the board recommends a pharmacy or clinic perform the inventory counts within the first 90 days after April 1 (i.e., July 1, 2018).

Additionally, any new PIC on or after April 1, 2018, is required to prepare a report upon assuming the PIC position. Within the first three months after April 1, 2018, the board would

expect the new PIC, within 30 days, to have performed an inventory count of all Schedule II medications consistent with the requirements to prepare an inventory reconciliation report.

10. An initial inventory does not appear to be required as part of this rule change. Since a reconciliation report cannot be compiled without an initial reference count, would it be appropriate for pharmacies or clinics to perform a physical count of all Schedule II drugs during the initial three-month period (after April 1), and then begin reconciliation processes after July 1st?

Yes. See the response to question 9.

11. A PIC must complete an inventory reconciliation report within 30 days of becoming pharmacist-in-charge. If there is a PIC change on April 1, 2018, how can the PIC create a reconciliation report, given there may not be a recent inventory or reconciliation report to refer to?

In this specific case, if prior data were unavailable because of the implementation date of the regulation, the board would expect the PIC to at least perform an inventory of all Schedule II medications consistent with the requirements to prepare the reconciliation report within 30 days (May 1, 2018).

12. Should the inventory reconciliation report encompass only significant losses, as defined by the DEA, or should the report encompass any discrepancy? If the former, doesn't a pharmacy's or clinic's filing of DEA Form 106 with the DEA already provide the requested information to the board if the board receives a copy of that report?

California law requires that any loss of controlled substances be reported to the board within 30 days – and reported within 14 days where drug theft, self-use or diversion have been committed by a board licensee. These are existing requirements, predating the inventory reconciliation requirements. The reconciliation regulation restates the reporting of drug loss requirements for clarity. A DEA Form 106 may be used to make this report to the board. Also, a separate report is required to the DEA (on a Form 106) of any significant loss of a controlled substance.

13. Will the board create a new process for reporting Schedule II controlled substances drug losses? Is there a standard form or email address to submit this information?

The board will not create a new or additional process for reporting the loss of controlled substances. A DEA Form 106 or a written statement containing specified details of the loss is sufficient. Check the board's website on how to report a drug theft or loss.

14. If my pharmacy or clinic is unable to identify the cause of the loss, should we wait to report the loss to the board until the cause is determined?

No. Reporting is required for any loss of controlled substances within, at most, 30 days regardless if a cause of the loss was identified. Should a cause be identified later, an additional

report can be made to the board. If the cause is theft, diversion or self-use by a board licensee, the report must be made within 14 days.

However, the regulation also directs that "further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substance" where the source of a loss cannot be readily identified.

15. Does a pharmacy have to maintain actual paper documents of the records used to compile each inventory reconciliation report? Are electronic records acceptable?

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. Provided the records are readily retrievable, electronic records are acceptable.

16. Can the inventory reconciliation report be completed by multiple persons?

Yes. All persons involved in performing the inventory must sign and date the report, which also must be countersigned by the PIC or professional director (if a clinic).

17. How do I physically count liquid Schedule II medications for the reconciliation report?

The board does not expect a count or measurement of every liquid you have as part of the quarterly reconciliation. Instead, the board recommends:

- **Where there is a unit of use container,** a pharmacist should accept the measurement printed on the container and include it in the physical count. However, if the unit of use container looks damaged or altered in some manner, treat the item as quarantined.
- **Where multidose containers are used,** a pharmacist should subtract the amount dispensed from the measurement printed on the container. Subsequently, the pharmacist should document the remaining amount on the container itself. Example: A pharmacist dispensed 240ml from a 473ml stock bottle. The pharmacist would subtract 240ml from 473ml and document the difference of 233ml on the stock bottle. The remaining amount of 233ml would be used as the physical count for the reconciliation report.

18. Can unlicensed personnel (e.g., clerks) perform the inventory necessary to complete the inventory reconciliation report?

As identified in CCR section 1793.2, the counting of pharmaceuticals is considered a "nondiscretionary task" – a duty a pharmacy technician may perform. Accordingly, unlicensed personnel cannot complete the inventory function.

19. How does a reconciliation report help detect drug diversion?

A reconciliation report aids in the identification of controlled substance inventory discrepancies. Pharmacies can respond to inventory shortages or overages by initiating a close

review, which may aid in detection of drug diversion. Recording of an inventory alone lacks review and analysis of acquisition and disposition information.

20. Wouldn't a perpetual inventory identify diversion?

A perpetual inventory is a beneficial tool and may aid in identification of drug diversion. However, a perpetual inventory with no discrepancies is not evidence of a lack of diversion. A perpetual inventory may only account for known drug acquisitions and dispositions. If acquisition invoices are destroyed or fraudulent prescriptions are processed and later deleted, a perpetual inventory may show no discrepancies. Further, all categories of drug acquisition and disposition may not be entered into a perpetual inventory.

21. The computer already counts acquisitions and dispositions of Schedule II controlled substances for the perpetual inventory. Is the count in the computer sufficient for the reconciliation report?

No. Electronic records can be used to aid in calculation of total acquisition and disposition information for the reconciliation report, but this information must be used in conjunction with an initial physical count and a final physical count to complete the requirement of CCR 1715.65. Any electronic records used should be reviewed for unauthorized manipulation and evaluated against other available records for consistency. Other records may include hard copy drug acquisition invoices, purchase orders, signatures for dangerous drug deliveries, drug acquisition summaries from wholesalers, reverse distribution documents, return to wholesaler for credit documents, drug destruction documents and/or hard copy prescription documents.

22. In an inpatient pharmacy, would "disposition" of Schedule II drugs refer to drugs that are 1) supplied into an ADDS (Pyxis, Omnicell, etc.) or as floor stock; or 2) dispensed to the patient?

In an inpatient pharmacy, disposition would refer to medications dispensed directly to the patient. Please see additional requirements for inpatient hospital pharmacies found in 1715.65(g)-(h).

23. Does the regulation require a reconciliation of <u>all</u> controlled substances or only Schedule II controlled substances?

As referenced in 1715.65(c), the compilation of a <u>quarterly</u> inventory reconciliation report is required only for all federal Schedule II controlled substances**.** However, as referenced in 1715.65(a), every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, still must perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. Additionally, other sections of pharmacy law (BPC 4081 and CCR 1718) require a pharmacy to have complete accountability of all dangerous drugs handled by every licensee.

24. Could you provide more guidance on periodic reconciliations of Schedule III – V drugs? For example, can Schedule III-V counts be estimates – as allowed for biennial inventories – or must they also be exact counts? Should Schedule III-V reconciliations be done more frequently?

CCR 1715.65(c)(1) requires a physical count, not an estimate of, of all quantities of federal Schedule II controlled substances. The regulation is silent regarding estimation of Schedule III – V counts; however, because BPC 4081 and CCR 1718 require licensees, including a pharmacy, to have complete accountability of all dangerous drugs, it is recommended Schedule III – V drugs be exact counts.

25. Subsection (a) of the regulation requires a pharmacy or clinic to "periodically" perform inventory and reconciliation functions for controlled substances. Does this mean every quarter I must count and reconcile all controlled substances?

No. However, periodically (and under federal law at least every two years) all controlled substances must be inventoried. The board encourages more frequent counting of controlled medications to identify and prevent losses of Schedule III, IV and V drugs. But the regulation only specifies the 90-day frequency of reconciliation duties for federal Schedule II drugs; the appropriate frequency for all other controlled drugs should be determined by the standard of practice in the community and under the circumstances of the pharmacy.

26. I am the PIC of a pharmacy that is so small there are no other staff. Do I still have to complete a reconciliation report, or is the perpetual inventory sufficient?

Yes. All pharmacies, regardless of size or staff, that stock federal Schedule II controlled substances must comply with CCR 1715.65.

27. I work in a chain pharmacy, where we store the data used to perform the reconciliation at the corporate level and keep a signed face sheet in the pharmacy. Are the acquisition and disposition records used to complete the reconciliation report required to be attached to the reconciliation/signature page?

Attachment is not mentioned in the regulation, but as referenced in 1715.65(c)(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. The board recommends all documents related to compilation of an inventory reconciliation report be stored together.

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 3, 2019

TO: Medication Safety Committee Members

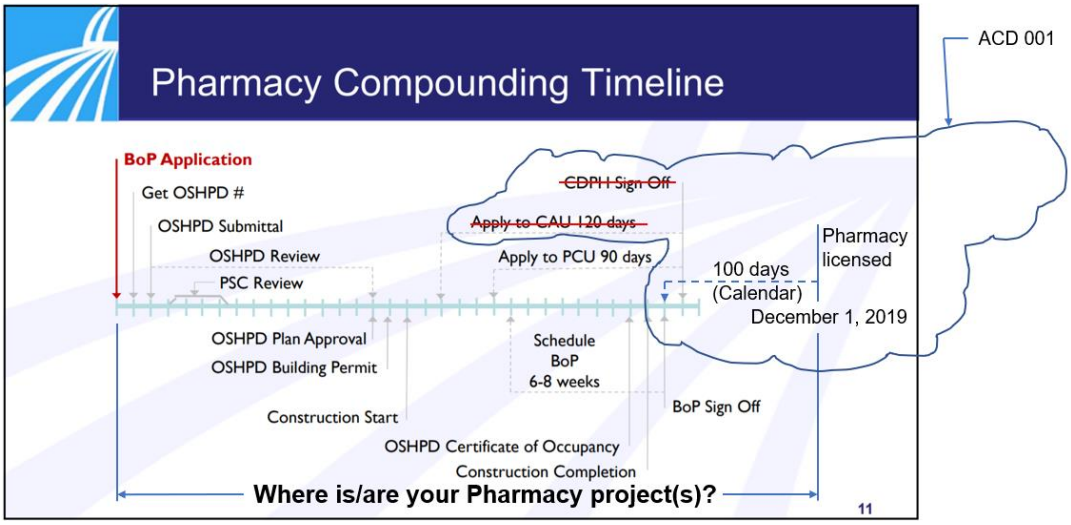
FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services

SUBJECT: Sterile Compounding Update

SUMMARY

Several issues are impeding successful hospital implementation of timely hospital sterile compounding implementation.

1. **CDPH's recent decision** to require all sterile pharmacy applications be completed before being sent to CDPH for review. The interpretation that all applications must be complete is not founded in the recently passed law related to hospital application timelines and will significantly delay the time sensitive sterile compounding projects. Below is the process originally agreed upon by CDPH, and now, with their change, will extend approximately 100 days beyond the originally agreed upon process. CHA sent a letter to CDPH Deputy Director, see attached, and discussed with CDPH staff the need to rescind this to prevent delays to meet UPS finalization in December.



2. **State of Hospitals** Under Delayed Implementation
   237 hospitals presently have "waivers" for delayed physician plant /construction completion and implementation of USP. Many sites will not meet the December 2019 deadline.

- 20% have greater than 50% of their projects completed to date and due for finalization by Dec, 2019= 48
- 21% have started construction but have completed less than 50% of the project = 49
- 13% have approved plans but have not started construction = 31
- 27% have plans under review = 64
- 19% are in a construction phase with no information as to % of project completion = 45
- X% do not have a waiver or reconstruction plans.

OSHPD has shared with us that many hospitals are not keeping them abreast of changes. CHA will be following up with hospitals listed and sharing information with CEO's in CHA News. We are also working with AHA to leverage USP on delayed implementation strategies. BoP is willing to address scope of compliance, but not able to officiate delayed implementation once USP is finalized.

3. Board of Pharmacy **Sterile Compounding Update for USP 797-** Several issues of concern were raised with some recent changes to USP 797 .
   a. Definition of Sterile Compounding- reconstituting and repackaging added, risk categories eliminated, Proprietary bag and vial systems- docking for future activation and administration is considered compounding- temperature changes, low-linting, section 7 equipment supplies and components, etc.
   b. SC Tools will need revision once USP finalized.
   c. Is power point available from BoP?

4. **USP 800 Implementation -** How are members addressing upcoming implementation strategies for employees and equipment? Will Cal OSHA reengage in the process defining hazardous drugs or use USP 800 definitions? See attached USP 800 Power Point from Cedars-Sinai.

