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

STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: October 18 and 19, 2011

LOCATION: The Westgate Hotel
1055 Second Avenue
San Diego, CA 92101

BOARD MEMBERS PRESENT:
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Anil Badlani, RPh
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member, 10/18 only
Deborah Veale, RPh
Tappan Zee, Public Member

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Shirley Wheat, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector, 10/18 only
Janice Dang, Supervising Inspector, 10/19 only
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

President Stanley Weisser called the meeting to order at 9:47 a.m.

President Weisser conducted a roll call. Board Members Zee, Badlani, Castellblanch, Lippe, Kajioka, Hackworth, and Veale were present. A quorum of the board was established.

I. GENERAL ANNOUNCEMENTS

President Weisser recognized former Board Members and Board Presidents Raffi Simonian and Darlene Fujiomoto as well as Dawn Benton, representing the California Society of Health System Pharmacists, who were in attendance in the audience.

II. APPROVAL OF THE FULL BOARD MEETING MINUTES OF JULY 26 & 27, 2011

MOTION: Approve the minutes of the July 26 and 27, 2011 Board Meeting.

M/S: Lippe/Hackworth

Support: 8 Oppose: 0 Abstain: 0

III. APPROVAL OF THE FULL BOARD MEETING MINUTES OF SEPTEMBER 7, 2011

MOTION: Approve the minutes of the September 7, 2011 Board Meeting.

M/S: Lippe/Hackworth

Support: 8 Oppose: 0 Abstain: 0

IV. RECOGNITION AND CELEBRATION OF PHARMACISTS LICENSED FOR 50 YEARS IN CALIFORNIA

President Weisser recognized John Magaudda. President Weisser presented Mr. Magaudda with a 50-year pin.

Mr. Magaudda shared that he was licensed as a pharmacist in 1961 and moved from Massachusetts to California in 1962 where he worked for Thrifty Drugs for 37 years. He now works part time at Sharp Hospital and Costco. Mr. Magaudda shared several items, including that leeches were commonly sold at pharmacies when he first became a pharmacist.

V. LEGISLATION AND REGULATION COMMITTEE REPORT

PART I – REGULATIONS

Carolyn Klein, Legislation and Regulation Manager, provided a brief overview of the following regulations.

a. Approved by the Office of Administrative Law

1. Amend Title 16 Sections 1715, 1784, 1735.2, and 1751– Update of Self Assessment Forms for Pharmacies, Sterile Injectable Compounding Pharmacies, Hospitals and Wholesalers [45-day comment period: March 11 – April 25, 2011] To take effect October 19, 2011

   Ms. Klein provided that this regulation was approved by the Office of Administrative Law (OAL) on September 19, 2011, and it will be operative/effective on October 19, 2011. She advised that the previous forms will be removed from the board's website and replaced with the updated forms.

2. Amend Title 16 Section 1793.5 – Pharmacy Technician Application; Requirement for Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB)
   [45-day comment period: April 8 – May 23, 2011]
   To take effect October 1, 2011

   Ms. Klein provided that this regulation to update the pharmacy technician application was approved by OAL on September 1, 2011, and the regulation became effective on October 1, 2011. She stated that this regulation updates the pharmacy technician application (Form 17A-5, Rev. 10/10), which is incorporated by reference; and also requires a pharmacy technician applicant to submit to the board with his or her application a self-query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB). Such reports will ensure that an applicant for a pharmacy technician license in California has not been disciplined by another state's regulatory board.

b. Board - Approved; Rulemaking File Being Prepared

1. Add Title 16 Section 1727.2 – Requirements for Pharmacist Interns – To Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) [45-day comment period: May 6-June 20, 2011]

2. Amend Title 16 Section 1728 – Requirements for Pharmacist Examination - Amend to Require Applicants to Submit a Self-Query from the National Practitioner Data Bank – Healthcare Integrity & Protection Data Bank (NPDB-HIPDB) [45-day comment period: May 6-June 20, 2011]

   Ms. Klein provided that these two rulemakings were adopted by the board in July 2011 and are being compiled to be submitted to the Department of Consumer Affairs (department) for administrative review by the end of October 2011.

c. Board - Approved; Undergoing Review by the Administration

1. Amend Title 16 CCR Section 1732.2 – Board Accredited Continuing Education [45-day comment period: October 8-November 22, 2010; February 4-21, 2011]

Ms. Klein provided that the board adopted this regulation in February 2011 and it is currently undergoing review by the department. She stated that the department extended the one-year notice period for this rulemaking for an additional 90 days on October 5, 2011 to complete its review.

2. Add Title 16 Section 1707.6 and to Amend Section 1707.2 Regarding Consumer Notices and Duty to Consult – Consumer Notice for Language Assistance Interpretive Services Provided in Pharmacies and the Ability to Request 12-Point Font on Prescription Drug Container Labels [45-day comment period: May 27-July 11, 2011]

Ms. Klein provided that the final 15-day public comment period for this regulation was completed in August 2011 and the regulation was subsequently adopted by the board. She stated that the rulemaking file was submitted to the department on September 2, 2011.

d. Undergoing Initial 45-Day Comment Period

Amend 16 California Code of Regulations Section 1760, regarding the Board's Disciplinary Guidelines and Integration of SB 1441 Standards for Substance Abuse Monitoring Programs [45-day comment period: October 14 – November 28, 2011]

Ms. Klein provided that the 45-day public comment period for this regulation began on October 14, 2011, and will conclude on November 28, 2011. She stated that a Regulation Hearing has been scheduled for January 31, 2012 at 1:30 p.m. at the Embassy Suites San Francisco Airport-Waterfront Hotel in Burlingame.

e. Board Approved – Under Development or Awaiting Notice (Update Only)

1. Proposed Amendments to § 1746 – Emergency Contraception Protocol

Ms. Klein provided that at this board meeting, the Communication and Public Education Committee will discuss a proposed rulemaking to update the board's Emergency Contraception protocol (16 CCR § 1746), to reflect the language/protocol approved by the Medical Board of California at its July 2011 Board Meeting.

2. Proposed Amendments to § 1751.9 – Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

   Ms. Klein provided that this proposed regulation has been referred back to the Licensing Committee for discussion and modification.

3. Proposed Amendments to § 1780 – Update the USP Standards Reference Manual (Minimum Standards for Drug Wholesalers) [referred to subcommittee]

   Ms. Klein advised that this proposed regulation is still pending as the subcommittee established for this purpose has not held any meetings due to board vacancies.

4. Proposed Amendments to § 1785 – Self-Assessment of a Veterinary Food-Animal Drug Retailer [referred to Licensing Committee]

   Ms. Klein provided that this regulation is pending review by the Licensing Committee.

   Ms. Klein provided a verbal update on the following regulations under development that were not provided in the meeting materials. She stated that these regulations will be noticed in November 2011 for possible action by the board at the January 2012 Board Meeting.

   - Proposed Amendments to 16 CCR section 1769 – Application Review and Criteria for Rehabilitation
   - Proposed Addition to 16 CCR section 1762 – Submission of Records to the Board
   - Proposal to Amend 16 CCR section 1745 – Partial Filling of Schedule II Prescription

Discussion

Board Member Ramón Castellblanch requested additional information on Sections 1707.2 and 1707.6 regarding consumer notices and duty to consult.

Executive Officer Virginia Herold provided that the Communication and Public Education Committee has begun development of the design for the new posters.

DCA Staff Counsel Kristy Shellans advised that the notice requirements will take effect 30 working days after approval by OAL.

Deputy Attorney General Joshua Room clarified that the effectiveness of the requirements is contingent on the development of the notice posters.

No public comment was provided.

PART II – LEGISLATION

Assistant Executive Officer Anne Sodergren reviewed the following legislation.

a. Board-Sponsored Legislation

SB 431 (Emmerson, Chapter 646, Statutes of 2011): Pharmacies - Regulation
In January 2010, the board voted to pursue legislation to improve the board's enforcement tools. Many of these provisions are incorporated in SB 431 as chaptered. Below are the specific code sections:

a. §4104 – Licensed Employee, Theft or Impairment, Pharmacy Procedure
   Clarifies that a pharmacy shall provide the board, within 14 days, evidence of a licensee's theft or impairment, and requires a pharmacy to conduct an audit to determine the scope of a drug loss and to provide the board with a certified copy of the audit results.
b. §4105 – Retaining Records of Dangerous Drugs and Devices on Licensed Premises; Temporary Removal; Waivers; Access to Electronically Maintained Records
   Specifies the time period within which records shall be provided to the board when requested by an inspector or authorized representative of the board.
c. §4112 – Nonresident Pharmacy; Registration; Provision of Information to Board; Maintaining Records; Patient Consultation
   Requires that a nonresident pharmacy cannot allow a pharmacist, whose license has been revoked in California, to provide pharmacist-related services to Californians.

Ms. Sodergren stated that SB 431 was signed by the Governor on October 9, 2011. She provided that the provisions will take effect on January 1, 2012 and stated that the board will provide education to its licensees on these new requirements.

Senate Bill 943 (Chapter 350, Statutes of 2011) Omnibus
At the October 2010 Board Meeting, the board voted to pursue an omnibus provision to eliminate a reference to the previous pharmacists examination in Business and Professions Code section 4200. This provision is contained in Senate Bill 943.

Ms. Sodergren provided that this bill was signed by the Governor on September 26, 2011 and will take effect on January 1, 2012.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. Controlled Substances

   AB 507 (Chapter 396, Statutes of 2011, Hayashi): Pain Management
   Version: As amended, July 1, 2011

Summary: As chaptered, this measure conforms findings and declarations and other references to severe chronic intractable pain and to the California Intractable Pain Treatment Act.

Current Status: Chaptered.

.

Ms. Sodergren provided that this bill has gone through several variations and no longer impacts the board's provisions in the Business and Professions Code.

2. Reporting Requirements/Records

AB 1280 (Hill): Ephedrine - Retail Sale
Version: As amended, August 15, 2011

Summary: The bill contains provisions requiring the secure storage and monitoring of products containing any amount of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine. This bill proposes a real-time tracking system beginning on or after July 1, 2012 through December 2018.

Board Position: Watch (As amended May 26, 2011)

Current Status: This measure was held under submission during the August 15, 2011 Senate Appropriations Committee.

Ms. Sodergren advised that this bill is now a two-year bill.

SB 360 (Chapter 418, Statutes of 2011, DeSaulnier): Controlled Substance Utilization Review and Evaluation System
Version: As amended, July 7, 2011

Summary: This bill specifies that data will be reported to CURES pursuant to drugs classified in the federal law's controlled substances schedules and changes the requirements for security printer forms to include the address of the prescribing practitioner and establishes the process by which health care providers may obtain approval to access information regarding the controlled substance history of a patient. This bill also expands the requirements for authorized printers of security forms managed by the Department of Justice.

Board Position: Watch
Current Status: Chaptered

Ms. Sodergren provided that this bill was signed by the Governor.

SB 850 (Chapter 714, Statutes of 2011, Leno) Medical Records: Confidential Information
Version: As Amended, September 1, 2011

Summary: This bill requires an electronic health or medical record system to automatically record and preserve any change or deletion of electronically stored medical information, and requires the record to include, among other things, the identity of the person who accessed and changed the medical information and the change that was made to the medical information.

Board Position: None

Current Status: Chaptered

Ms. Sodergren provided that this bill has been signed by the Governor.

3. Healing Arts/DCA

SB 541 (Chapter 339, Statutes of 2011, Price) Regulatory boards: Expert Consultants
Version: As amended, June 21, 2011

Summary: This bill authorizes boards to enter into an agreement with an expert consultant, subject to the standards regarding personal service contracts described, to provide enforcement and examination assistance. The bill requires each board to establish policies and procedures for the selection and use of these consultants.

Current Status: Chaptered. This bill was an urgency measure and as such became effective immediately upon signature of the Governor.

Ms. Sodergren provided that the board had a support position on this bill.

4. Other

AB 389 (Mitchell): Bleeding disorders - blood clotting products
Version: As amended, March 30, 2011

Summary: This bill would impose specified requirements on providers of blood clotting products for home use for products used for the treatment and prevention of symptoms associated with bleeding disorders, including all forms of hemophilia.
Current Status: This measure was moved to the inactive file September 1, 2011.

Ms. Sodergren stated the board has an oppose position on this bill.

AB 604 (Chapter 744, Statutes of 2011, Skinner): Needle Exchange Programs
Version: As amended, September 2, 2011

Summary: This bill authorizes, until January 1, 2019, the State Department of Public Health to approve certain entities, after consultation with the local health officer, law enforcement officers and others, to provide hypodermic needle and syringe exchange services in any location where the department determines that the conditions exist for the rapid spread of HIV, viral hepatitis, or any other potentially deadly or disabling infections that are spread through the sharing of used hypodermic needles and syringes. Such authorization will be for a two year period, unless reauthorized.

Current Status: Chaptered.

Ms. Sodergren provided that the board had a support position on the April 5, 2011 version of this bill. She advised that the Governor signed this bill and offered a signing message.

SB 41 (Chapter 738, Statutes of 2011, Yee): Disposal of Hypodermic Needles and Syringes
Version: As amended, August 15, 2011

Summary: This bill allows, until January 1, 2015, a physician or pharmacist to furnish 30 or fewer hypodermic needles and syringes solely for personal use to a person 18 years of age or older. The bill addresses the storage of products to ensure they would be available only to authorized personnel, requires that disposal options are provided to consumers, and requires pharmacies to provide written information or verbal counseling at the time of furnishing on how to access drug treatment.

Current Status: Chaptered

Ms. Sodergren stated that the board had a position of support if amended on this bill.

SB 514 (Chapter 199, Statutes of 2011, Simitian): Dextromethorphan - Sale to Minors Prohibited
Version: As amended, May 10, 2011

Summary: This bill makes it illegal to sell dextromethorphan to a person under the age of 18 without a prescription.

Current Status: Chaptered

Ms. Sodergren provided that the board had a support position on this bill and advised that it has been signed by the governor.

AB 1424 (Chapter 455, Statutes of 2011, Perea) Franchise Tax Board Delinquent Tax Debt
Version: September 2, 2011

Summary: This bill requires the State Board of Equalization and the Franchise Tax Board to each make available a list of the 500 largest tax delinquencies at least twice each calendar year. This bill requires the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and license number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. This bill specifies that a license may be suspended for failure to pay tax delinquencies.

Board Position: Oppose

Current Status: Chaptered

Ms. Sodergren discussed that the department is looking at possible implementation efforts for this legislation. She stated that it is anticipated that 14 licensees from the department will be impacted by this provision. Ms. Sodergren provided that the board has a position of oppose on this bill.

5. Additional Legislation Impacting the Board or Its Regulatory Jurisdiction

Ms. Sodergren provided that the legislative session will reconvene on January 14, 2012. She stated that information regarding legislative changes will be posted on the board's website and summaries of the changes made to many of the code sections will be provided in the next issue of *The Script*.

Discussion
Dr. Castellblanch asked if the board's concern on SB 41 regarding the disposal of hypodermic needles and syringes has been addressed.

Ms. Sodergren provided that the board's concern regarding the repeal of Business and Professions Code section 4140 has been conveyed to the bill's author. She advised, that although the language is not as clear as the provision in the Business and Professions Code, there is a penalty provision in the Health and Safety Code. Ms.

Sodergren also discussed that the board does not typically rely on Section 4140; however, law enforcement does.

Public Comment
Steve Gray, representing Kaiser Permanente, sough clarification on SB 514 regarding dextromethorphan. He discussed that a $200 fine will be assessed for an infraction of this provision and asked whether this will be levied by the board or law enforcement.

Ms. Herold discussed that this provision will be handled by law enforcement.

Mr. Room clarified that the board will not rely on this fine authority itself.

PART III – Legislation and Regulation Committee

First Quarterly Report on the Committee's Goals for 2011/12

Ms. Sodergren referenced the first quarterly report on the Legislation and Regulation Committee's goals provided in the meeting materials.

There was no board discussion or public comment.

VI. ENFORCEMENT COMMITTEE REPORT

There was no meeting of the Enforcement Committee this Quarter

a. Discussion about Compliance Monitoring for California Patient-Centered Requirements for Prescription Drug Containers as Authorized by Section 4076.5 of the California Business and Professions Code

Background
The Board of Pharmacy approved the final version of its patient-centered regulation in June 2010. While the regulation was undergoing review by the Administration and approval by the Office of Administrative Law, the board announced the board's finalization of the regulation's provisions in its newsletter and via several subscriber alerts.

The regulation (16 California Code of Regulations section 1707.5) was approved by the required agencies and took effect on January 1, 2011 (as required by Business and Professions Code section 4076.5).

Report
Board Member Randy Kajioka provided that as of October 2011, the board's inspectors are doing educational compliance to ensure the patient-centered labels will become available where they are not already in use. He advised that full compliance has not yet been achieved.

Dr. Kajioka sought feedback from the board regarding when the board should begin stronger compliance of this regulation – using its compliance criteria and sanctions to secure full implementation for all patients in California as required by statute.

Discussion
Ms. Herold advised that the board's enforcement staff has been issuing correction orders for the past two months. She discussed the balance of implementation challenges vs. the need for consumers to have these new labels. Ms. Herold indicated that the board has not started aggressive enforcement of the requirements and recommended that the board pursue more aggressive action starting January 1, 2012.

Board Member Deborah Veale questioned what type of action the board will pursue.

Ms. Herold indicated that letters of admonishment or a citation and fine will be issued for non-compliance.

Board Member Rosalyn Hackworth sought information regarding the number of pharmacies currently not in compliance with the requirements.

Ms. Herold indicated that she is unaware of the exact number but does know that corrections are being ordered.

Dr. Kajioka asked if the board has received any patient complaints regarding the new label requirements.

Ms. Herold responded that the board had received some initial complaints regarding failure to comply with the new requirements.

Dr. Castellblanch discussed that not all consumers are aware of these new requirements as the new notice to consumers is still under development. He asked what fine would be assessed for a violation of the labeling requirements.

Ms. Shellans discussed that fines issued for violation of these requirements will vary and are dependant on many factors that are considered when issuing a citation and fine. She advised that the board has a variety of ways to enforce the requirements including letters of reprimand or an accusation to seek revocation or probation of a license for noncompliance.

Board Member Anil Badlani suggested that perhaps the board could request those that are noncompliant to self report to the board.

Ms. Herold discussed that the board's goal is to bring all licensees into compliance.

Board Member Tappan Zee recommended that staff begin to enforce the provisions and discussed that aggressive enforcement may result in the resolution of noncompliance issues.

Supervising Inspector Judi Nurse stated that there has been plenty of time for voluntary compliance. She recommended that the board now pursue aggressive enforcement of the labeling requirements.

Board Member Greg Lippe offered a proposal to begin aggressive enforcement action effective January 1, 2012.

Public Comment

Steve Gray, representing the Pharmacy Foundation of California, stated that one of the most important elements of the regulation is the inclusion of the purpose of the medication on the prescription label. He suggested that the board evaluate how it will ensure compliance with this element.

Dr. Gray indicated that Kaiser prescribers include the purpose in the directions for use. He also indicated that in other systems, the prescription message typically includes the ICD9 diagnostic codes. Dr. Gray explained that the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT) database will translate diagnostic codes to language that a consumer can understand. He stated that pharmacists need guidance on what to do with this information.

Dr. Kajioka spoke in support of the need for the purpose to be included on the label. He asked if Kaiser has spoken with physicians to encourage them to include the purpose on the prescription so it can be included on the label.

Dr. Gray indicated that he is not aware of any significant education campaigns that advise prescribers that the purpose should be provided on the prescription. He also responded that if no purpose is provided, it is incumbent on the pharmacist to determine what the purpose is to perform a competent consultation.

Ms. Herold expressed concern regarding the use of a diagnosis code instead of the purpose due to possible disclosure on a label of a patient's medical condition and violation of privacy rights.

Dr. Gray stated that use of ICD9 codes does present some challenges and warrants discussion by the board on how the codes should be used by pharmacists.

Dr. Kajioka discussed that prescribers need to take an active role in this issue and requested that associations reach out to prescribers and educate them about the benefit of the purpose being included on the prescription.

Dr. Gray suggested that the board take an active role in educating prescribers.

John Cronin, representing the California Pharmacists Association, spoke in response to Mr. Lippe's proposal and indicated that many pharmacies are reliant upon the software provider and stated that the pharmacist should not be held accountable for failure to comply with labeling requirements. He discussed that the goal should be compliance and suggested that the board use the proof of abatement option to allow compliance with the requirements. Dr. Cronin suggested that then when compliance is achieved, the fine could be waived.

MOTION: Effective January 1, 2012, begin more aggressive enforcement of the patient-centered requirements for prescription drug containers as authorized by California Business and Professions Code section 4076.5 effective January 1, 2012.