DISCUSSION

1. Where are hospitals regarding above changes with CDPH, and meeting the potential December 2019 deadline?
2. Any suggestions on other activity to protect hospitals as the implement planned changes after deadlines?

ACTION REQUESTED

- If you have delayed implementation past projected USP deadline, please make your senior leadership aware.
- If you are meeting challenges with stakeholders please let me know

Attachments: USP800 Overview – Cedars-Sinai
CHA letter to CDPH

BJB:br

USP 800 Hazardous Drugs – Handling in Healthcare Settings
Official December 1, 2019

CEDARS-SINAI
LEADING THE QUEST™

cedars-sinai.edu

Agenda

1. Definitions
2. Scope
3. CSMC Multidisciplinary Task Force
4. Key Requirements and Operational Impacts
5. Hazardous Communication Plan and Training
6. Personnel Protective Equipment
7. Medical Surveillance
8. Workforce Considerations
9. FY 20 Budget Impact

2

What is USP 800 Hazardous Drugs

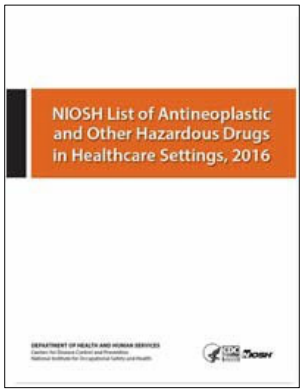
- Based on published reports of adverse effects in healthcare personnel from occupational exposure to HDs
- USP 800 consistent of 18 chapters (see Appendix)
- Any drug defined as hazardous by the National Institute for Occupational Safety and Health (NIOSH) on the basis of at least one of six criteria:
  1. Carcinogenicity
  2. Teratogenicity or developmental toxicity
  3. Reproductive toxicity in humans
  4. Organ toxicity at low doses in humans or animals
  5. Genotoxicity
  6. New drugs that mimic existing hazardous drugs in structure or toxicity

National Institute for Occupational Safety and Health (NIOSH)

Categories

1. Antineoplastics (e.g.,chemotherapy)
2. Non-antineoplastics that meet 1 or more criteria and may pose reproductive risk for some populations
3. Reproductive only hazards
4. Investigational drugs-if no information available

HDs are ubiquitously used throughout the medical center and include, infusions, injections, ophthalmic, inhalation, oral and topic drugs

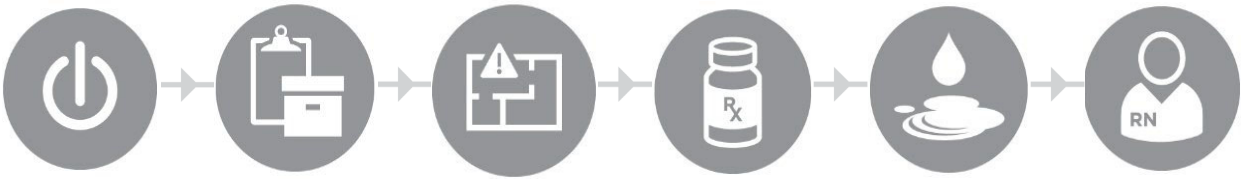


https://www.cdc.gov/niosh/docs/2016-161/images/2016-161.jpg, accessed 9/30/18

USP 800
Hazardous Drugs (HDs)

- Designed to protect employees, patients and the general public who may be accessing facilities where hazardous drugs (HDs) are stored, prepared, transported or administered.
- Includes but not limited to
  - Pharmacists, technicians, nurses, physicians, respiratory therapists, environmental services staff, allied health professionals, other healthcare workers, patients, families
- Applies to entities that handle HDs
  - Pharmacies, hospitals and other healthcare institutions, clinics, physicians' offices or veterinarians' offices
- **Employees <u>must</u> receive HD training and be assessed for an understanding of the training**.

Hazardous Drug Lifecycle



Getting Started – People and Processes

Receiving and Storage

Infrastructure for Compounding

Compounding HD and the Necessary PPE

Spills, Cleaning and Disposal

Administering HDs and the Necessary PPE

6

USP 800 Key Components
(see Appendix for complete list)

- Hazardous Drug (HD) List Risk Assessment
- Hazardous Drug Communication Plan and Training
- Operations
  - Hospital flow of HDs
  - Personnel Protective Equipment
  - Containment of HDs
    - Ex: If non-antineoplastic or reproductive risk HD drugs require crushing tablet(s) or opening capsule(s), containment and work practices defined in the risk assessment must be used (e.g. appropriate personnel protective equipment (PPE), plastic pouch to contain any dust or particles generated).
  - Cleaning of medication rooms, patient rooms
  - Waste management including storage
  - Job descriptions and Job Hazard Analysis-incorporate HD handling
- Monitoring
  - Employees-Medical Surveillance
  - Facilities

7

CSMC USP 800 Hazardous Drug Task Force

- Established multidisciplinary team in 2017
- Goal: Develop policies, standard operating procedures and conduct risk assessment to Hazardous Drugs List to support education, training and management of HDS

1. Nursing
2. Pharmacy
3. ORs
4. Epidemiology
5. Infusion Centers
6. Ambulatory Clinics
7. Human Resources
8. OLAR
9. Respiratory Therapy
10. Purchasing
9. EVS
10. Environmental Safety
11. Physicians
12. Employee Health
13. Transporters
14. Facility Services
15. Supply Chain
16. EIS
17. SOCCI, THO, TACRI and Valley Oncology Group
18. MDR

8

Hazard Communication Program Plan

- A written plan that describes how the standard will be implemented
- All containers of hazardous chemicals must be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings
- Entities must have an Safety Data Sheet (SDS) for each hazardous chemical they use (29 CFR 1910.1200)
- Entities must ensure that the SDSs for each hazardous chemical used are readily accessible to personnel during each work shift and when they are in their work areas
- Personnel who may be exposed to hazardous chemicals when working must be provided information and training before the initial assignment to work with a hazardous chemical, and also whenever the hazard changes
- Personnel of reproductive capability must confirm in writing that they understand the risks of handling HDs. Chapter applies to anyone capable of reproduction.

http://www.usp.org/sites/default/files/usp/document/our-work/healthcare-quality-safety/general-chapter-800.pdf, accessed 13119
http://www.usp.org/frequently-asked-questions/hazardous-drugs-handling-healthcare-settings, accessed 13119

9

Workforce Considerations: USP 800 Scenario

Organizations should establish a mechanism by which those workers who are actively trying to conceive, are pregnant, or are breast-feeding can request alternative duty or protective reassignment.
https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html, accessed 13119

- Scenario: Healthcare worker notifies Cedars that they want to start a family and are starting IVF and then intends to breastfeed for 12 months. Where will the worker be assigned? For how long? Should others pick up the employee's workload? Should there be a cross-trained workforce to cover shifts?

10

USP <800> Hazard Communication Program at Other Hospitals- 01/16/2019

Hospital	How are you identifying applicable employee types?	How are you identifying applicable employees?	At what point within the employment process are you notifying employees, and what tools are you using?
Penn Medicine	All employees	All employees	1. Outlined in job description, which is signed upon hire. 2. Annual performance evaluation, additional USP 800 document
Nebraska Medicine	All employees	All individuals with applicable job titles/roles	Upon hire Tools: Internal learning/training management software system AND simple paper forms that get filed
Ochsner Health System	All employees **Rationale:** Any employee may walk through a facility and have the potential for exposure to hazardous drug residue on surfaces.	**Training for Jobs with Hazardous Drug Handling duties/Direct Patient Care** Specific online training upon hire and annually • More detailed attestation of awareness of risk • Training and attestation speak to the risk for all people of child bearing years • Understanding of steps to protect themselves and others • Agreement to follow policies and procedures	**All Employees** "USP 800 Awareness " online training module upon hire and annually. Time" five minutes • Reproductive risk is addressed but not in detail • Attestation of awareness of risk, training and understanding of steps to protect themselves and others • Agreement to follow policies and procedures. • Recognition of the HD symbol.
University of Wisconsin Health	Those who might enter a patient care area	All individuals with applicable job titles/roles	1. Upon hire - added to onboarding checklists for RNs, hazardous drug training for RNs 2. Annual education renewal - included in annual safety and infection control Tools: Internal learning/training management software

11

Personnel Protective Equipment Requirements
Will be embedded at the drug level in CS-Link for all HDs identified in risk assessment

CSMC Recommended Minimum Standards for Personal Protective Equipment for Hazardous Drug Administration

HD 1: Antineoplastic

Double chemotherapy gloves
Gown (for injectable medications)
Face shield and goggles if liquid could splash

HD 2: Non-Antineoplastic Hazardous

Formulation/Scenario	Activity	Gloving Requirements	Gowning Requirements	Eye/Face Requirements	Respiratory Requirements
Intact tablet or capsule	Administration from unit-dose package	Single chemo gloves	No gown	None	None
Manipulating tablets or capsules	Crushing tablets or capsules; handling uncoated or cut tablets for administration	Double chemo gloves	No gown	None	Mask
Oral liquid drug or feeding tube	Administration	Double chemo gloves	Gown	Face shield and goggles, if vomit or potential to spit up	None
Topical drug	Administration	Double chemo gloves	No gown	Face shield and goggles, if liquid that could splash	None
Injectable	Preparation (withdrawing from vial/mixing)	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
	Administration from prepared syringe or IV bag	Double chemo gloves	Gown	None	None
Solution for irrigation	Administration (bladder, HIPEC, limb perfusion, etc.)	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
Powder/solution for inhalation/serosol treatment	Administration	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	Mask
Any hazardous medication	If patient could vomit or spit up	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None
Any hazardous medication	If liquid could splash	Double chemo gloves	Gown	Face shield and goggles, if liquid that could splash	None

HD 3: Reproductive Risk- PPE ABOVE ONLY REQUIRED FOR AT-RISK PERSONNEL
(Personnel who are pregnant, possibly pregnant or trying to conceive (male or female))

Additional PPE may be added in any situation with a higher risk of exposure
Adapted from NIOSH 2016 Table 5

12

Recommended Medical Surveillance Content for HD Handlers

CSMC Surveillance Plan
To be determined in collaboration with:
Peggy Miles, MD,
Jonathan Grein, MD,
Sarah Kilpatrick, MD,
Risk Management,
HR,
Employee Health

	NIOSH (1)	(2)	ONS (3)	ISOPP (4)	ashp (5)	OSHA (6)	USP (7)
Medical and exposure history	✓	✓	✓	✓	✓	✓	✓
Physical exam	✓	✓	✓	✓	✓	✓	✓
Routine labs	✓	✓	✓	✓	✓	✓	✓
Specialized tests	✓ *		✓ *	✓ **		✓ ***	✓ ***

* Biological monitoring as needed for workers who have shown health changes suggesting toxicity or who have experienced acute exposure (spill)
** Follow up recommended for workers who have shown health changes and/or have been exposed to HDs.
*** Post-exposure evaluation is tailored to the type of exposure; treatment and laboratory studies follow as indicated

1. NIOSH [2013]. Medical Surveillance for Healthcare Workers Exposed to Hazardous Drugs. National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2013-103. [http://www.cdc.gov/niosh/docs/wp-solutions/2013-103/pdfs/2013-103.pdf]. NIOSH [2004]. NIOSH alert: preventing occupational exposure to antineoplastic and other hazardous drugs in health care settings. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.
2. Department of the Army (2014). Technical Bulletin. Occupational and Environmental Health. Occupational Health and Industrial Hygiene Guidance for the Management, use and Disposal of Hazardous Drugs.
3. Polovich, M [2011]. Safe handling of hazardous drugs. 2nd ed. Pittsburgh, PA: Onc Nurs Soc.
4. ISOPP (International Society of Oncology Pharmacy Practitioners) [2007]. Standards of Practice. Safe Handling of Cytotoxics.
5. ASHP (American Society of Health-System Pharmacists) [2006]. Guidelines on handling hazardous drugs. Am J of Health Syst Pharm 63:1172-1193.
6. OSHA [1999]. OSHA technical manual, TED 1-0.15A, Sec VI, Chapt II: Categorization of drugs as hazardous. [www.osha.gov/dts/osta/ otm/otm_vi/otm_vi_2.html#2]. Date accessed:

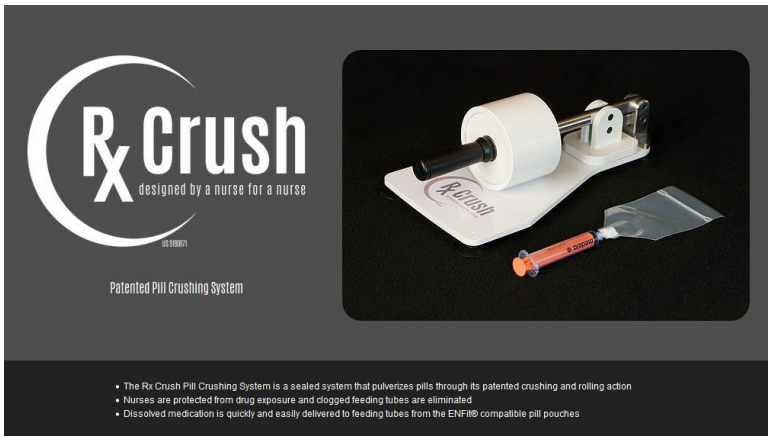
13

USP 800 Hazardous Drugs – Chapter and Status

1. List of HD (90% done)
2. Type of Exposure (done)
3. Responsibilities Personnel Handling HD (70% done)
4. Facilities & Engineering Controls (80% done, contingent on Facility completion)
5. Environmental Quality and Control (not started; Wipe Sampling)
6. Personal Protective Equipment (90% done)
7. HD Communication Program (50% done)
8. Personnel Training (to start 8/19)
9. Receiving (9/17 done)
10. Labeling (1/19 done), Packaging, Transport, Disposal (9/17 done)
11. Dispensing Final Dosage Forms (80% done)
12. Compounding (90% done)
13. Administering (90% done)
14. Deactivating, Decontaminating, Cleaning, Disinfecting (80% done)
15. Spill Control (80% done)
16. Documentation & SOPs (50% done)
17. Medical Surveillance (50% done)

14

Pill Crushing System – Self Contained; Works with ENFit*



*ENfit™ Prevention of enteral feeding misconnection, required in California, effective 7/16. Manufacturer issues delayed implementation

- Self-contained
- Current disposable device: $4.35/dose
- Rx Crush Cost:
  Device: $225-does not come into contact with medication
  Bag: $1.00/dose

15 https://www.bing.com/videos/search?q=rxcrush&pc=MOZI&ru=%2fsearch%3fq%3drxcrush%26pc%3dMOZI%26form%3dMOZLBR&view=detail&mmscn=vwrc&mid=50C65E2E547C23B1499950C65E2E547C23B14999&FORM=WRVORC, accessed 13119

Key Considerations

–Hazard Communication Plan and Workforce Considerations
- Determination of employee job classifications to be training
- Contingency planning for staffing based on reproductive concerns

–Budget impact of Personnel Protective Equipment and disposables across CSHS

–Medical Surveillance scope decision

–Waste management and storage

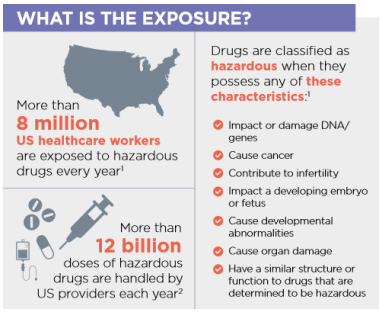
–CSHS unlicensed sites compliance determination

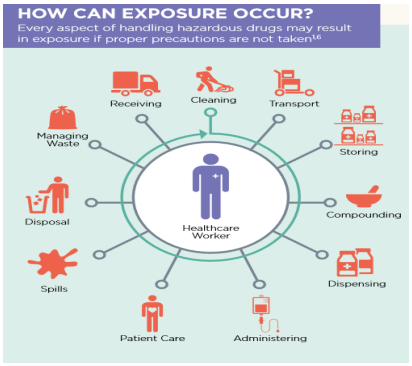
16

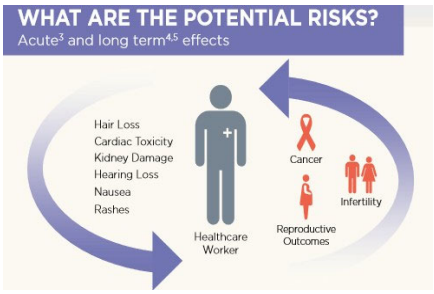
Appendix

17

USP 800 Infographic (excerpt)







http://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare, accessed 13119

USP 800 Hazardous Drugs Chapters

1. Introduction Scope
2. List of HD
3. Type of Exposure
4. Responsibilities of Personnel Handling HDs
5. Facilities & Engineering Controls
6. Personnel Training
7. Personal Protective Equipment
8. HD Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, Disinfecting
16. Spill Control
17. Documentation & SOPs
18. Medical Surveillance

19

PPE Unit Costs – Pharmacy Sterile Compounding Areas Estimate

PPE Item	Cost Per Unit	Est Pharmacy Cost/Day
Gloves: Sterile chemo	$1.35	x 300 = $405
Mask (isolation)	$0.05	x 200 = $10
Mask surgical duckbill	$0.08	x 50 = $4
Mask N95	$1.14	x 50 = $57
R95 Mask (Odors cleaning soln)	$3.19	
Bouf Surg Cap	$0.03	x 300 = $9
Isolation gown (yellow)	$0.52	N/A
Chemo gown	$0.83	x 75 = $63
Splashguard Visor Mask (Can be Reusable)	$0.46	N/A
Eye shield (Can be Reusable)	$1.21	N/A
Goggles (Can be Reusable)	$0.23	N/A
Chemo Spill Kit	$24.35	Rarely used
PAPR	Reusable – cleaning required-Cartridges costs	
Closed System Transfer Devices	Varied	12 month Expense in Pharmacy $400,000

Need estimated costs for additional areas(non-sterile compounding, pharmacy, nursing, EVS, dietary, etc)

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

March 27, 2019

Heidi Steinecker, Deputy Director
California Department of Public Health
Center for Health Care Quality
P.O. Box 99737
Sacramento, CA 95899-3201

Subject: Sterile Compounding Applications Process

Dear Ms. Steinecker:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) respectfully requests that the California Department of Public Health (CDPH) rescind its recent decision to require all sterile compounding pharmacy applications be completed before being sent CDPH for review. The interpretation that all applications must be complete is not founded in the recently passed law related to hospital application timelines, and will significantly delay the time-sensitive sterile compounding projects.

As you know, CDPH, the Office of Statewide Health Planning and Development (OSHPD), and the Board of Pharmacy (BoP) have worked collaboratively with CHA to develop an agreed upon process for hospitals to follow related to sterile compounding requirements. The partnership involved a year of extensive planning, development and coordination to assure precise activity alignment and meet sterile compounding regulations in a timely manner. This new interpretation will significantly confuse stakeholders, cause construction delays, and threatens the availability of life saving medications.

Legal Opinion
Assembly Bill 2798 (Chapter 922, Statutes of 2018), which took effect January 1, 2019, states:

If a general acute care hospital or an acute psychiatric hospital submits a written application to the department's centralized applications unit, the department shall do both of the following:
(1) Complete its evaluation and approve or deny the application within 100 days of receiving it, including completing any activities pursuant to paragraph (2).

(2) Once the written application is approved, the district office shall … (Health and Safety Code 1272 (a)).

The same law requires CDPH to act upon an application within 30 days of 'receipt of the completed application' (Health and Safety Code 1272 (b)). If the Legislature had intended to require all applications to be complete before submission to CDPH, it would have stated so in the law.

It is important to note that the law does not prohibit submitting an incomplete application, which was the process agreed upon with OSHPD, BoP and CDPH in 2018.

Background
California compounding legislation (SB 294) was signed into law in 2014 to regulate sterile compounding pharmacies in the wake of national news reports of deaths and illness from contaminated compounded products shipped to patients throughout the country. The bill increased state oversight of compounding pharmacies in and outside the state by requiring a sterile compounding pharmacy license from the California State Board of Pharmacy. Comprehensive regulatory changes for AB 294 have included amendments to multiple sections of Article 4.5 and Article 7 of Division 17 of Title 16 of the California Code of Regulations, governing preparation of sterile, non-sterile and hazardous compounded drugs.

The new regulations were approved by the Office of Administrative Law and went into effect January 1, 2017. These regulations closely align with the pending pharmacy compounding chapters of the United States Pharmacopeia (USP)-National Formulary (USP 41-NF36). Because significant pharmacy physical plant changes were required, the state regulations established a waiver mechanism allowing pharmacies to request a compliance delay for requirements related to physical construction or alteration. The waiver remains in effect under current law but would not be available once the USP standards are finalized and promulgated by the state as official state sterile compounding law. The USP standards are pending finalization December 1, 2019.

Hospitals and health systems produce both hazardous and non-hazardous drugs. Both types require primary (space) and secondary (hoods/compounding aseptic isolators) engineering control upgrades per USP standards and state regulations. While some hospitals meet all the engineering requirements for both, many hospital pharmacies required physical plant upgrades, particularly for hazardous compounding. The substantial financial commitment and the complex coordination between numerous regulatory bodies, engineers, and contractors may delay hospitals in meeting the pending USP deadline despite efficient planning and project management.

The latest, additional requirement from CDPH will further burden already strained timelines.

Hospital Construction Progress
CHA understands there are approximately 237 hospitals with plans submitted to OSHPD for changes in their physical pharmacy plants. The available data show that hospitals are in various states of construction or planning: 27 percent have plans under review at OSHDP; 13 percent have approved plans but have not started construction; 21 percent have started construction but have completed less than 50 percent of the project; 20 percent have greater than half of the project completed; 19 percent are in the construction phase, but there is no information as to the percentage of completion of the project. CHA is committed to working with our member hospitals to ensure they are making needed progress on this tight timeframe.

Patient Care at Risk
CDPH's policy change has significant patient care implications. If hospitals are unable to meet the December 2019 deadline, because the timeline has been extended by 100 days there may be a shortage of these critical medications. Impacted hazardous medications include oncological agents, as well as reproductive agents such as oxytocin. The 100-day delay will only compound the delays and threaten an adequate supply of both hazardous and non-hazardous medications necessary for patient care.

Thank you in advance for your consideration of this request to rescind the CDPH decision requiring applications related to sterile compounding. We look forward to working with the department, along with OSHPD and BoP, to find solutions that will ensure patients in California have access to needed medications compounded by hospital and other pharmacies.

If you have any questions, please do not hesitate to contact me at bjbartleson@calhospital.org or (916) 552-7537.

Sincerely,

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 3, 2019

TO: Medication Safety Committee Members

FROM: BJ Bartleson, MS, RN, NEA-BC, Vice President, Nursing & Clinical Services
Rita Shane, Pharm D, FASHP, FCHP, Cedars-Sinai Medical Center
Sarah Stephens, Pharm.D, BCPS, CPPS, Kaweah Delta Health District

SUBJECT: SB 1254 Update

SUMMARY

Following the passage of SB 1254, hospitals have been establishing their medication profiles for high-risk patients upon admission to perform medication profiles. On January 15, CHA convened a webinar with experts to explain the bill provisions and learn about nuances within the law. Examples were given from 3 hospital/health system sites who are in different stages of implementation.

Several members are collaborating to discuss potential research on patient care outcomes before and after the bill implementation.

DISCUSSION

1) How is the implementation of SB 1254 going? Are there any new issues?
2) What further discussion occurred regarding follow up research?

BJB:br

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 3, 2019

TO: Medication Safety Committee Members

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

SUBJECT: Biosimilars

SUMMARY

Aetna had indicated via a certification letter that they were selecting a specific biosimilar for use, analogous to the payer dictating which generic to use. They have designated Fulphila as the preferred biosimilar for cancer patients who are at risk for neutropenia. This poses numerous issues for hospitals affected. There is risk of an immune reaction when replacing a specific biosimilar, and the decision-making authority for what drugs are used for hospital patients are defined by regulatory agencies as part of the formulary process. See attached, Cedars-Sinai SBAR and Illustrative Case.

This puts the patient at risk and burdens the hospitals by having to increase inventory, increase EMR build out, ensuring right drug ordered based on payer, dispensed and billed- compounds risk of wrong drug due to mix-up of products and associated immunogenicity reactions.