M/S: Lippe/Castellblanch

Support: 8 Oppose: 0 Abstain: 0

b. Board-Sponsored CE Scheduled for November 7 at Loma Linda University School of Pharmacy: a Joint Presentation with the Drug Enforcement Administration "Diversion of Controlled Substances, What Every Pharmacist Should Know to Prevent Diversion"

Report

Dr. Kajioka provided that on November 7, 2011, board staff will join with the DEA to host a day-long conference on pharmacy issues at Loma Linda University. He stated that a similar presentation was held in April at the DEA's Los Angeles office, and over 100 board licensees in the Los Angeles area attended.

Dr. Kajioka provided that the board awarded 5 hours of continuing education (CE) credit for those pharmacists and pharmacy technicians who attended the April meeting. He asked whether CE credit should also be offered at the November conference.

Discussion

Ms. Hackworth offered a proposal to award 5 hours of CE credit for attendance at the upcoming conference.

President Weisser indicated that the April conference was well attended and evaluations from those who attended were strongly positive. He encouraged those in attendance to participate at the upcoming conference.

Ms. Herold indicated that Supervising Inspector Nurse will provide a presentation at the conference on diversion and drug theft.

No public comment was provided.

MOTION: Award 5 hours of continuing education credit for attendance at the conference on November 7, 2011 at Loma Linda University.
M/S: Hackworth/Veale

Support: 8 Oppose: 0 Abstain: 0

c. Selection of Enforcement Committee Meeting Dates for 2012

Dr. Kajioka referenced the following proposed Enforcement Committee Meeting dates for 2012.

- December 6, 2011 – Sacramento
- March 13, 2012
- June 12, 2012
- September 11, 2012
- December 4, 2012

There was no board discussion or public comment. These dates will be posted on the board's website.

d. Review of Enforcement Statistics and Performance Standards of the Board

Ms. Herold provided an overview of the board's enforcement statistics for fiscal year 2011/12. A copy of the statistics is attached, following this meeting summary.

There was no board discussion or public comment on this item.

e. First Quarterly Update of the Committee's Strategic Performance Goals for 2010/11

Ms. Herold referenced the first quarter's update report on the Enforcement Committee's strategic plan.

Ms. Herold advised the board that a new format for updates may be implemented pending changes from the new strategic plan that are currently under development.

There was no board discussion or public comment.

The board recessed for a break at 10:50 a.m.

The board resumed at 11:00 a.m.

VII. PRESENTATION BY UNITED PARCEL SERVICE REGARDING DURABLE MEDICAL EQUIPMENT SUPPLIES BEING DISPENSED TO PATIENTS LOCATED OUTSIDE CALIFORNIA, AND THE TYPE OF LICENSE REQUIRED

Bruce Mac and David Salitros, representing UPS, provided a presentation on medical device distribution from a pharmacy. They reviewed current distribution of medical devices and explained that UPS is requesting the ability to establish a medical device only mail order pharmacy operation within California to meet the needs of patients outside California, for devices, not drugs that are prescription only.

Mr. Mac and Mr. Salitros stated that in addition to this request for a limited pharmacy license, they are also seeking an exemption to the technician to pharmacist ratio to allow for a ratio of six technicians to one pharmacist.

Discussion

Ms. Shellans advised that the board does not have the authority to issue a provisional license.

Mr. Room discussed a possible waiver pursuant to Business and Professions Code section 4118(a). He provided comment regarding the challenges of implementing such a waiver. Mr. Room stated that a better solution would be to pursue a legislative change.

Mr. Mac indicated that UPS is working with an author's office to seek a legislative fix. He discussed that UPS is making this request to address the needs of consumers.

Mr. Zee asked whether a probationary license could be issued to allow for this request.

Mr. Room responded that the board is not permitted to issue a probationary license unless it is based on a disciplinary action.

Mr. Zee suggested a two-track option including pursuit of a legislative remedy as well as a memorandum addressing Section 4118 for board consideration.

Mr. Salitros specified a desired timeline of December 1, 2011 for the board's recommendation.

Ms. Herold advised that the next Board Meeting is scheduled for January 28 and 29, 2012.

Mr. Salitros indicated that UPS will submit its proposal in advance of this meeting for board consideration.

Ms. Shellans discussed that the board needs time to evaluate this request and advised that approval of a waiver would set a precedent for future requests, an action never considered by the board before.

Public Comment
John Cronin sought clarification on the request and expressed concern about a waiver of Section 4118(a). He discussed whether a waiver would be fair and whether it would create a competitive edge for UPS. Dr. Cronin also indicated that the waiver would result in the issuance of a license that would allow for conducting business far beyond what is being proposed.

VIII. COMMUNICATION AND PUBLIC EDUATION COMMITTEE REPORT

Summary of the Committee Meeting Held September 26, 2011

a. Discussion and Possible Action to Consider Recommendations to Initiate a Rulemaking to Amend 16 California Code of Regulations Section 1746, Emergency Contraception Protocol Regulation

Report
Ms. Herold provided that earlier this year, the Board of Pharmacy initiated the process to update the emergency contraception protocol authorized by California Business and Professions Code section 4052.3 and 16 California Code of Regulations section 1746.

Ms. Herold provided that the existing state protocol was developed by the Medical Board in 2004 and then later adopted by the Board of Pharmacy as a regulation. She indicated that since the time of adoption, there have been changes in the availability of emergency contraception medication, the manufacturers who produce the medication, and there is a typo that needs correction (mcg instead of mg).

Ms. Herold provided that at the July 2011 Board Meeting, the board reviewed the proposed changes submitted from CPhA's representative (a women's health specialist pharmacist Katherine Besinque, PharmD, from USC, and two representatives of the American College of Obstetricians and Gynecologists (Shannon Smith Crowley and Phillip Diamond, MD).

Ms. Herold provided that after this meeting, she attended the Medical Board of California's meeting to request their adoption of the updated protocol. She indicated that the Medical Board approved the protocol at its meeting.

Ms. Herold requested that the board consider approval of the proposed regulation changes and initiate the rulemaking to facilitate implementation of these amendments.

Discussion
Dr. Besinque provided information on the protocol and some of the benefits including access to contraception for individuals who would otherwise be unable to obtain this medication.

President Weisser reviewed the recommendation of the Communication and Public Education to initiate the rulemaking. He explained that a new motion is required to

address some suggested changes to the committee's recommendation that have been suggested by staff.

No public comment was provided.

MOTION: Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR § 1746 to conform to the emergency contraceptive protocol approved by the Medical Board in July 2011; authorize the executive officer to make any non-substantive changes to the rulemaking package; and provide a 45-day public comment period.

If after the public comment period, no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the executive officer the authority to make any non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulation at Section 1746 as described in the notice.

M/S: Lippe/Castellblanch

Support: 8 Oppose: 0 Abstain: 0

b. Discussion and Possible Action to Add to the Board's Website the Developed Translations of Directions for Use on Patient Medication Containers as Required by 16 California Code of Regulations Section 1707.5

Report

Ms. Herold provided that the California Endowment agreed to fund a project to develop and vet translations of the standardized directions for use that are contained in the board's patient-centered label requirements. She indicated that the project is complete and the translations were vetted in local CA (and IL) communities with a survey of native speakers.

Ms. Herold advised the board that the translations are now going through review by a contractor secured by the department. She also indicated that the regulation requires that the board place these translations on its website by October 2011.

Ms. Herold referenced the developed translations provided in the meeting materials. She discussed that board counsel has developed a disclaimer about board liability for use and shared this disclaimer to the board.

Ms. Herold requested the board's approval to post the translations on the board's website if no additional changes are noted by the department's contractor.

Discussion
Ms. Veale offered a proposal to approve posting of the translations on the board's website.

Mr. Room advised that there is no translation for the following phrase:

- if you have pain, take ___ at a time. Wait at least ___ hours before taking again. Do not take more than ____.

Ms. Herold indicated that this direction for use was added after the project began and was not tested during the vetting process. She also indicated that the word "pill" was used in the translations instead of "insert appropriate dosage form."

Public Comment
John Cronin requested clarification on the requirement to use the translation given the disclaimer. He expressed concern regarding the accuracy of the translations.

Mr. Room clarified that use of the translations are voluntary as there is no requirement that the translations be used on the label. He discussed that oral interpreter services are also available from a pharmacy.

MOTION: Add to the Board's website the developed translations of directions for use on patient medication containers as required by 16 California Code of Regulations section 1707.5 pending review by the department's contractor.

M/S: Veale/Castellblanch

Support: 8 Oppose: 0 Abstain: 0

c. Discussion on Existing Requirements for Patient-Centered Prescription Drug Container Labels

Report
Ms. Herold advised that in conformance with Business and Professions Code section 4076.5, the Communication and Public Education Committee has begun discussions of the existing requirements to determine whether modifications to the requirements are needed.

There was no board discussion or public comment on this item.

d. Discussion Regarding USP's Guidance for Patient Prescription Container Labels

Report
Ms. Herold provided an overview of the standards for prescription container labeling that were developed by the United States Pharmacopeia (USP). She discussed that USP's standards are similar to the board's regulation as USP considered the board's draft requirements at an early state in the development of their standards. A comparison of these requirements was provided in the meeting materials.

There was no board discussion or public comment on this item.

e. Discussion Regarding the Future Design of New Notice to Consumers Posters (Pending 16 California Code of Regulations Section 1707.6)

Report
Ms. Herold provided that the Communication and Public Education Committee has started work on the new notice to consumers requirements in the following areas:

1. Proposed design elements
2. Concepts for the video display
3. Concepts for interpreter services (likely a separate notice)

Ms. Herold stated that staff will take the recommendations from the committee and work with various graphic designers to develop prototypes for the new posters and bring these to the next committee meeting, which will be scheduled before the January 2012 Board Meeting.

There was no board discussion or public comment on this item.

f. Discussion Surrounding a Proposal to Develop a Standardized Form for Pharmacies to Use to Request Refills

Report
Ms. Herold provided that the board received a proposal from Assembly Member Feuer that had been submitted to him by a constituent as a possible legislative proposal to require use of a standardized form for pharmacies to use to request refills. She discussed that the proposal was made to address the numerous and diverse refill requests that are faxed to prescribers for review and the potential for a medication error.

Ms. Herold provided that she brought the proposal and sought the reaction or need from Cedars Sinai, (where the MD constituent practices), the California Pharmacists Association, the California Retailers Association, and various board inspectors. She indicated that no one was opposed, but no one was especially motivated either.

Ms. Herold advised that the committee also did not believe there was a need to develop such a form.

There was no board discussion or public comment on this item.

g. Update on an Assessment of the Board's Public Education Materials

Report
Ms. Herold provided that a subcommittee of the board has been working to improve the board's website design and placement of its public education materials. She stated that all state agencies are being directed to transfer to a new state government web design, and the board will make the website changes when it migrates to the new web format.

Ms. Veale provided that the subcommittee has identified the following five areas to improve the current layout of the website:

1. Public Information
2. Professional Information
3. Applicant Information
4. Board Information
5. Regulation Information

There was no board discussion or public comment on this item.

Dr. Castellblanch left the meeting room at 12:01 p.m.

h. Update on The Script

Report
Ms. Herold provided that the next issue of *The Script* is being written and should be released in January 2012. She explained that this will be a consolidated issue because the board was unable to complete a fall newsletter due to staffing issues in the Legal Office.

There was no board discussion or public comment on this item.

i. Public Outreach Activities Conducted by the Board

Report

Ms. Herold provided that a travel freeze was implemented in May 2011 pursuant to the governor's executive order, suspending travel for all but the most essential and mandated purposes. She stated that in accordance with this mandate, the board reduced its public appearances. Ms. Herold referenced the following presentations that have been provided:

- July 8: Executive Officer Herold and President Weisser attend the CSHP's Board of Directors meeting in Sacramento to provide an update on board activities.
- August 18: Executive Officer Herold provides a Webinar on California's e-pedigree requirements to a conference hosted by the National Coalition of Pharmaceutical Distributors.
- September 14: Executive Officer Herold attend a California Pharmacy Council Meeting to discuss pharmacist manpower today and in the future.

There was no board discussion or public comments on this item.

k. Minutes of the September 26, 2011 Meeting

Ms. Herold referenced the meeting summary of the September 26, 2011 Communication and Public Education Committee Meeting.

There was no board discussion or public comment.

l. First Quarterly Update of the Committee's Strategic Performance Goals for 2011/12

Ms. Herold referenced the first quarterly updated of the Communication and Public Education Committee's strategic performance goals for 2011/12 provided in the meeting materials.

There was no board discussion or public comment.

The board recessed for lunch at 12:03 a.m.

The board reconvened at 1:07 p.m.

IX. PETITION FOR REINSTATEMENT OF LICENSE

a. William Packer – Petition for Reinstatement of Pharmacist License

The board heard a petition from Mr. Packer regarding the reinstatement of his pharmacist license.

Dr. Castellblanch returned to the meeting room at 1:45 p.m.

The board recessed for a break at 1:51 p.m. and reconvened at 1:53 p.m.

b. Stephanie (Boyle) Werner -- Petition for Reinstatement of Pharmacy Technician License

The board heard a petition from Ms. Werner regarding the reinstatement of her pharmacy technician license.

X. CLOSED SESSION

The board convened in closed session pursuant to Government Code section 11126(c)(3) to deliberate on the petitions for reinstatement.

XI. ORAL ARGUMENTS REGARDING NONADODPTION OF THE PROPOSED DECISION IN THE MATTER OF THE ACCUSATION AGAINST ANDREW MARK STERNBERG, RPH 32370

The board did not hear oral arguments on this matter.

XII. CLOSED SESSION

The board convened in closed session pursuant to Government Code section 11126(c)(3) to discuss the matter of the accusation against pharmacist Andrew Mark Sternberg.

RECESS FOR DAY

The board meeting was recessed at 3:08 p.m.

Wednesday, July 27, 2011

The board reconvened at 8:34 a.m. on Wednesday, October 19, 2011.

Board Members Weisser, Zee, Badlani, Castellblanch, Lippe, Kajioka, and Veale were present. A quorum of the board was established.

XIII. ORGANIZATIONAL DEVELOPMENT COMMITTEE REPORT

There was no meeting of the Organizational Development Committee this quarter

a. Budget Update/Report

President Weisser reported on the following items. An opportunity for public comment was provided at the end of the committee report.

1. Budget Report for 2011/12

President Weisser provided that the Governor's budget included $14.4M spending authorization for the board.

2. Fund Condition Report

President Weisser provided that according to a fund condition report prepared by the department, the board will have the following fund conditions at the end of the identified fiscal years:

2010/11	$13,796,000	11.6 months in reserve
2011/12	$11,412,000	9.4 months in reserve
2012/13	$8,618,000	6.9 months in reserve
2013/14	$5,385,000	4.2 months in reserve

President Weisser stated that the board will continue to closely monitor its fund condition to ensure the fiscal integrity of the board's operations and pursue a fee increase only when necessary.

3. Final Budget Report for 2010/11

President Weisser provided that the fiscal year ended June 30, 2011. He stated that the board's maximum spending authority for the year was $12,800,000. President Weisser reviewed the board's revenue and expenditures for fiscal year 2010-11.

4. Update on BreEZe, DCA's Plans for a New Computer System

Ms. Herold provided and overview on the development of Breeze, the department-wide computer system that will allow for online renewal and application processing, and will also replace the board's Consumer Affairs Systems and the Applicant Tracking System.

Ms. Herold advised that the board has committed a significant amount of resources and staff time to this project to ensure the board's operational needs are met. She indicated that the project is on track and the board is scheduled for the second phase of implementation which is anticipated to occur in the spring of 2013.

5. Reimbursement to Board Members

President Weisser referenced the expenses and per diem payments to board members that are provided in the meeting materials.

b. Recognition Program of Pharmacists Who Have Been Licensed 50 Years

President Weisser stated that since July 2005, the board has acknowledged 1,147 pharmacists with 50 or more years of licensure as pharmacists in California.

c. Personnel Update

1. Board Member Vacancies

As of today, the board has 10 board members, and three board member vacancies. The vacant positions are Governor appointments and are for professional members.

This item was not discussed by the board.

2. Staff Changes

Ms. Herold provided that the statewide hiring freeze has prohibited the board from filling vacancies and has consequently delayed processing times for some application types to times that considerably exceed processing times of the board in the past. This has generated complaints. She indicated that the board has received hiring freeze exemptions for additional inspectors which has allowed the board to resume opening inspections for new site licenses.

d. First Quarterly Report on the Committee's Goals for 2011/12

President Weisser referenced the first quarterly report on the Organizational Development Committee's goals provided in the meeting materials.

Public Comment
Raffi Simonian, representing the University of California, San Diego Health System, asked whether the board has secured any technical staff to assist with the implementation of the BreEZe system.

Ms. Herold provided that the board has two dedicated in-house staff and one inspector to provide technical support during the implementation process.

XIV. REPORT OF THE COMPOUNDING REGULATION SUBCOMMITTEE

a. Presentation to the Board by Rita Shane, PharmD, regarding Compounding Practices in Hospital Pharmacies

Rita Shane, representing Cedars-Sinai Hospital, provided a presentation on sterile compounding and related safety strategies in hospital pharmacies to ensure patient safety. A copy of the presentation is attached, following this meeting summary.

Dr. Shane provided an overview of sterile compounding and an analysis of current requirements in this area. She reviewed U.S. reported events and recalls associated with sterile compounding from 1991 to present and indicated that 65 percent of these events were caused by contamination.

Dr. Shane highlighted specific areas of challenge with respect to Section 1735.3 and offered proposed definitions and interpretations for the following terms:
- Hospital patient-specific compounded medications
- Components – 1735.3(a)(5) and (6)
- Equipment – 1735.3(a)(7)

Dr. Shane discussed the critical timeframes required for the administration of compounded drug products. She demonstrated the components of epidural medication and the 38 elements of documentation required to compound this medication. Dr. Shane discussed the balance between meeting compounding requirements while also providing timely patient care.

Dr. Shane provided an overview on the comprehensive guidelines for sterile compounding and dating of such products pursuant to US Pharmacopeia Chapter 797 (USP 797).

Dr. Shane discussed dating of sterile compounded medications. She indicated that 24-hour dating of these products and change in patient condition or medication dose

contributes to product waste, including waste of medications that are part of a drug shortage. Dr. Shane stated that the medication cannot be reused unless board recording requirements are met. This takes too much time for immediate use medications.

Dr. Shane submitted a proposal to the board for an exemption to the recording requirements under Section 1735.3 (a)(6) and (7) for patient-specific compounded medications for use within 24 hours. She discussed that patient-specific medications should not require the recording of manufacturer and lot numbers for the following reasons:

- The need to handwrite the manufacturer and lot number of each medication component slows the preparation of medications to treat critical patient conditions.
- Harmful events with sterile compounded medications have not been due to recalled medications or components but rather due to contamination during preparation or human error.
- Critical medications that are on shortage (or may be in the future) are being discarded even though they are still sterile and stable, based on national standards.
- Quarantining all recalled products would ensure patient safety and timely management of the recall.
- Sterile compounded medications discontinued due to changes in the patient's condition that meet standards for sterility and stability could be dispensed for another patient based on a specific medication order even if they had been made for another patient that did not receive the drug.

  Example: 1 dose of vancomycin 1.5 gram prepared for patient A, discontinued and used for patient B on the same day or within 14 days if refrigerated per USP 797.

Dr. Shane provided that she supports the recording of lot number and manufacturer for compounding of batches or sterile products from non-sterile ingredients.

Dr. Shane recommended that quantitative analysis be reserved for hospital high-risk medications that are quantitatively assayed by current assay technology. She also recommended that all cytotoxic agents bear a label which states "cytotoxic" rather than "chemotherapy" as currently stated in Section 1751.2(d).

b. Discussion and Possible Action Regarding Proposed Modifications to Interpretations Involving Implementation of the Compounding Regulations and Modifications to the Text of Title 16 California Code of Regulations §1735 – §1735.8, and §1751 -- §1751.8

Report
Dr. Kajioka provided an overview of the history of the compounding regulations. He stated that many of the provisions for sterile injectable compounding were promulgated after California's public health event in 2001 where a pharmacy compounded contaminated injectable products that killed three patients and put more than 30 in the hospital.

Dr. Kajioka provided that the current requirements became effective in July 2010. He stated that the board has been discussing implementation of the requirements since that time and established a subcommittee that has developed a series of questions and answers in response to questions received from licensees.

Discussion
The board discussed the definitions and request proposed by Dr. Shane.

It was suggested that the board first discuss the definitions of "component" and "equipment."

Mr. Room discussed the definition of component and whether it should include equipment or just the medications. He indicated that the definition would only include the medications.

Dr. Kajioka indicated that equipment that requires calibration would need to be documented.

Ms. Shellans recommended that the definition of equipment be clarified via regulation.

Ms. Herold discussed that clarification in this area can be added by regulation in Section 1735.3(a)(7). She purposed the following language:

> (7) The equipment used in compounding the drug product. For purposes of this section, equipment means items that must be calibrated or maintained.