CHA has had extensive discussions with DMHC. DMHC, while willing to clarify its certification letter, is unwilling to withdraw its intent. CHA is working with AHA and needs to collect any and all hospitals/health systems this affects.

DISCUSSION

1) Does this affect your hospital?
2) Do you have concerns?

ACTION REQUESTED

- Contact BJ if this is affecting you.

Attachments: Biosimilar Implications
Biosimilar Illustrative Case

BJB:br

Biosimilar Selection by Payers: Implications and Challenges

S/B: Payers such as Aetna are selecting which biosimilar drugs are to be administered in hospitals and health-systems as well as provider-based program. The designation of which biosimilar we should use is analogous to the payer telling us which company's generic drug to use. We would need to stock a different generic for each payer and ensure it was dispensed to the right patient based on the respective payer.

For example, Aetna has designated Fulphila® as the preferred biosimilar for cancer patients who are at risk for febrile neutropenia (low white blood count leading to hospitalization due to risk of life-threatening infections). This is likely due to an arrangement that the payer or their prescription benefit manager has with the manufacturer.

Biosimilar drugs are considered therapeutically equivalent, however, because they are made from living organisms, there is a risk of an immune reaction if patients are switched from one product to another.

The decision-making authority for which drugs are used for hospital patients are defined by regulatory agencies as part of the formulary process as described below.

Regulatory Agency	Regulatory Reference	Regulatory Language
The Joint Commission (TJC)	MM.02.01.01	• Members of the medical staff, licensed independent practitioners, pharmacists, and staff involved in ordering, dispensing, administering, and/or monitoring the effects of medications develop written criteria for determining which medications are available for dispensing or administering to patients. Note: This element of performance is also applicable to sample medications. • The hospital maintains a formulary, including medication strength and dosage. Note 1: Sample medications are not required to be on the formulary. Note 2: In some settings, the term "list of medications available for use" is used instead of "formulary." The terms are synonymous.
The Centers of Medicare and Medicaid Services (CMS) conditions of participation	482.25(b)(9)	A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs

Regulatory Agency	Regulatory Reference	Regulatory Language
The California Department of Public Health (CDPH)	Title 22 – 70263(c)	(c) A pharmacy and therapeutics committee, or a committee of equivalent composition, shall be established. The committee shall consist of at least one physician, one pharmacist, the director of nursing service or her representative and the administrator or his representative. (1) The committee shall develop written policies and procedures for establishment of safe and effective systems for procurement, storage, distribution, dispensing and use of drugs and chemicals. The pharmacist in consultation with other appropriate health professionals and administration shall be responsible for the development and implementations of procedures. Policies shall be approved by the governing body. Procedures shall be approved by the administration and medical staff where such is appropriate. (2) **The committee shall be responsible for the development and maintenance of a formulary of drugs for use throughout the hospital**.

Additionally, there are significant operational, financial, safety and revenue compliance (different billing codes for different products) implications if payers designate which biosimilar product we should use.

Example (continued from above)

- Fulphila® is one of 2 biosimilars for peg-filgrastim
- Fulphila® has a Q code;
- Peg-filgrastim has a J code
- CHS-1701 (Coherus) is another biosimilar approved in November that will have a different Q code,

If each payer determines a different biosimilar, we would need to

- Purchase all 3 for inventory
- Build out all 3 in the EHR
- Ensure the right one is ordered based on payer, dispensed and billed
- Increased risk of mixup of products and associated immunogenicity reaction.

Biosimilar Selection by Payers: Implications and Challenges

Patient implications and considerations

- A requirement to have a specific biosimilar available based on the patient's health plan would require significant resources to procure, store, label and dispense the payer-specific biosimilar" to the patient. If this became the standard, given the number of biosimilars expected to become available (see below*), the additional time involved to order, store, label and pick the "right payer-specific drug" would add complexity to these processes. The consequence would be a significant increase in the risk of harmful medication errors by adding more steps and time to medication management processes**

- Since each biosimilar has a different code for billing, if there is a mixup of drugs, and the payer-specific biosimilar is not the one that is given, the payer would deny the payment and the patient would be responsible for paying the full cost of the medication.

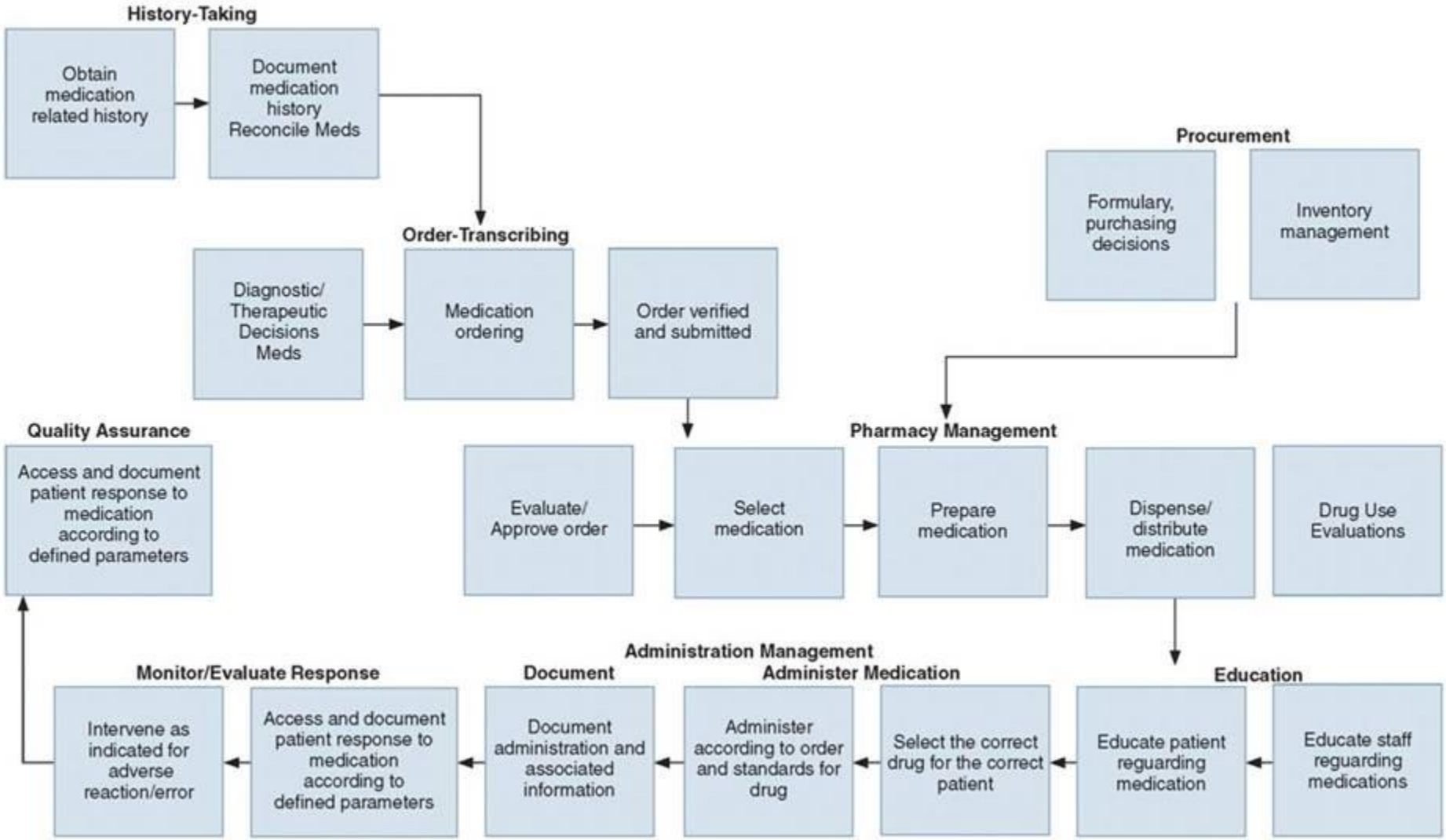
- It would be important to determine if the payer decision to specify which biosimilar is to be used is based on financial benefit to the payer.

A/R: Incorporate language into our contracts that specifies: As biosimilars become commercially available, the medical center will determine which medication will be used based on the evaluation by the Pharmacy and Therapeutics Committee. This P&T Committee's responsibility for formulary decision-making is required by CMS, The Joint Commission and the California Department of Public Health

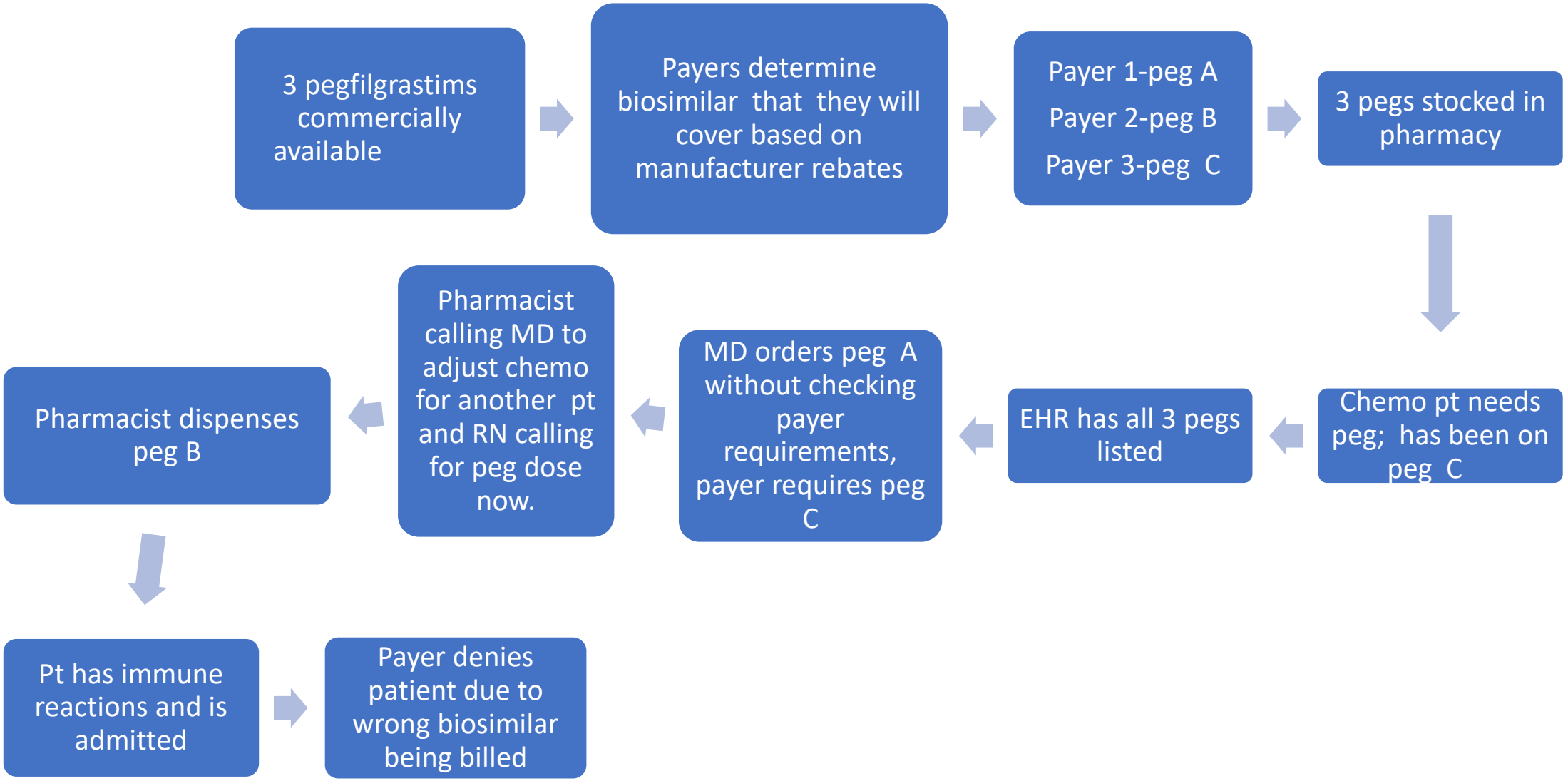
*There are currently 11 biosimilars approved in the US with 260 approved in some international market and 188 more in development (https://www.businesswire.com/news/home/20180615005799/en/Charting-Global-Biosimilar-Pipeline-2018-Biosimilars-Development). The FDA approval process for biosimilars was approved in 2010; the process is rigorous which is why the initial release has been slow.