Ms. Herold stated that this same definition can also be provided in Section 1751.3(a)(3).

Ms. Veale offered a proposal to direct staff to develop proposed changes to add this clarification.

Discussion on the definition of component continued. It was suggested that the components of a product sometime includes the container. Clarification was provided that component is synonymous with ingredient.

Public Comment

Steve Gray, representing Kaiser Permanente, stated that it is critical to provide as much clarity in the definitions as possible. He stated that the definition of component within the industry "is everything that ends up in the product."

Dr. Gray indicated that there are instances where the container can make a difference and stated that the master formula must indicate the container if a special container is required.

Dr. Gray suggested that the board discuss how quantitative and qualitative issues are being addressed by board inspectors.

Raffi Simonian, speaking as an individual, thanked Dr. Shane for her presentation and indicated that he agrees with her recommendations. He asked the board to consider several areas with respect to this issue including the level of training of pharmacy technicians and the lack of support from industry. Dr. Simonian suggested that the board evaluate whether the regulations should be more like USP 797.

MOTION: Direct staff to draft language to amend Sections 1735.3(a)(7) and 1751.3(a)(3) to reflect the board's discussion that the definition of equipment means items that must be calibrated of maintained for consideration by the board for a future rulemaking.

M/S: Veale/Lippe

Support: 7 Oppose: 0 Abstain: 0

The board discussed Dr. Shane's request to exempt the recording of the manufacturer and lot number for patient-specific compounded medications prepared for "one-time use" and to permit that these products be reused beyond 24-hours.

Dr. Kajioka provided that the subcommittee is recommending that the 24 hour use requirement and the recording of these items be maintained.

Ms. Veale expressed concern regarding the amount of products that are being wasted due to this requirement. She discussed that it may be reasonable to permit reuse of these products beyond 24-hours as long as the products are stored properly.

Ms. Herold cautioned the board that permitting use beyond 24-hours is beyond the current requirements and needs discussion by the board.

Dr. Castellblanch requested additional data regarding the wastage of compounded products.

The board discussed that this recording requirement was established for emergency compounding and evaluated whether granting this exemption would negatively impact patients.

Ms. Veale provided that the subcommittee believes that these items should be recorded to ensure consumer safety.

Ms. Herold recommended that pharmacies always document the lot number and manufacturer for products that are in short supply to ensure that they can be reused beyond 24-hours.

Mr. Lippe offered a proposal to refer this matter regarding the exemption to the manufacturer and lot number recording back to the subcommittee for further consideration.

Public Comment

Gale Romanowski, representing Rady Children's Hospital San Diego, spoke in support of the information provided by Dr. Shane and Dr. Simonian. She discussed that the recording requirements have shifted the focus away from sterile compounding. Dr. Romanowski stated that the USP standards are in the best interest of the patient.

Public comment was provided indicating that it is common practice that in the event a product is recalled, all of that product in a hospital, regardless of lot number, will be pulled.

Raffi Simonian, representing the University of California, San Diego Health System, suggested that rather than requiring the recording of the lot number and manufacturer; the regulation should require that all of a recalled product be pulled from hospitals to respond to the board's concern regarding patient safety.

Ms. Herold advised the board that the provision for these recording requirements is the main component for all compounding in general.

The board recessed for a break at 10:45 a.m. and reconvened at 11:04 p.m.

President Weisser advised those in attendance that the board will have a quorum issue for the remainder of the meeting. He suggested that in order to take action on other agenda items, the board should schedule a full-day Subcommittee Meeting to further discuss this issue.

Mr. Lippe withdrew his proposal.

c. Summary of the Meeting Held August 22, 2011

Dr. Kajioka referenced the summary of the August 22, 2011 Compounding Subcommittee Meeting provided in the meeting materials.

There was no board discussion or public comment.

XV. LICENSING COMMITTEE REPORT

Report of the Meeting held September 26, 2011

a. Review of Requests and Possible Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies:

1. Pharmacy Compounding Accreditation Board (PCAB)
2. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP)

Report

Mr. Lippe provided that California Business and Professions Code section 4127.1 establishes a specialized category of pharmacy licensure for pharmacies that compound injectable sterile drug products and sets forth the requirements for licensure including:

- Licensure as a pharmacy
- Inspection by the board prior to issuance of a license and prior to renewal of a license

Mr. Lippe provided that Section 4127.1(d) creates an exemption in existing law from this specialty category of board licensure for pharmacies if the pharmacy is:

- licensed by the board or the Department of Public Health
  AND
- currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Mr. Lippe provided that consistent with the statute, the board has approved three accreditation agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)
2. Community Health Accreditation Program (CHAP)
3. Det Norske Veritas (DNV).

Mr. Lippe provided that the following agencies are also seeking approval by the board:

1. Pharmacy Compounding Accreditation Board (PCAB)
2. American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP)

Mr. Lippe provided that in 2003, the Licensing Committee developed criteria for approval of accreditation agencies for sterile injectable compounding pharmacies under Business and Professions Code section 4127.1, and generally that these criteria should assess the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors:

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years. *(Note during 2011 discussions with the accrediting agencies, the board urged annual inspections during the review process.)*
2. Documented accreditation standards -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. Evaluation of surveyor's qualifications -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. Acceptance by major California payers -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. Unannounced inspection of California accredited sites -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. Board access to accreditor's report on individual pharmacies.
7. Length of time the accrediting agency has been operating.
8. Ability to accredit out-of-state pharmacies. Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Mr. Lippe provided that during the Licensing Committee Meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and a representative from Pharmacy Compounding Accreditation Board (PCAB). Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Mr. Lippe provided that both organizations were asked to respond to the following requirements:

<u>Survey teams will include a pharmacist.</u>

HFAP would need to restructure its survey teams to include a pharmacist.

PCAB surveyor teams consist of all pharmacists.

Agency agrees to provide the board access to accreditation reports.

HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.

PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Agency agrees to conduct an annual inspection of each pharmacy.

HFAP will conduct annual inspections if required by the board but that routine inspections will impact efficiency and lead to additional costs for the pharmacies.

PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

The board requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

Mr. Lippe provided that board staff has prepared a comparison chart detailing the commitments by PCAB and HFAB and the accreditation agencies currently recognized by the board. He reviewed the following recommendations from the committee:

Recommend to the board to conditionally approve HFAP and PCAB as accreditation agencies pending confirmation that they meet the requirements of other accreditation agencies recognized by the board and the guidelines established for all accreditation agencies to follow at the October 2011 Board Meeting.

Discussion

Ms. Sodergren provided that the comparison chart was developed to ensure that HFAP and PCAB are not being subjected to additional requirements that are not also being required of the other accreditation agencies currently approved by the board.

Dr. Dang reviewed the comparison chart provided in the meeting materials. She also shared correspondence from HFAP regarding this matter which is also provided in the meeting materials.

Ms. Shellans provided comment regarding the requirements for the agencies and indicated that the board has discretion with respect to different standards for the agencies. She advised that pursuant to Section 4127.1 and 4127.2, the board is required to recognize JCAHO an accreditation agency.

The board discussed the responses from each accreditation agency as well as the need for clear requirements for accreditation agencies.

Mr. Room provided that the board has statutory authority to approve or deny accreditation agencies. He stated that the board would need to pursue regulatory change to establish requirements for this approval.

It was the consensus of the board to refer this issue back to the committee for further evaluation and consideration of requirements for accreditation agencies.

The board took no action on the committee's recommendation.

There was no public comment.

b. Discussion and Possible Action to Pursue a Statutory Amendment to Business and Professions Code Section 4209 to allow for the Reporting of Intern Hours to the Board of Pharmacy by Other State Boards of Pharmacy

Relevant Statutes
Business and Professions Code section 4209 specifies that an intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. This section also specifies that an intern pharmacist shall submit proof of his or her experience on a board-approved affidavit and established the criteria for submission.

Background
Until last year, the board accepted intern hours earned in another state, if the hours were either:

1. Verified by the state board of pharmacy in which the hours were earned or
2. Accepted board affidavits.

After further review of this policy, it was noted that acceptance of intern hour verification was contrary to legal requirements established in B&PC section 4209(b). The result is a significant increase in staff resources to complete the necessary license verifications, not only on the out of state intern, but also each pharmacist providing verification of the experience earned.

Report
Mr. Lippe provided that the committee discussed the issue regarding the importance of training and experience earned in a pharmacy.

Mr. Lippe reviewed the committee's recommendation to modify Section 4209 regarding intern hours.

There was no board discussion or public comment.

MOTION: Licensing Committee: Sponsor legislation to modify Business and Professions Code section 4209 as provided below.

> 4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam
>
> (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
>
> (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
>
> (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.
>
> (c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

Support: 7 Oppose: 0 Abstain: 0

c. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Report

Chair Lippe provided that Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education (CE) credit every two years as a condition of renewal.

Chair Lippe provided Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

- Pharmacology
- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration

- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Chair Lippe provided that at several prior meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. He advised that to establish such a requirement would require either a legislative or regulation change.

Chair Lippe provided that at the February 2011 Board Meeting, the board directed that the committee continue its discussion about such a requirement and specified that if the recommendation is approved, authorize staff to investigate implementation.

Chair Lippe provided that suggested topics considered by the committee included:
- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Patient Consultation
- Ethics
- Drug Abuse
- Defined Content Areas
- Certification in a pharmacist specialty by a accreditation agency

Chair Lippe provided that the committee has also heard comments about content specific course mandates and CE in general, and whether a portion of CE should be obtained in specific manner (e.g., live, web-based, journal, etc.).

Chair Lippe provided that the committee discussed that any topic identified by the board should have generally broad-based applicability for pharmacists.

Chair Lippe provided that the committee discussed possible implementation of this policy including:
- Statutory changes
- Regulation changes
- Preferential credit for completing courses in specified areas
- Encouraging completion of certain courses in *The Script*

Chair Lippe reviewed the following recommendation from the committee:

> Direct staff to research implementing incentives for licensees who earn CE in specific content areas including ethics, substance abuse, emergency/disaster response and patient consultation. Recommend that the board reconsider and

possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

Discussion
Ms. Veale provided that the committee is looking for direction from the board regarding the amount of CE that can be awarded for attendance at meetings of the board. She discussed that attending board meetings may not benefit a licensee's competency as effectively as CE in other areas. Ms. Veale suggested that the board consider decreasing the amount of CE (currently six hours per year) awarded in this area.