**Medication Management Processes-see next page

Rita Shane, Pharm.D., FASHP, FCSHP
Chief Pharmacy Officer
Professor of Medicine
Cedars-Sinai Medical Center


History-Taking
Obtain medication related history
Document medication history Reconcile Meds
Procurement
Formulary, purchasing decisions
Inventory management
Order-Transcribing
Diagnostic/ Therapeutic Decisions Meds
Medication ordering
Order verified and submitted
Quality Assurance
Access and document patient response to medication according to defined parameters
Pharmacy Management
Evaluate/ Approve order
Select medication
Prepare medication
Dispense/ distribute medication
Drug Use Evaluations
Administration Management
Monitor/Evaluate Response
Document
Administer Medication
Education
Intervene as indicated for adverse reaction/error
Access and document patient response to medication according to defined parameters
Document administration and associated information
Administer according to order and standards for drug
Select the correct drug for the correct patient
Educate patient reguarding medication
Educate staff reguarding medications

Biosimilar Illustrative Case



CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

DATE: April 3, 2019

TO: Medication Safety Committee Members

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

SUBJECT: 2019-20 Legislation

SUMMARY

The activity level in policy committees is high, as hearings are scheduled on several hundred bills that must be acted on by the April 26th deadline.

Clean up bills for AB 2760 (Wood) and AB 1753 (Low) are in place- AB 149 (Cooper), the clean up bill for AB 2760 (Low) was approved and chaptered, Chapter 4, Statutes of 2019. This will facilitate the delay in the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2021. An additional six-month exemption clause is available if delays persist.

AB 714 was re-referred to committee for some amendments that included site exemptions and clarifying language.

DISCUSSION

1) **AB 387 (Gabriel)** - Physician and surgeon prescription – indicate the purpose on the prescription unless the patient opts out. **Does this affect operations?**

2) **AB 528 (Low) –** Controlled substances CURES database- information required in one working day. **Is this an operational issue?**

3) **AB 690 (Agular-Curry) –** See attached **suggested amends** from Rita, the bill, and **fact sheet**. The amendments would require the 1000-hour experience requirement within the previous year of the new role, and narrow the Pharm Tech ratio to 1:3 for these roles**. Any concerns about these changes?**

4) **AB 973(Irwin) –** Would impose USP-NF as state compounding regulations.

5) **AB 1468 (McCarty)-** manufacturer tax that could be passed on to hospitals- we are watching closely- what is your interpretation? See attached bill. **Do we need to amend hospitals out?**

6) **SB 159 (Wiener) –** HIV: Pre-exposure and post-exposure prophylaxis – authorizes a pharmacist to initiate and furnish if a pharmacist completes a training program. **Do you support and should we?**

7) **SB 476 (Stone) –** Pharmacist in charge, disciplinary proceedings. Would exempt a PIC from disciplinary actions for a violation of another person of which the pharmacist had no knowledge. **Who is the sponsor? Is this appropriate and how would members like us to move forward?**

8) **SB 491 (Stone) –** Would authorize a pharmacy that provides compounding services to manufacture a non-patient specific dangerous drug for a general acute care hospital to help alleviate a commercial shortage. **Who does this apply to? Is it feasible? How should CHA move forward?**

9) **SB 655 (Roth)** – Pharm tech. This bill changes the requirement for a pharm tech and require the externship to be for a period of no fewer than 120 hours and no more than 140 hours. **Is this acceptable – who is the sponsor? Does CHA need to weigh in?**

ACTION REQUESTED

- Please review and comment, particularly on any opposing bills?
- Please inform committee members of any other bills not listed?

Attachments: 2019-20 Pharmacy Bills
AB 690 Suggesed Amends (Shane)
AB 690
AB 690 Fact Sheet
AB 1468

BJB:br

AB 149 **(Cooper D) Controlled substances: prescriptions.**

Status: 3/11/2019-Approved by the Governor. Chaptered by Secretary of State - Chapter 4, Statutes of 2019.

Summary: Current law classifies certain controlled substances into designated schedules. Current law requires prescription forms for controlled substance prescriptions to be obtained from security printers approved by the department, as specified. Current law requires those prescription forms to be printed with specified features, including a uniquely serialized number. This bill would delay the requirement for those prescription forms to include a uniquely serialized number until a date determined by the Department of Justice that is no later than January 1, 2020. The bill would require, among other things, the serialized number to be utilizable as a barcode that may be scanned by dispensers.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
S		AH, MS*	BJ*, LR	Pharmacy

AB 387 **(Gabriel D) Physician and surgeons: prescriptions.**

Status: 2/15/2019-Referred to Com. on B. & P.

Summary: Would require a physician and surgeon to indicate the purpose for a drug or device on the prescription for that drug or device when providing a prescription to a patient unless the patient chooses to opt out of having the purpose for the drug or device included on the prescription.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		KAS*, MS	BJ	Medical Staff-Physician and Peer Review, Pharmacy

AB 528 **(Low D) Controlled substances: CURES database.**

Status: 2/21/2019-Referred to Com. on B. & P.

Summary: Would require a dispensing pharmacy, clinic, or other dispenser to report the information required by the CURES database no more than one working day after a controlled substance is dispensed.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

AB 544 **(Brough R) Professions and vocations: inactive license fees and accrued and unpaid renewal fees.**

Status: 3/25/2019-Re-referred to Com. on B. & P.

Summary: Current law provides for the licensure and regulation of professions and vocations by various boards within the Department of Consumer Affairs. Existing law provides for the payment of a fee for the renewal of certain licenses, certificates, or permits in an inactive status, and, for certain licenses, certificates, and permits that have expired, requires the payment of all accrued fees as a condition of reinstatement of the license, certificate, or permit. This bill would limit the maximum fee for the renewal of a license in an inactive status to no more than 50% of the renewal fee for an active license.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

AB 690 **(Aguiar-Curry D) Remote dispensing site pharmacy: pharmacy technician: qualifications.**

Status: 2/28/2019-Referred to Com. on B. & P.

Summary: Would establish qualifications for a registered pharmacy technician to work at a remote dispensing site pharmacy, relating to licensing, certification, education, and minimum work experience.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

AB 714 **(Wood D) Opioid prescription drugs: prescribers.**

Status: 3/26/2019-From committee: Do pass and re-refer to Com. on HEALTH. (Ayes 20. Noes 0.) (March 26). Re-referred to Com. on HEALTH.

Summary: Current law requires a prescriber, as defined, to offer to a patient a prescription for naloxone hydrochloride or another drug approved by the United States Food and Drug Administration for the complete or partial reversal of opioid depression when certain conditions are present, including if the patient presents with an increased risk for overdose or a history of substance use disorder, and to provide education on overdose prevention to patients receiving a prescription and specified other persons. This bill would make those provisions applicable only to a patient receiving a prescription for an opioid or benzodiazepine medication, and would make the provisions specific to opioid-induced respiratory depression, opioid overdose, opioid use disorder, and opioid overdose prevention, as specified.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
S		AH, MS*	BJ	Pharmacy

AB 824 **(Wood D) Business: preserving access to affordable drugs.**

Status: 3/27/2019-From committee: Do pass and re-refer to Com. on JUD. (Ayes 12. Noes 0.) (March 26). Re-referred to Com. on JUD.

Summary: Would provide that an agreement resolving or settling, on a final or interim basis, a patent infringement claim, in connection with the sale of a pharmaceutical product, is to be presumed to have anticompetitive effects if a non-reference drug filer receives anything of value from another company asserting patent infringement and if the non-reference drug filer agrees to limit or forego research, development, manufacturing, marketing, or sales of the non-reference drug filer's product for any period of time, as specified. The bill would provide various exceptions to this prohibition.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

AB 973 **(Irwin D) Pharmacies: compounding.**

Status: 3/26/2019-From committee: Do pass and re-refer to Com. on APPR. (Ayes 20. Noes 0.) (March 26). Re-referred to Com. on APPR.

Summary: Would require the compounding of drug preparations by a pharmacy for furnishing, distribution, or use to be consistent with standards established in the pharmacy compounding chapters of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The bill, by imposing a new requirement on pharmacies, the violation of which would be a crime, would impose a state-mandated local program. The bill would authorize the California State Board of Pharmacy to adopt regulations to impose additional standards for compounding drug preparations.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

AB 1468 **(McCarty D) Opioid Prevention and Rehabilitation Act.**

Status: 3/14/2019-Referred to Com. on HEALTH.

Summary: Would, commencing with the 2021–22 fiscal year, require a manufacturer or wholesaler that sells or distributes opioid drugs in this state to submit to the State Department of Public Health a report, including specified information, that details all opioid drugs sold or distributed in this state during the preceding fiscal year. The bill would, commencing with the 2021–22 fiscal year, require the department, in consultation with the board, to calculate the ratable share of a manufacturer or wholesaler, which is the individual portion of the collective sum of $100,000,000 to be paid by the manufacturers and wholesalers, based on the information reported.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MR, MS*	BJ	Pharmacy

AB 1803 **(Committee on Health) Pharmacy: healthcare coverage: claims for prescription drugs sold for retail price.**

Status: 3/21/2019-Referred to Com. on HEALTH.

Summary: The Pharmacy Law requires a pharmacy to inform a customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug, except as specified, and, if the customer pays the retail price, requires the pharmacy to submit the claim to the customer's health care service plan or health insurer. This bill would instead make the provision requiring the pharmacy to submit the claim to the health care service plan or health insurer operative on January 1, 2020. The bill would also repeal a provision that is similar to the provision being amended by the bill.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	AK	Medi-Cal Managed Care, Pharmacy

SB 159 **(Wiener D) HIV: preexposure and postexposure prophylaxis.**

Status: 3/19/2019-Set for hearing April 3.

Summary: Would authorize a pharmacist to initiate and furnish preexposure prophylaxis and postexposure prophylaxis if a pharmacist completes a training program approved by the California State Board of Pharmacy, complies with specified requirements, such as assessing a patient and providing a patient with counseling and tests, and provides these services in a private and sanitary location. Because a violation of these requirements would be a crime, this bill would impose a state-mandated local program.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS*	BJ	Pharmacy

SB 476 **(Stone R) Pharmacist-in-charge: disciplinary proceedings.**

Status: 3/26/2019-From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.

Summary: The Pharmacy Law requires the California State Board of Pharmacy, if it disciplines a pharmacist-in-charge for the violation of a state or federal law or regulation committed by another person and the pharmacist-in-charge reported to the board that violation or suspected violation, to use the report as a mitigating factor if prescribed conditions are met. This bill would revise that mitigating factor provision to, instead, exempt a pharmacist-in-charge from disciplinary action by the board for the violation of a state or federal law or regulation committed by another person of which the pharmacist-in-charge had no knowledge, or in which the pharmacist-in-charge did not knowingly participate, if prescribed conditions are met.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

SB 491 **(Stone R) Pharmacies: compounding.**

Status: 3/7/2019-Referred to Com. on B., P. & E.D.

Summary: This bill would authorize a pharmacy that provides compounding services to manufacture a nonpatient-specific dangerous drug for a general acute care hospital in order to help alleviate a commercial shortage of that drug.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

SB 569 **(Stone R) Pharmacy.**

Status: 3/7/2019-Referred to Com. on RLS.

Summary: Current law, the Pharmacy Law, provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. This bill would make a nonsubstantive change to this provision.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

SB 624 **(Wilk R) Qualified medical supplies providers: sales taxes: repayment.**

Status: 3/14/2019-Referred to Com. on GOV. & F.

Summary: Would provide a procedure for a qualified medical supplies provider to submit a claim for qualified repayments, as defined, with the California Department of Tax and Fee Administration, as provided.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH*, BG	RW	Medi-Cal Managed Care, Pharmacy

SB 650 **(Rubio D) Unused medications: cancer medication recycling.**

Status: 3/27/2019-From committee with author's amendments. Read second time and amended. Re-referred to Com. on RLS.