President Weisser discussed that CE for board meeting attendance was intended to engage licensees. He stated that the board is now more focused on ensuring a licensee's competency.
Dr. Castellblanch provided comment in support of awarding CE for board meeting attendance but agreed that the amount offered should be reconsidered.

Ms. Veale discussed that specific content areas required by the board should be dynamic and evaluated regularly by the board to ensure applicability to the profession.

Mr. Badlani discussed that not all content areas are applicable to all areas of pharmacy.

Mr. Lippe suggested that the committee discuss this issue of applicability at its next meeting.

The board discussed that the committee is moving in the right direction on this issue.

d. Discussion Concerning DCA's Focus on Continuing Competency

Report
Mr. Lippe provided that the department has asked all boards to evaluate how they can ensure the continued competency of their practitioners and this item has been discussed at several Board and Licensing Committee Meetings over the last year.

Mr. Lippe provided that during the July 2011 Board Meeting, Scotti Russell from the National Association of Boards of Pharmacy (NABP) provided a presentation on a new self-assessment exam that they are developing - - The Pharmacist Assessment for Remediation and Evaluation (PARE). He stated that accouding to the NABP, the PARE provides a multidimensional assessment that the boards of pharmacy may use as a contributory factor when making decisions regarding pharmacist practice deficiencies that result from disregarding pharmacy practice standards, non-compliance with laws and regulations, and/or threats to patient safety. Mr. Lippe indicated that Ms. Russell discussed that the PARE can be used as a tool to evaluate pharmacist's competence when reactivating or reinstating a license. He stated that Ms. Russell advised that the exam is internet based and should be administered in a monitored or proctored setting.

Mr. Lippe provided that the PARE will be psychometrically validated and will be updated regularly to address current drug therapies. Mr. Lippe stated that the exam will be available for use in 2012 and will cost $250.

Mr. Lippe provided that Board Member Veale and former Member Ken Schell have agreed to take the examination as pre-testers (to help calibrate the exam).

There was no board discussion or public comment.

e. Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees

Background
As part of Senate Bill 139 (Chapter 522, Statutes of 2007) the Office of Statewide Health Planning and Development (OSHPD) was directed to establish the California Healthcare Workforce Clearinghouse (Clearinghouse) to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state.

Report
Ms. Sodergren provided that the department is encouraging all boards to collect the necessary information to assist OSHPD in their charge to, among other items, serve as the repository for comprehensive data and standardize data collection tools and methods.

Ms. Sodergren indicated that the committee discussed the information that is required to be collected and use of an on-line resource such as Survey Monkey that could serve as an easy collection method that would have minimal impact on board staff as well as possible ways to incentivize completion of the survey. She advised that the committee requested that the survey include language indicating that participation is voluntary and counsel offered to provide possible disclosure language.

Ms. Sodergren referenced the updated draft survey incorporating counsel's language provided in the meeting materials.

No public comment was provided.

MOTION: Approve posting of the Survey for Health Licensing Entities and disclosure language on the board's website.

M/S: Veale/Lippe

Support: 7 Oppose: 0 Abstain: 0

Dr. Castellblanch left the meeting at 12:00 p.m.

f. Competency Committee Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE).
The board instituted a quality assurance review of the CPJE effective August 8, 2011. This process is done periodically to ensure the reliability of the examination. On September 27, 2011, the quality assurance review was removed and results have been released.

CPJE Statistics
CPJE statistics for all candidates who took the CPJE examination between 4/1/11 – 9/30/11, were distributed.

Examination Development
Each Competency Committee workgroup met this fall to continue for examination development activities.

There was no board discussion or public comment on this item.

g. Licensing Statistics

Mr. Lippe referenced the licensing statistics for the first quarter of 2011/12 provided in the meeting materials.

There was no board discussion or public comment.

h. Minutes of the Meeting Held September 26, 2011

Mr. Lippe referenced the meeting summary from the September 26, 2011 Licensing Committee Meeting provided in the meeting materials.

There was no board discussion or public comment.

i. First Quarterly Report on the Committee's Goals for 2011/12

Mr. Lippe referenced the first quarterly report on the Licensing Committee's goals provided in the meeting materials.

Public Comment
Marcie Lepkowskey, representing the University of California, San Diego, suggested that the board may want to consider requiring that pharmacy students attend a board meeting.

She also sought clarification from the board on the process for issuing a pharmacist license for purposes of residency.

Ms. Herold recommended that hospitals who have residency programs need to advise applicants to apply to take the pharmacist exams as soon as they accept admission into a residency program.

XVI. DISCUSSION AND POSSIBLE ACTION TO ADOPT THE 2012-2017 STRATEGIC PLAN UPDATE FOR THE BOARD OF PHARMACY

Report
President Weisser advised that the new Strategic Plan is still under development and will be brought to the board for consideration at the January 2012 Board Meeting.

There was no board discussion or public comment.

XVII. EXECUTIVE OFFICER'S REPORT

a. Discussion and Possible Action Regarding the Board's 2011 Sunset Review Process and Report for Submission to the Senate Committee on Business, Professions and Economic Development

Report
Ms. Herold provided that the Sunset Report is still in development and will be distributed to the board and posted on the board's website on November 1, 2011.

There was no board discussion or public comment.

b. General Report of the Executive Officer

Report
Ms. Herold provided an overview of the budget constraints and travel limitations impacting the board.

Ms. Herold reported that the board has secured 12 hiring freeze exemptions as well as additional office space.

Ms. Herold provided that she and President Weisser recently met with Agency Secretary, Anna Caballero. She also indicated that the department has loaned a public information officer for the board's public education needs for the next three months.

Ms. Herold advised the board that there needs to be full participation in the mail voting process to ensure timely disciplinary decisions, because there has been issues with a quorum of the board member voting timely.

There was no board discussion or public comment.

XVIII. PUBLIC COMMENT ON ITEMS NOT ON THE AGENDA/AGENDA ITEMS FOR FUTURE MEETINGS

Marcie Lepkowsky discussed the challenge of complying with the ASHP residency program. She advised that residents who fail the exam have to wait 90 days to retake the exam.

Darlene Fujimoto, representing the University of California, San Diego, suggested that the board discuss the issue of specialty pharmacies. She also suggested the possibility of a pain summit to address appropriate pain treatment.

The meeting was adjourned at 12:25 a.m.

Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Complaints/Investigations					
Received	611				611
Closed	413				413
Pending (at the end of quarter)	1772				1772
Cases Assigned & Pending (by Team) at end of quarter*					
Compliance Team	537				537
Drug Diversion/Fraud	226				226
Probation/PRP	101				101
Routine Inspection	33				33
Mediation/Enforcement	64				64
Criminal Conviction	561				561
Application Investigations					
Received	217				217
Closed					
Approved	135				135
Denied	18				18
Total**	243				243
Pending (at the end of quarter)	209				209
Letter of Admonishment (LOA) / Citation & Fine					
LOAs Issued	20				20
Citations Issued	239				239
Citations Closed	273				273
Total Fines Collected***	$319,115.00				$319,115.00

* This figure include reports submitted to the supervisor.

** This figure includes withdrawn applications.

*** Fines collected (through 9/30/2011 and reports in previous fiscal year.)

Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Administrative Cases (by effective date of decision)					
Referred to AG's Office*	85				85
Pleadings Filed	61				61
Pending					
Pre-accusation	194				194
Post Accusation	279				279
Total*	533				533
Closed					
Revocation					
Pharmacist	2				2
Intern Pharmacist	0				0
Pharmacy Technician	16				16
Designated Representative	1				1
Pharmacy	0				0
Revocation,stayed; suspension/probation					
Pharmacist	2				2
Intern Pharmacist	0				0
Pharmacy Technician	1				1
Designated Representative	0				0
Pharmacy	0				0
Revocation,stayed; probation					
Pharmacist	3				3
Intern Pharmacist	0				0
Pharmacy Technician	6				6
Designated Representative	0				0
Pharmacy	3				3
Surrender/Voluntary Surrender					
Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	7				7
Designated Representative	0				0
Pharmacy	0				0

Board of Pharmacy Enforcement Statistics
Fiscal Year 2011/2012

Workload Statistics	July-Sept	Oct-Dec	Jan-Mar	Apr-June	Total 10/11
Public Reproval/Reprimand					
Pharmacist	0				0
Intern Pharmacist	0				0
Pharmacy Technician	0				0
Designated Representative	0				0
Pharmacy	0				0
Cost Recovery Requested**	$88,205.00				$88,205.00
Cost Recovery Collected**	$78,117.99				$78,117.99

* This figure includes Citation Appeals

** This figure includes administrative penalties

Probation Statistics

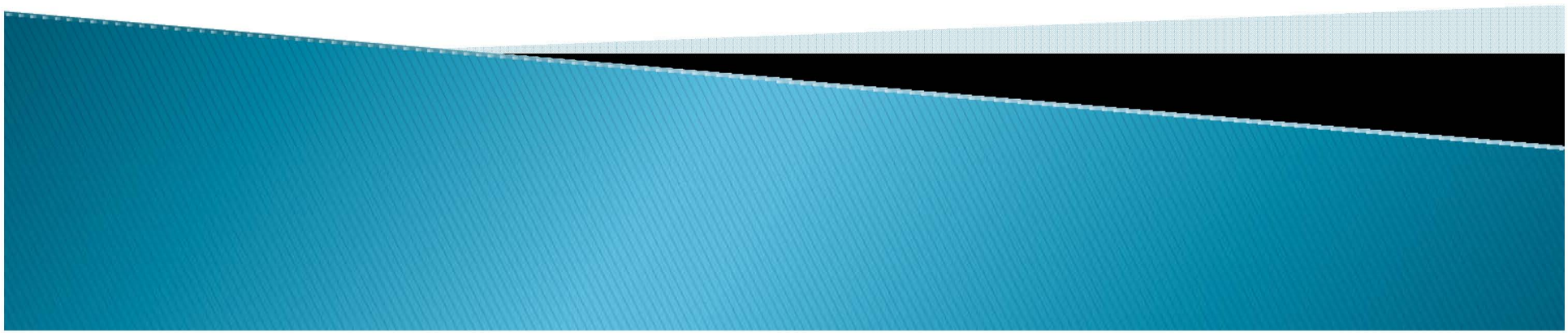
Licenses on Probation					
Pharmacist	111				111
Intern Pharmacist	5				5
Pharmacy Technician	31				31
Designated Representative	2				2
Pharmacy	18				18
Wholesaler	2				2
Probation Office Conferences	17				17
Probation Site Inspections	73				73
Probationers Referred to AG for non-compliance	0				0

As part of probation monitoring, the board requires licensees to appear before the supervising inspector at probation office conferences. These conferences are used as 1) an orientation to probation and the specific requirements of probation at the onset, 2) to address areas of non-compliance when other efforts such as letters have failed, and 3) when a licensee is scheduled to end probation.