Summary: Would establish a program for the collection and distribution of unused cancer medications, to be known as the Cancer Medication Recycling Act. The bill would require each participating practitioner, as defined, in the collection and distribution of those medications to be licensed by the board, as specified, and would require the California State Board of Pharmacy to create a registry for participating practitioners, including developing both a donor and a recipient form containing specified information. The bill would authorize the board to charge a fee, not to exceed $300, as specified, to issue or renew the license of a participating practitioner under the program.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		AH, MS*	BJ	Pharmacy

SB 655 **(Roth D) Pharmacy.**

Status: 3/27/2019-From committee with author's amendments. Read second time and amended. Re-referred to Com. on B., P. & E.D.

Summary: The Pharmacy Law provides for the licensing and regulation of pharmacists and pharmacies by the California State Board of Pharmacy in the Department of Consumer Affairs. That law authorizes a pharmacy technician trainee to be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacist. That law prohibits the externship from being for a period of more than 120 hours, except if a pharmacy technician trainee's externship involves the rotation between a community pharmacy and a hospital pharmacy, in which case the externship is authorized to be for a period of up to 320 hours. That law prohibits more than 120 hours of the 320 hours from being completed in a community pharmacy setting or in a single department in a hospital pharmacy. This bill would instead require the externship to be for a period of

no fewer than 120 hours and no more than 140 hours.

CHA Position	Priority	Lobbyist	Issues	CHA Subject
F		MS	BJ	Pharmacy

Total Measures: 17
Total Tracking Forms: 17

California State Board of Pharmacy – AB 690
Proposed Regulations – Comments

Institution/Contact	Cedars-Sinai Medical Center Department of Pharmacy Services 310-423-5611 Rita Shane, Pharm.D., Chief Pharmacy Officer; shane@cshs.org

Subdivision	**Proposed Language**	**Recommendations/ Comments**
(a)(4) Page 2: lines 19-21	(4) Complete a minimum of 1,000 hours of experience working as a pharmacy technician within the three years preceding first commencing work in the remote dispensing site pharmacy.	**Recommendations:** Revise proposed regulation to: "Complete a minimum of 1,000 hours of experience working as a pharmacy technician within the one year preceding first commencing work in the remote dispensing site pharmacy." **Comments:** - 1000 hours is roughly equivalent to a cumulative 6 months of work; this number of hours dispersed across a period of 3 years may not be sufficient to ensure proficiency to safely work in a remote dispensing site. - The recommendation is that the required hours be completed within one year preceding first commencing work in the remote dispensing site.
(d) Page 3: lines 15-19	(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.	**Recommendation:** Revise proposed regulation to: "Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy; not to exceed a total of 3 technicians to be supervised at all sites. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy; however, these technicians will be included in the total count allowable." **Comments:** - Nationally, a pharmacist/technician ratio is more commonly between 1:3 (an additional 1 if certified = 4) and 1:4. - The recommendation is to establish a pharmacist/technician ratio of a maximum of 1:3, as anything above this ratio may not ensure safe practices at the remote dispensing sites and may hinder patient safety.

ASSEMBLY BILL No. 690

Introduced by Assembly Member Aguiar-Curry

February 15, 2019

An act to amend Section 4132 of the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 690, as introduced, Aguiar-Curry. Remote dispensing site pharmacy: pharmacy technician: qualifications.

The Pharmacy Law requires the California State Board of Pharmacy within the Department of Consumer Affairs to license and regulate the practice of pharmacy, including pharmacists, pharmacy technicians, and pharmacies. The Pharmacy Law requires the board to issue a remote dispensing site pharmacy license to a supervising pharmacy, as defined, of a remote dispensing site pharmacy, as defined, if certain requirements are met. The Pharmacy Law authorizes a registered pharmacy technician who meets certain requirements, including meeting qualifications established in regulations adopted by the board, to work at a remote dispensing site pharmacy and perform specific tasks under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

This bill would establish qualifications for a registered pharmacy technician to work at a remote dispensing site pharmacy, relating to licensing, certification, education, and minimum work experience.

The Pharmacy Law makes a knowing violation of any of its provisions punishable as a crime.

By expanding the scope of an existing crime, this bill would result in a state-mandated local program.

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

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

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

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

SECTION 1. Section 4132 of the Business and Professions Code is amended to read:

4132. (a) In addition to the requirements of Section 4202, a pharmacy technician ~~working at a remote dispensing site pharmacy~~ shall ~~meet the qualifications promulgated by the board. The regulations developed by the board shall only apply to pharmacy technicians~~ *satisfy each of the following requirements before* working at *a* remote dispensing ~~sites.~~ *site pharmacy:*

(1) Possess a pharmacy technician license that is in good standing.

(2) Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

(3) Possess one of the following:

(A) A minimum of an associate degree in pharmacy technology.

(B) A minimum of a bachelor's degree in any subject.

(C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.

(4) Complete a minimum of 1,000 hours of experience working as a pharmacy technician within the three years preceding first commencing work in the remote dispensing site pharmacy.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or his or her agent regarding a prescription, either ~~prior to~~ *before* or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(7) Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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AB 690 – TELEPHARMACY

SUMMARY

In 2017, the Legislature authorized the California Board of Pharmacy to issue remote dispensing pharmacy licenses for facilities to connect a licensed pharmacist to patients in rural communities through telepharmacy technology. These remote dispensing pharmacies are staffed by a registered pharmacy technician on a day-to-day basis, while the "pharmacist-in-charge" provides supervision, oversight, and consultation from another pharmacy location.

AB 690 would establish the qualifications necessary for a registered pharmacy technician to be eligible to work at such a remote dispensing site pharmacy.

BACKGROUND

AB 401 (Chapter 548, Statutes of 2017) created a state license for the development of remote dispensing pharmacies that use telepharmacy in "medically underserved areas," which are communities that do not have a pharmacy that serves the general public within 10 miles. There are approximately 102 identified areas in 41 counties that fit this description, with many at a distance much farther than 10 miles from a pharmacist.

To operate a remote dispensing pharmacy, a licensed California pharmacist must serve as the "pharmacist-in-charge." The remote site itself it staffed by registered pharmacy technician, who is virtually supervised by a licensed pharmacist at a separate location. The onsite technician prepares the prescriptions, which are reviewed and verified by the licensed pharmacist at the supervising pharmacy location. Through telepharmacy technology, the patient then receives live, interactive video counseling directly from the pharmacist when they pick up their prescriptions as if he or she were present in person.

People living in pharmacy-deprived areas, both rural and urban, face many barriers to obtaining comprehensive medical care. These patients desire more convenient access to their health care services, and remote pharmacy dispensing is a proven model to provide improved care that is both safe and effective. Making pharmacists more readily available can result in significant improvements to an individual's health and the health of entire communities that currently lack a pharmacist.

PROBLEM

Although AB 401 became law in 2017, there is no current authorization for licenses to be issued to remote dispensing pharmacies; and therefore, there is no existing use of telepharmacy in California. When the law was developed, the Board of Pharmacy was tasked with the responsibility of promulgating regulations that set the required additional training qualifications necessary for a pharmacy technician to work at a remote dispensing site. To date, the Board of Pharmacy has not yet been able to establish these regulations, and waiting could mean an additional two to five years before telepharmacy is a reality in California.

THIS BILL

AB 690 codifies draft regulations from the Board of Pharmacy that would require a licensed pharmacy technician to meet the following qualifications in order to work in a remote dispensing pharmacy:

1. Possess a pharmacy technician license that is in good standing;
2. Possess and maintain a certification issued by a board-approved pharmacy technician certification program;
3. Possess one of the following:
    a. Associate degree in pharmacy technology;
    b. Bachelor's degree in any subject; or
    c. Certificate of completion from a course of training specified by regulations adopted by the Board of Pharmacy; and,
4. Complete a minimum of 1,000 hours working as a pharmacy technician within three years prior to working at the remote dispensing site.

By codifying these standards, AB 690 will allow remote dispensing pharmacies to open and operate in areas of the state currently without pharmacy access. This will provide opportunities for improved patient education, increased medication adherence, and better overall health outcomes in these communities.

ASSEMBLY BILL No. 1468

Introduced by Assembly Members McCarty and Gallagher

February 22, 2019

An act to add and repeal Division 10.4 (commencing with Section 11730) of the Health and Safety Code, relating to opioids, and making an appropriation therefor, to take effect immediately, tax levy.

LEGISLATIVE COUNSEL'S DIGEST

AB 1468, as introduced, McCarty. Opioid Prevention and Rehabilitation Act.

Existing law establishes the State Department of Public Health, which has authority over various programs promoting public health. Existing law requires the department, subject to an appropriation in the Budget Act of 2016, to award naloxone grant funding to local health departments, local government agencies, or other specified entities, in order to reduce the rate of fatal overdose from opioid drugs, including heroin and prescription opioids.

Under existing law, the department licenses and regulates manufacturers of drugs or devices in this state, and the California State Board of Pharmacy licenses and regulates wholesalers of dangerous drugs or devices, as specified.

This bill would, commencing with the 2021–22 fiscal year, require a manufacturer or wholesaler that sells or distributes opioid drugs in this state to submit to the department a report, including specified information, that details all opioid drugs sold or distributed in this state during the preceding fiscal year. The bill would, commencing with the 2021–22 fiscal year, require the department, in consultation with the board, to calculate the ratable share of a manufacturer or wholesaler,

which is the individual portion of the collective sum of $100,000,000 to be paid by the manufacturers and wholesalers, based on the information reported. The bill would subject the manufacturer and wholesaler to specified civil penalties for failing to comply with the reporting or payment requirements.

The bill would require the deposit of the payments and penalties, less refunds and the department's administrative costs, into the continuously appropriated Opioid Prevention and Rehabilitation Program Fund, which the bill would create, thereby making an appropriation. The bill would require the department to distribute moneys in the fund to counties for purposes of opioid prevention and rehabilitation programs. The bill would base the distribution of moneys on county needs, using only specified information relating to opioid overdose in the counties.

This bill would make these provisions inoperative on July 1, 2027, and would repeal them as of January 1, 2028.

This bill would include a change in state statute that would result in a taxpayer paying a higher tax within the meaning of Section 3 of Article XIII A of the California Constitution, and thus would require for passage the approval of ⅔ of the membership of each house of the Legislature.

This bill would take effect immediately as a tax levy.

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

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

SECTION 1. Division 10.4 (commencing with Section 11730) is added to the Health and Safety Code, to read:

DIVISION 10.4. OPIOID PREVENTION AND REHABILITATION ACT

PART 1. GENERAL PROVISIONS

11730. (a) This division shall be known, and may be cited, as the Opioid Prevention and Rehabilitation Act.

(b) This division shall become inoperative on July 1, 2027, and, as of January 1, 2028, is repealed.

PART 2. DEFINITIONS

11731. For purposes of this division, the following definitions apply:

(a) "Department" means the State Department of Public Health.

(b) "Opioid stewardship payment" means the total amount to be paid into the Opioid Prevention and Rehabilitation Program Fund for each fiscal year, as described in Section 11734.

(c) "Ratable share" means the individual portion of the opioid stewardship payment to be paid by each manufacturer or wholesaler that is subject to this division.

(d) "Opioid" means an opiate or any synthetic or semisynthetic narcotic that has opiate-like activities but is not derived from opium and has effects similar to natural opium alkaloids, and any derivatives thereof.

(e) "Opiate" means the dried, condensed juice of a poppy, Papaver somniferum, that has a narcotic, soporific, analgesic, and astringent effect.

(f) "Distribute" or "distribution" means the delivery for sale of an opioid drug other than by administering or dispensing to the ultimate user, including intracompany transfers between any division, affiliate, subsidiary, parent, or other entity under complete common ownership and control.

PART 3. OPIOID SALE OR DISTRIBUTION REPORTING

11732. Commencing with the 2021–22 fiscal year, and for each fiscal year thereafter, a manufacturer or wholesaler that sells or distributes opioid drugs in this state shall submit to the department a report that details all opioid drugs sold or distributed by the manufacturer or wholesaler in this state during the preceding fiscal year. To the extent permitted by federal law, the report shall include all of the following information:

(a) The name, address, telephone number, federal Drug Enforcement Agency (DEA) registration number, and license number of the manufacturer or wholesaler, as applicable.

(b) The name, address, and DEA registration number of the entity to which the opioid drug was sold or distributed.

(c) The date of the sale or distribution of the opioid drug.

(d) The gross receipt total, in dollars, of all opioid drugs sold or distributed.

(e) The name and National Drug Code (NDC) of the opioid drug sold or distributed.

(f) The number of containers and the strength and metric quantity of controlled substances in each container of the opioid drug sold or distributed.

(g) The total number of morphine milligram equivalents (MMEs) attributed to the opioid drugs sold or distributed. MMEs shall be determined pursuant to a formulation that is issued by the department and updated as the department deems necessary to determine the ratable share pursuant to Section 11733.

(h) Any other elements relating to the sale or distribution of the opioid drug, as the department deems necessary to determine the ratable share pursuant to Section 11733.

PART 4. RATABLE SHARE DETERMINATION

11733. (a) Commencing with the 2021–22 fiscal year, and for each fiscal year thereafter, the department, in consultation with the California State Board of Pharmacy, shall calculate the ratable share of a manufacturer or wholesaler that is subject to Section 11732, according to all of the following steps:

(1) The total number of morphine milligram equivalents (MMEs) attributed to opioid drugs sold or distributed in this state by the manufacturer or wholesaler for the preceding fiscal year, as reported pursuant to Section 11732, shall be divided by the total number of MMEs attributed to opioid drugs sold or distributed in this state by all manufacturers and wholesalers subject to this division for the preceding fiscal year, in order to determine the payment percentage for the manufacturer or wholesaler.

(2) The payment percentage shall be multiplied by the opioid stewardship payment, as described in Section 11734.

(3) The product of the calculation described in paragraph (2) shall be the manufacturer’s or wholesaler’s ratable share.

(4) For purposes of the calculation of the ratable share, the total number of MMEs attributed to opioid drugs sold or distributed by a manufacturer or wholesaler shall not include either of the following:

(A) The number of MMEs attributed to opioid drugs that are manufactured in this state but the final point of delivery or sale of which is outside this state.

(B) The number of MMEs attributed to buprenorphine, methadone, or morphine.

(b) The department shall notify the manufacturer or wholesaler, in writing, of the value of the ratable share for that manufacturer or wholesaler.

(c) In any fiscal year for which the department determines that a manufacturer or wholesaler that is subject to Section 11732 failed to report information required pursuant to Section 11732, the department shall estimate, based on available data, the number of MMEs attributed to opioid drugs sold or distributed by that manufacturer or wholesaler, and the other manufacturers and wholesalers complying with this division shall receive a decreased assessment of their corresponding ratable share in the following fiscal year, with the decrease equaling the amount that was overpaid by that compliant manufacturer or wholesaler in the current fiscal year.

(d) (1) The manufacturer or wholesaler shall have the opportunity to appeal the ratable share determination by submitting information to the department explaining why the ratable share determined pursuant to this section is erroneous or otherwise not warranted.

(2) Upon receipt of the information described in paragraph (1), if the department determines that all or a portion of the ratable share is not warranted, the department may do one of the following:

(A) Adjust the ratable share if the payment has not yet been made.

(B) Adjust the assessment of the ratable share in the following fiscal year by decreasing the ratable share by the amount that was overpaid in the current fiscal year.

(C) Refund the amount that was overpaid.

PART 5. RATABLE SHARE PAYMENT

11734. (a) Commencing with the 2021–22 fiscal year, and for each fiscal year thereafter, a manufacturer or a wholesaler subject to this division shall make quarterly payments, to the department,

of the manufacturer's or wholesaler's corresponding ratable share of the opioid stewardship payment.

(b) A manufacturer or wholesaler shall not pass the cost of the ratable share quarterly payment to the purchaser of the opioid drug, including the ultimate user of the opioid drug.

(c) All ratable share payments described in subdivision (a), less refunds and the department's administrative costs, shall be deposited quarterly into the Opioid Prevention and Rehabilitation Program Fund created pursuant to Section 11736.

(d) (1) The opioid stewardship payment shall be equal to one hundred million dollars ($100,000,000) for each fiscal year, which shall be the amount used to calculate the ratable share for a manufacturer or wholesaler pursuant to Section 11733.

(2) Notwithstanding paragraph (1), the combined sum of ratable share payments by manufacturers and wholesalers may be less than one hundred million dollars ($100,000,000) in a fiscal year, if the department makes adjustments to the ratable share of a manufacturer or wholesaler pursuant to Section 11733.

PART 6. PENALTIES

11735. (a) A manufacturer or wholesaler that fails to comply with the reporting requirements described in Section 11732 shall be subject to a civil penalty not exceeding one thousand dollars ($1,000) per calendar day.

(b) A manufacturer or wholesaler that fails to make a ratable share quarterly payment pursuant to subdivision (a) of Section 11734 shall be subject to a civil penalty of not less than 10 percent of, and not greater than 300 percent of, the ratable share quarterly payment that is due.

(c) A manufacturer or wholesaler that fails to comply with subdivision (b) of Section 11734, by passing the cost of the ratable share quarterly payment to the purchaser of the opioid drug, shall be subject to a civil penalty not exceeding one million dollars ($1,000,000) per incident.

11735.1. Any penalties collected pursuant to Section 11735 shall be deposited in the Opioid Prevention and Rehabilitation Program Fund created pursuant to Section 11736.

PART 7. OPIOID PREVENTION AND REHABILITATION PROGRAM FUND

11736. (a) There is hereby created in the State Treasury the Opioid Prevention and Rehabilitation Program Fund.

(b) Notwithstanding Section 13340 of the Government Code, all moneys in the fund are continuously appropriated to the department to carry out the purposes described in Section 11736.1.

11736.1. (a) The department shall distribute moneys in the Opioid Prevention and Rehabilitation Program Fund to counties on an annual basis pursuant to subdivision (b) for purposes of opioid prevention and rehabilitation programs.

(b) Distribution of moneys in the fund to counties shall be based on county needs, using the most recent data of only the following information, as provided by the department:

(1) The ratio of opioid overdose deaths per county population.

(2) The ratio of opioid overdose emergency department visits per county population.

(3) The ratio of opioid overdose hospitalizations per county population.

SEC. 2. This act provides for a tax levy within the meaning of Article IV of the California Constitution and shall go into immediate effect.

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ALSTON & BIRD

EPA'S HAZARDOUS WASTE PHARMACEUTICAL RULE

What Health Care Facilities Need to Know

 www.alston.com

Speakers

Elise Paeffgen

Kevin Minoli

5 Things Healthcare Facilities Need to Know

1. You might be generating hazardous waste... and definitely solid waste
2. No more counting HWPs generated per month
3. No more segregating acute HWPs
4. No more triple-rinsing empty containers
5. No more flushing - *sewer ban takes effect this August*

Why does this matter today?

- Less than 5 months to sewer ban
- Current enforcement risk
- Opportunity to influence state rules
- Compliance deadlines will be here before you know it

Key Terms

- Healthcare facility
- Pharmaceutical
- Hazardous waste pharmaceutical (HWP)
- Potentially creditable HWP
- Non-creditable HWP
- Very small quantity generator (VSQG)

5 Things Healthcare Facilities Need to Know

1 **YOU MIGHT BE GENERATING HAZARDOUS WASTE *AND DEFINITELY SOLID WASTE***

New Management Standards: 40 CFR Part 266 Subpart P

- Changes point of generation to healthcare facility for Rx HWPs
- Applies to healthcare facilities that generate above VSQG amounts of HW
- Applies to all reverse distributors
- Will be adopted in <u>every state</u>

How does EPA Define a "Healthcare Facility"?

- Provide care to humans or animals re physical or mental condition
- Distribute, sell, or dispense pharmaceuticals

"Healthcare Facility" Examples

- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians' offices
- Optical and dental providers
- Chiropractors
- Long-term care facilities
- Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals
- Veterinary clinics & hospitals
- Wholesale distributors
- 3PLs that serve as forward distributors
- Military medical logistics facilities

Definition of "Long-Term Care Facility" (LTCF)

= LTCF:

- Hospice facilities
- Nursing facilities
- Skilled nursing facilities
- Nursing and skilled nursing care portions of continuing care retirement communities

≠ LTCF:

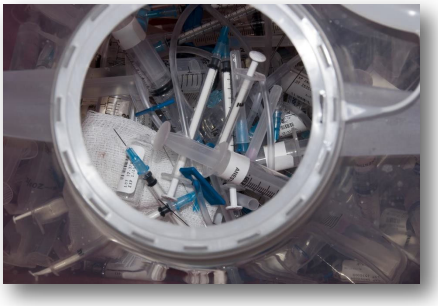
- Group homes
- Independent living communities
- Assisted living facilities
- Independent and assisted living portions of continuing care retirement communities

Broad Definition of "Pharmaceutical"

- Drug for use by humans or animals
- Dietary supplements
- Electronic nicotine delivery systems (e-cigarettes, vaping pens)
- Liquid nicotine and e-liquid packaged for retail sale
- Pharmaceuticals in non-empty containers
- PPE contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals

≠"Pharmaceutical"

- Dental amalgam
- Sharps
- Medical waste



"Hazardous Waste Pharmaceutical" (HWP) — Federal

- To be a hazardous waste, something must be:
  1. Solid waste, that
  2. Exhibits one or more characteristics *or* is listed

OTC pharmaceuticals ≠ solid waste
if reasonable expectation of use/reuse

Hazardous Waste Pharmaceutical (HWP)

There are 3 types of *Hazardous Waste Pharmaceuticals:*

1. Potentially creditable HWP
2. Non-creditable HWP
3. Evaluated HWP

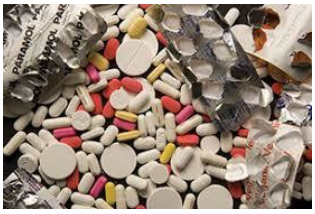
Potentially-Creditable HWP

Can we get $ back from manufacturer?

- Original manufacturer packaging (except recalls)
- Undispensed
- < 1 year past expiry

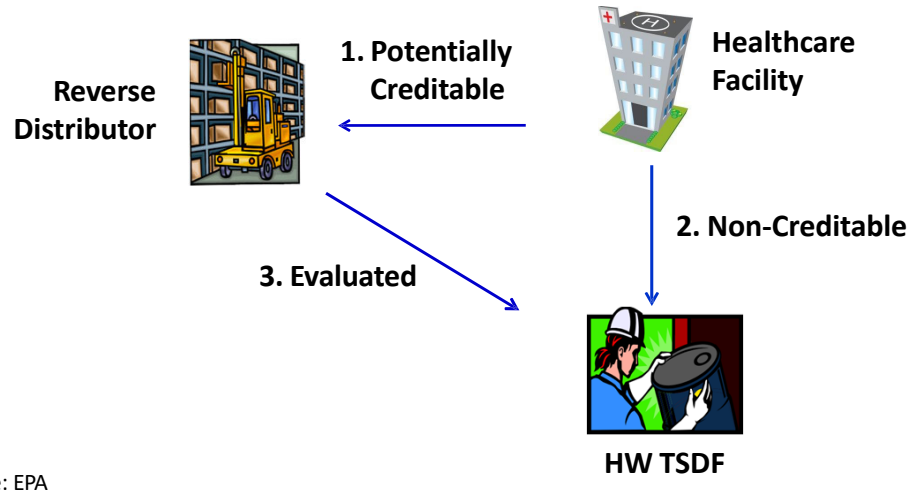
Non-Creditable HWP

No $ back from manufacturer



- Repackaged for dispensing
- Dispensed/refused by a patient
- Returned to pharmacy after pharmacy received compensation from third-party payer (e.g. health insurance company)
- Expired ≥ 1 year
- Broken or leaking
- Contaminated PPE
- Clean-up material

3 Types of HWPs



Source: EPA

Healthcare Facility Requirements

- Submit one-time notification to EPA
- Train employees managing non-creditable HWPs on waste handling and emergency procedures
- Make hazardous waste determinations, unless all waste pharmaceuticals are managed under new standards
  - If all managed under new standards, can comingle HWPs and non-HWPs
- Options for VSQGs