As of September 30, 2011

Sterile Compounding to Ensure Patient Safety

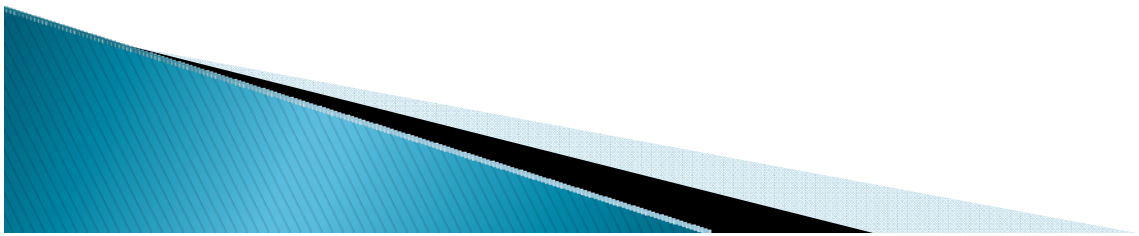
October 19, 2011



Goal and Objectives

- **Goal**: Collaborate on safety strategies to reduce harm associated with sterile compounding in the hospital setting

- **Objectives**:
  - Describe causes of harmful patient events associated with sterile compounding
  - Discuss interpretation of regulations related to:
    1. Component and Equipment
    2. Hospital Patient-Specific Compounding
    3. Quantitative Analysis
    4. Labeling cytotoxic medications as “chemotherapy”
  - Describe USP 797 and California hospital sterile compounding practices



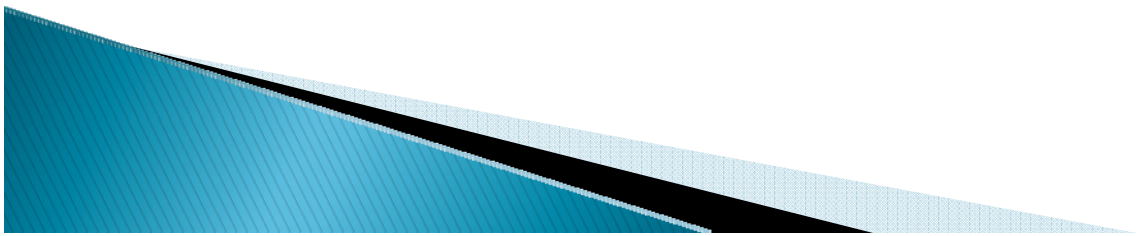
Balancing Requirements with Patient Care Needs

Documentation required by Compounding Regulations

Timely availability of sterile compounded medications for hospital patients

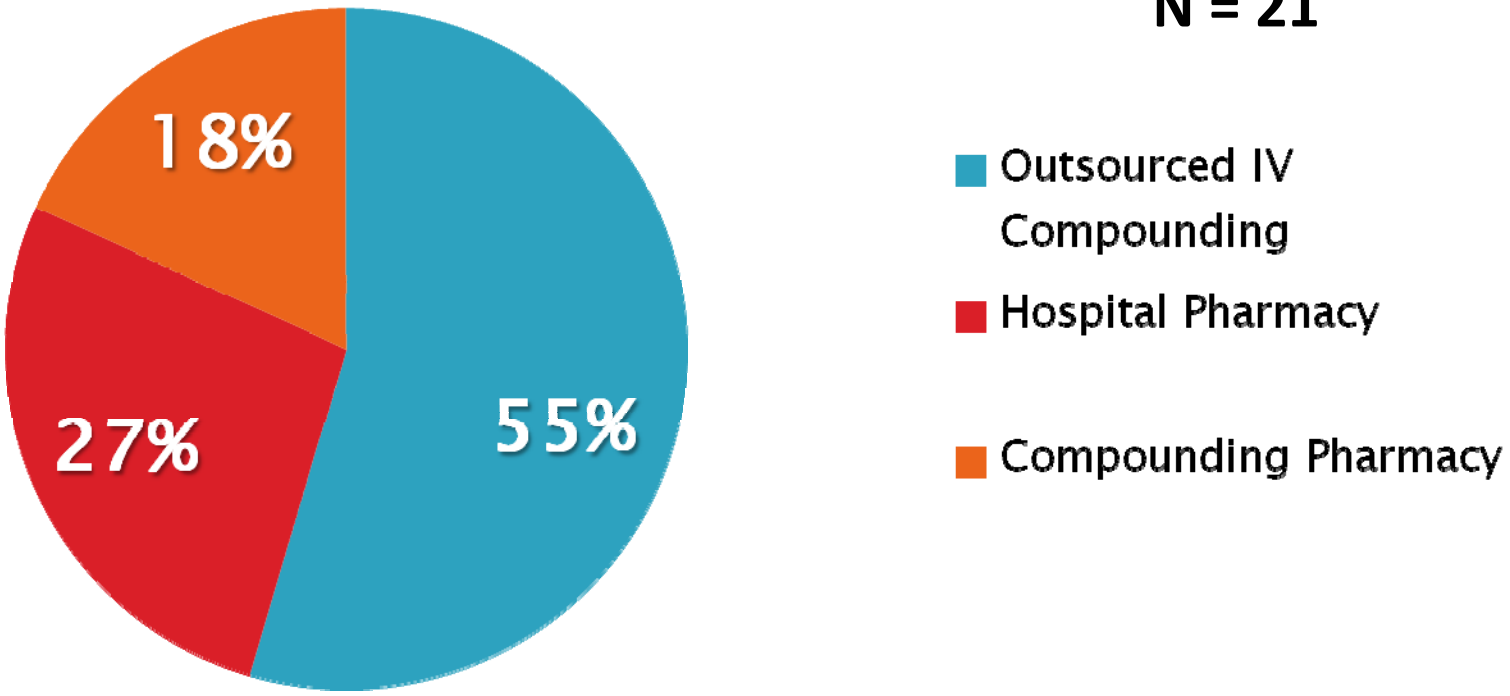
Types of Pharmacies that Compound Sterile Products

- Hospital Pharmacies
  - Generally use only sterile products to compound
- Outsourced Sterile Compounding Pharmacies
  - Use both non-sterile and sterile products to compound
- Compounding Pharmacies
  - Use both non-sterile and sterile products to compound



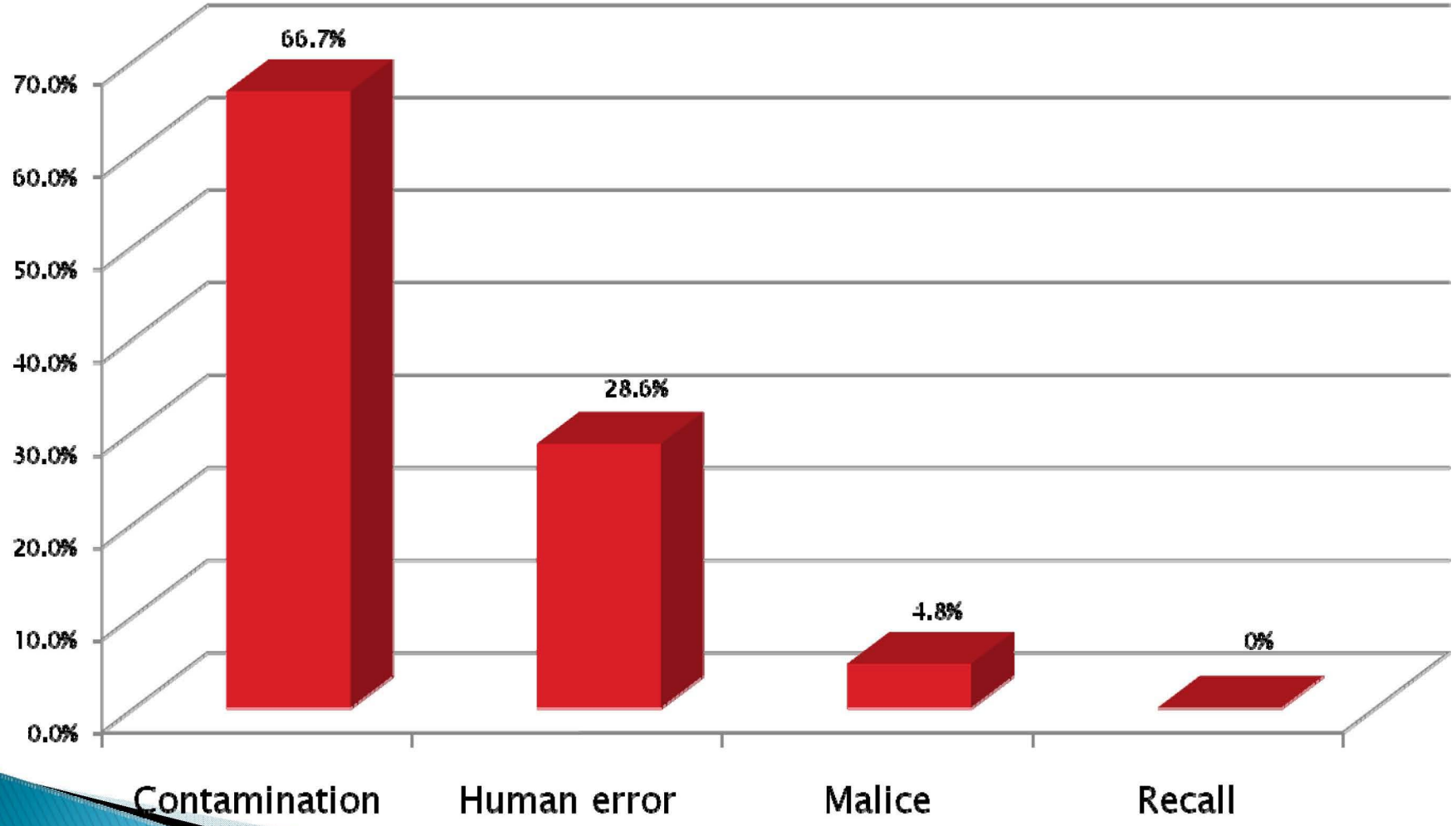
U.S. Publicly Reported Events Associated with Sterile Compounding

Site of Events (1991 – Present)