5 Things Healthcare Facilities Need to Know

2 **NO MORE COUNTING HWPs GENERATED PER MONTH**

3 **NO MORE SEGREGATING ACUTE HWPs**

Healthcare Facility Standards

	Non-Creditable HWPs	Potentially Creditable HWPs
Labeling	✓ "Hazardous Waste Pharmaceuticals"	None
Waste Code	None	None
Container Standards	✓ compatible, closed and secured	None
Maximum Accumulation Time	✓ 1 year	None
Hazardous Waste Determinations*	✓	✓
Over-Managing Non-HWPs & Commingling w/ HWPs	Allowed	Allowed
Include HWPs on BR	No	No
Shipment	Hazardous waste transporter	Common carrier, w/ delivery confirmation
Manifest	✓ Waste code "PHARMS"	None
Ship to	TSDF	Reverse distributor

*Not required for either type if managing all pharmaceutical waste as hazardous

5 Things Healthcare Facilities Need to Know

4 NO MORE TRIPLE-RINSING EMPTY CONTAINERS

Empty Containers

- Acute & non-acute
- No triple rinsing

"RCRA EMPTY"

	Non-Acute HWPs	Acute HWPs
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-Dose Containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or §261.7(b)(1)	Fully administer contents
Other Containers	§261.7(b)(1) or (2)	Cannot be RCRA empty

5 Things Healthcare Facilities Need to Know

5

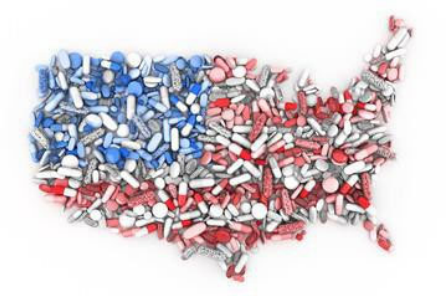
NO MORE FLUSHING:
SEWER BAN TAKES EFFECT THIS AUGUST

Sewer Ban

- In effect EVERYWHERE for EVERY healthcare facility on August 21, 2019
- No disposal down the drain
- No flushing
- Ban includes HWPs that are controlled substances

Effective Dates & State Adoption

- August 21, 2019:
  - Sewer ban effective in all states
  - Subpart P effective in Alaska and Iowa
- July 1, 2021/2022:
  - States must adopt Subpart P



State Adoption → *patchwork quilt of more stringent/broader state regulations?*

- RCRA § 3009 allows states to have more stringent regulations
- EPA cannot enforce regulations that are more stringent or broader in scope; states can enforce such regulations

Examples of More Stringent/Broader State Regulations

- **California**: discarded federal HWPs cannot be sent to RD; discarded California-only HWPs can be sent to a RD
- **Colorado:** all pharmaceuticals sent to a RD are waste; if HW waste, must be managed as HW by healthcare facility (cannot be sent to RD)
- **New Mexico**: expired pharmaceuticals are waste at the healthcare facility; expired HWPs cannot be sent to a RD
- **Rhode Island**: additional wastes must be handled as HW, R006 (extremely hazardous waste) and R009 (mercury containing wastes)
- **Washington**: additional characteristic for solid corrosivity and two additional state-specific characteristics for "toxicity" and "persistence"

What to Do Now?

- Examine current practices
- Count how much HW your facility generates per month
- Prepare to stop sewering
- Map out rulemaking
- Advocate in state

Questions?

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MEDICATION SAFETY COMMITTEE
MEETING MINUTES
January 22, 2019 / 2:00 pm – 4:00pm

CHA
ZOOM Teleconference

Members Participating:	**Eddie Avedikian, Carolyn Brown, Candace Fong, Jeannette Hanni, Kim Kirchmeyer, Christine Low, Lori Nolan, Doug O'Brien, Diana Schultz, Anne Sodergren, Sarah Stephens, Steve Thompson**
Guests:	**Joan Eng, Dan Ross, Margaret Swisher, Daniel Nguyen (intern to Sarah Stephens)**
CHA Staff:	**BJ Bartleson, Barb Roth**

I. CALL TO ORDER/INTRODUCTIONS – Hanni/Fong
The committee meeting was called to order by chair Ms. Hanni at 2:05 p.m. Ms. Hanni briefly reviewed committee mission, goals and objectives, and the 2019 meeting schedule.

II. REVIEW OF PREVIOUS MEETING MINUTES –Fong
The minutes of the October 10, 2018 Medication Safety Committee meeting were reviewed.

IT WAS MOVED, SECONDED AND CARRIED:

- *ACTION: Approved.*

III. OLD BUSINESS

A. SB 1254
FAQs are being compiled and should be ready by end of this week. The next step is to research outcomes. The workgroup is seeking volunteers, interested committee members should contact Ms. Stephens or Ms. Shane. A conference call with Ms. Stephens, Ms. Shane and UC Davis will be scheduled to discuss direction, then opened to statewide participation. Ms. Hanni estimates about $3 million for system-wide staffing. Ms. Stephens reported that there is a website in the Marquis Manual that helps estimate cost.

- *ACTION: Send information from webinar to committee members.*
- *ACTION: Committee members to contact Ms. Shane or Ms. Stephens if interested in volunteering.*
- *ACTION: Conference call with Ms. Stephens, Ms. Shane and UC Davis.*

B. FDA Drug Storage Letter and Testimony (Bartleson)
CHA made recommendations to Congress in a letter to the FDA in November 2018. Committee reports intermittent shortages, but not like last year.

- *ACTION: Information only.*

C. Board of Pharmacy Waiver Process (Bartleson)
Mr. O'Brien reported that AHA sent a letter to USP asking for further delay. CDPH and CMS have conditions of participation to meet USP standards, these are other agencies of concern regarding construction.

- *ACTION: Ms. Bartleson to follow up with Ms. Sodergren.*

D. Inventory Reconciliation from Automatic Dispensing Units (Bartleson)

BoP regulation requires an inventory to be done for the entire hospital pharmacy and pharmacy satellites. A drug dispensing system is not considered a pharmacy satellite. Ms. Sodergren reported that the Board of Pharmacy (BoP) is working on developing additional FAQs that should provide more guidance. This is still under review, but will hopefully be finalized by the end of this week. BoP will send CHA a copy to assist with dissemination.

- *ACTION: Provide information to committee upon receipt from the Board of Pharmacy.*

IV. NEW BUSINESS

A. AB 2760

Hospitals experiencing problems are encouraged to contact the bill's author (Wood). Documentation showing that the offer of a prescription was made is required. Some physicians are automatically prescribing Naloxone at the same time they are prescribing the opioid without discussing it with the patient, which is not the intent of the bill. It was reported that some insurance carriers will not cover the inhaled version of the product or will only cover the injectable. There is also discussion about the FDA approving the inhaled Naloxone for OTC use.

- *ACTION: Send reports of unintended consequences of this bill to CHA, Medical Board and the bill's author.*

B. AB 1753

There is nothing in this bill that allows for a transition time. However, there is a new bill - AB 149 (Cooper) - making an allowance for the transition. In the meantime, the BoP has put out a letter. The BoP enforcement committee has provided recommendations to their pharmacists and the Medical Board is providing the same information to their physicians.

- *ACTION: Send copy of AB 149 to committee.*

C. Enhanced Sterile Medication Compounding Evaluation – TJC

There is more emphasis from The Joint Commission (TJC) regarding sterile medication compounding. Most often it is the physician doing the compounding. Mr. O'Brien reported that TJC gives their surveyors a detailed checklist and sometimes they provide it to the hospital. Ms. Hanni said that TJC provided the checklist to them so that they can review the checklist and make sure that hospital personnel are knowledgeable and can speak with the surveyor about the issues.

- *ACTION: Send checklists from Mr. O'Brien and Ms. Hanni to committee.*

VII. ROUNDTABLE

Biosimilars

Ms. Shane reports that Cedars Sinai noticed an Aetna certification letter that they were going to prioritize a particular biosimilar. CHA is seeking others who may have received this certification letter.

- *ACTION: Send information to Ms. Low.*
- *ACTION: Committee members to advise Ms. Bartleson if they have received this letter.*

VIII. NEXT MEETING

Wednesday, April 3, 2019 10 am – 12 pm (Virtual Meeting – if needed)

IX. ADJOURNMENT

Having no further business, the committee adjourned at 3:20 PM

CHA MEDICATION SAFETY COMMITTEE
2019 ROSTER

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Medication Safety Committee
Hospital Representation

BY COUNTY

As of March 29, 2019

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

Contact	Position Type	Represented Organization	County (Represented Org
Candace Fong, Pharm.D	Chair	Dignity Health	San Francisco
Jeanette Hanni, R.Ph, MPA, FCSHP	Chair	Sutter Health	Sacramento
Amy Gutierrez, PharmD	Member	Kaiser Permanente	Alameda
Carolyn Brown, RN, MS	Member	Santa Clara Valley Medical Center	Santa Clara
Chris Patty, DNP, RN, CPPS	Member	Kaweah Delta Health Care District	Tulare
Christine Low, Pharm.D	Member	Scripps Health	San Diego
Deepak Sisodiya, PharmD, MHA	Member	Stanford Health Care	Santa Clara
Diana Schultz, RPh, MHSA	Member	Palomar Medical Center Escondido	San Diego
Doug O'Brien, Pharm.D	Member	Kaiser Foundation Hospitals	Sacramento
Eddie W. Avedikian, PharmD	Member	Providence Holy Cross Medical Center	Los Angeles
Kathy Ghomeshi, Pharm.D, MBA, BCPS, CPPS	Member	UCSF Medical Center	San Francisco
Kevin Dorsey Tyler, MD, PhD	Member	Enloe Medical Center - Esplanade Campus	Butte
Lori Nolan-Mullenhour, MSN, RN, NE-BC, CEN	Member	Providence Little Company of Mary Medical Center Torrance	Los Angeles
Nasim Karmali, RPh	Member	Kaiser Permanente Redwood City Medical Center	San Mateo
Richard B. Rabens, MD, MPH, FAAP	Member	Kaiser Permanente	Alameda
Rita Shane, Pharm.D, FASHP, FCSHP	Member	Cedars-Sinai Medical Center	Los Angeles
Sarah Stephens, Pharm. D, BCPS, CPPS	Member	Kaweah Delta Health Care District	Tulare
Anne Sodergren	Ex-officio	California Board of Pharmacy	
Art Woo, Pharm.D	Ex-officio	California Department of Public Health	
Cari Lee, Pharm.D	Ex-officio	California Department of Public Health	
John Christensen, Pharm.D	Ex-officio	California Department of Public Health	
Kimberly Kirchmeyer	Ex-officio	Medical Board of California	
Kimberly Tomasi, RN, MSN	Ex-officio	Association of California Nurse Leaders	
Loriann DeMartini, Pharm.D	Ex-officio	California Society of Health System Pharmacists	
Patti Owens	Ex-officio	California Association of Health Facilities	
Randy Kajioka, Pharm.D	Ex-officio	California Correctional Health Care Systems	
Steve Thompson	Ex-officio	California Society of Health System Pharmacists	

GUIDELINES FOR THE
CALIFORNIA HOSPITAL ASSOCIATION
MEDICATION SAFETY COMMITTEE

I. NAME

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

II. MISSION

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

III. PURPOSE

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

IV. COMMITTEE

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

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

A. MEMBERSHIP

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

B. MEMBER RESPONSIBILITIES

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

C. COMMITTEE MEETINGS

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

D. VOTING

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

E. QUORUM

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

F. MINUTES

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

V. OFFICERS

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

A. SUB-COMMITTEES

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

VI. GENERAL PROVISIONS

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

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

The Committee staff liaison shall be an employee of CHA.

VII. AMENDMENTS

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

VIII. LEGAL LIMITATIONS

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

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

IX. CONFIDENTIALITY FOR MEMBERS

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

X. CONFLICT OF INTEREST

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

CALIFORNIA HOSPITAL ASSOCIATION

Providing Leadership in Health Policy and Advocacy

December 4, 2017

TO: Medication Safety Committee Members

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

SUBJECT: 2019 Proposed Meeting Schedule

Following is the proposed meeting schedule for 2019 Medication Safety Committee meetings:

January 22, 2019	Virtual Meeting	2 pm – 4 pm
April 3, 2019*	Virtual Meeting (if needed)	10 am – 12 pm
July 17, 2019	In Person - Sacramento, CHA Offices Board Room	10 am – 2 pm
October 17, 2019	In Person (in conjunction with CSHP Annual Meeting/Anaheim)	TBD

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