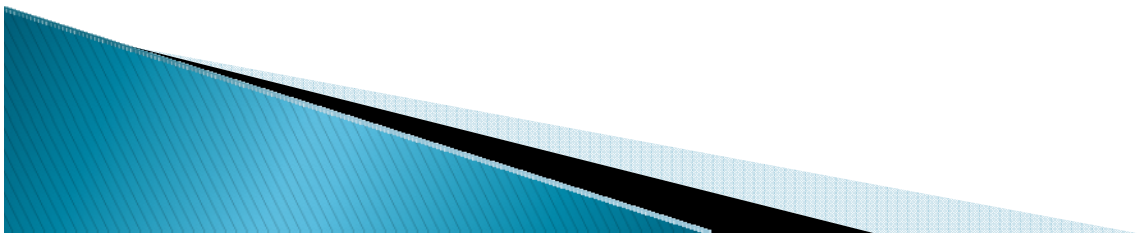
Mortality Weekly Report (MMWR) on CDC.gov;PubMed for reported cases; ISMP.org; FDA.gov; Google.com; Professional presentations related to sterile compounding)

U.S. Publicly Reported Events Associated with Sterile Compounding
Analysis of Causes of Harmful Patient Events



1735.3.Records of Compounded Products

- (a) For each compounded drug product, the pharmacy records shall include:
- (6) The **manufacturer and lot number of each component**. If the manufacturer name is demonstrably unavailable, the name of the supplier may be substituted. Exempt from the requirements in this paragraph are **sterile products compounded on a one-time basis for administration within twenty-four hours to an inpatient in a health care facility** …
- (7) The **equipment** used in compounding



Sterile Compounding Processes in Ambulatory and Hospital Settings

Ambulatory Setting

- One prescription iw generally represents multiple days' supply of medications

Home Infusion

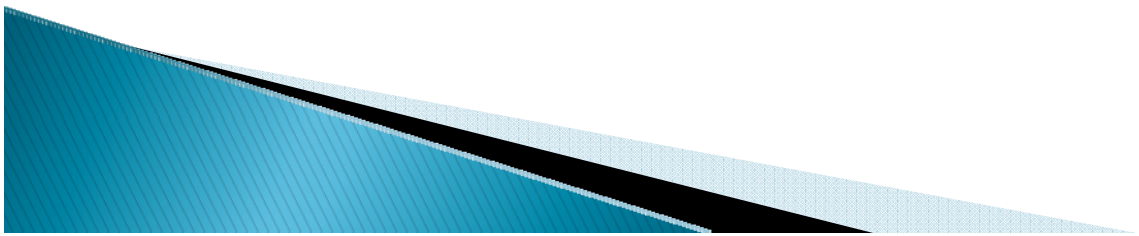
- One prescription is compounded for multiple days at the same time

Hospital Setting

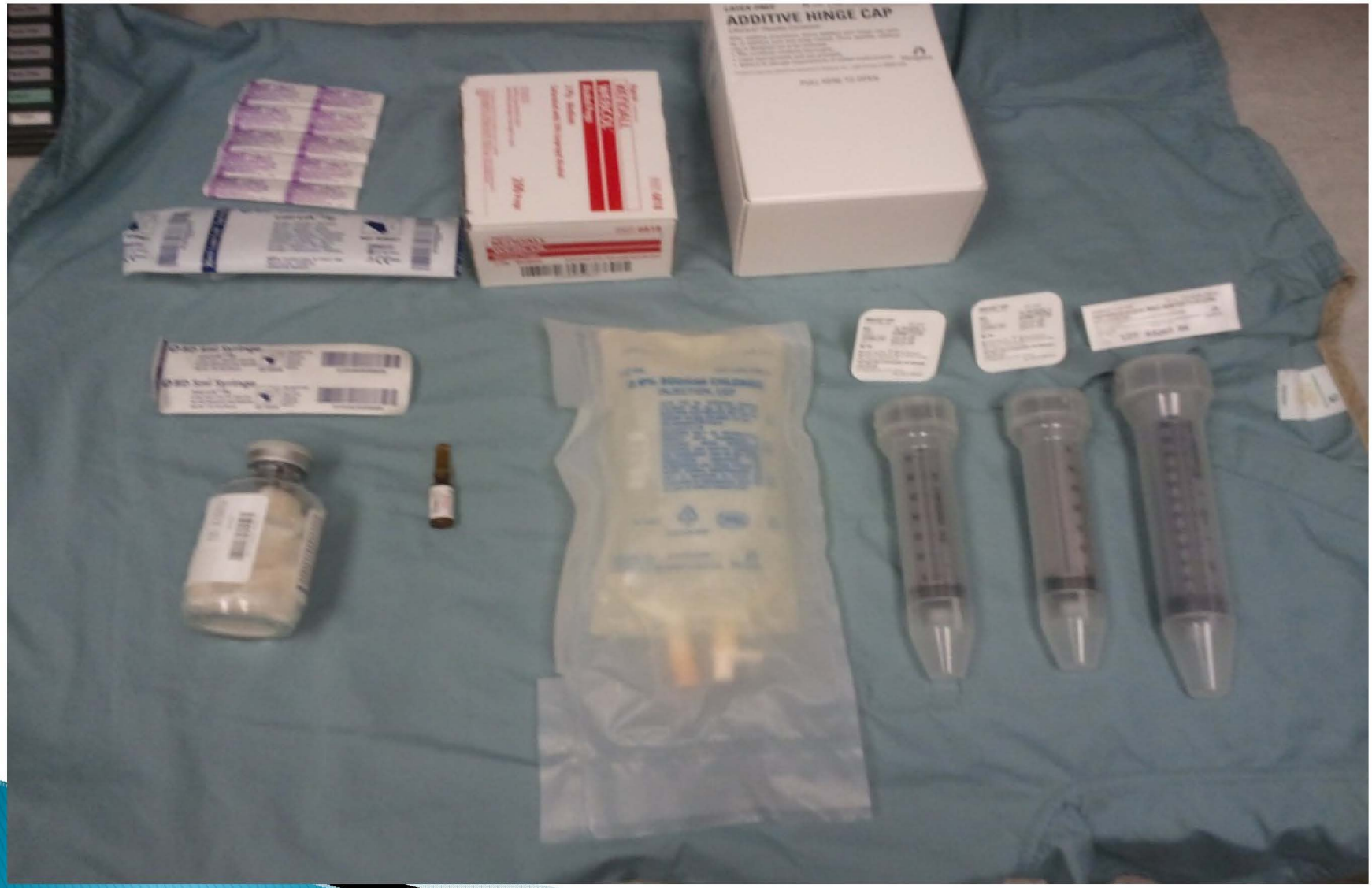
- One prescription represents multiple days of medications that are generally compounded multiple times per day for the duration of treatment
- Number of sterile products is approximately equal to the # of beds,
  - 300 bed hospital compounds approx. 300 sterile products/day

Proposed Definitions and Interpretations

- **Hospital Patient-Specific Compounded Medications:**
  - Definition: Medications compounded using sterile products for an individual patient based on a physician order (prescription) intended to be given within 24 hours.
  - Interpretation: Medications prepared and not administered due to changes in patients' condition could be dispensed if stability and sterility standards are met.
- **Components: 1735.3. (a) (5) and (6)**
  - Interpretation: Medications used to compound sterile product (excludes needles, syringes, etc)
- **Equipment: 1735.3 (a) (7)**
  - Interpretation: List of items used in compounding to ensure medications are accurately and safely prepared which are documented on the Master Formula Record.



Epidural Medication Components



Equipment Needed for Epidural Compounding

38 elements of documentation required

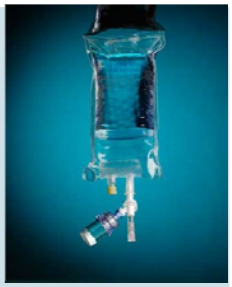
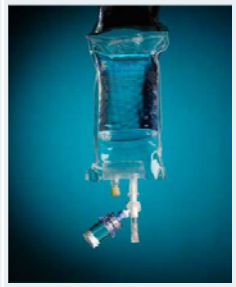
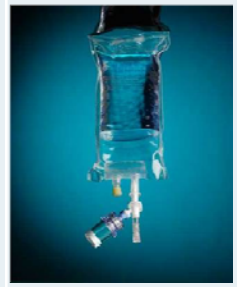
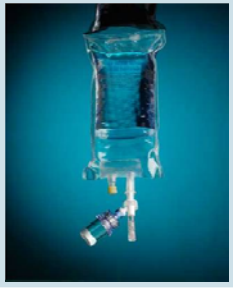
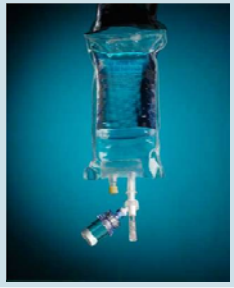
Each lot number is 7-10 characters

Item	Lot Number Source	Source of Manufacturer Name	Tally
Bupivicaine	Vial	Vial	2
Fentanyl	Ampule	Ampule	4
Normal Saline 250 ml	Bag	Bag	6
Syringes x3	Syringe	Outer box	12
Syringe	Syringe pkg	Syringe pkg	14
Regular needle x5	Needle pkg	Needle pkg	24
Filter x2	Needle pkg	Needle pkg	28
Adapter	Pkg	Pkg	30
Alcohol pads x3	Outer box	Individual pkg	36
[illegible] cap	Outer box	Cap	38

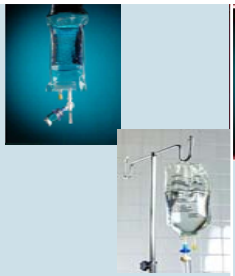
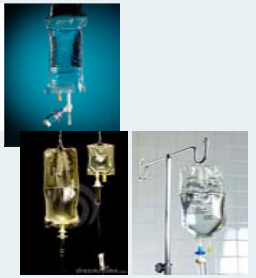
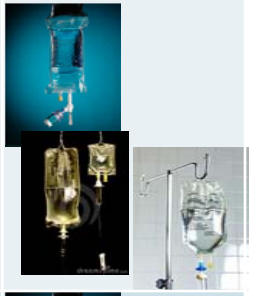
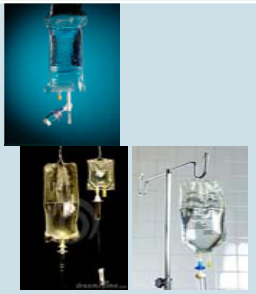
Critical Timeframes for Medication Administration to Ensure Survival

Example Drugs	Timeframe for Administration
Thrombolytics (tPA) for stroke	30 minutes from time detected (ED/inpatient)
Epidural pain medication for post-operative patient	Immediate
Nitroprusside for hypertensive crisis	Immediate

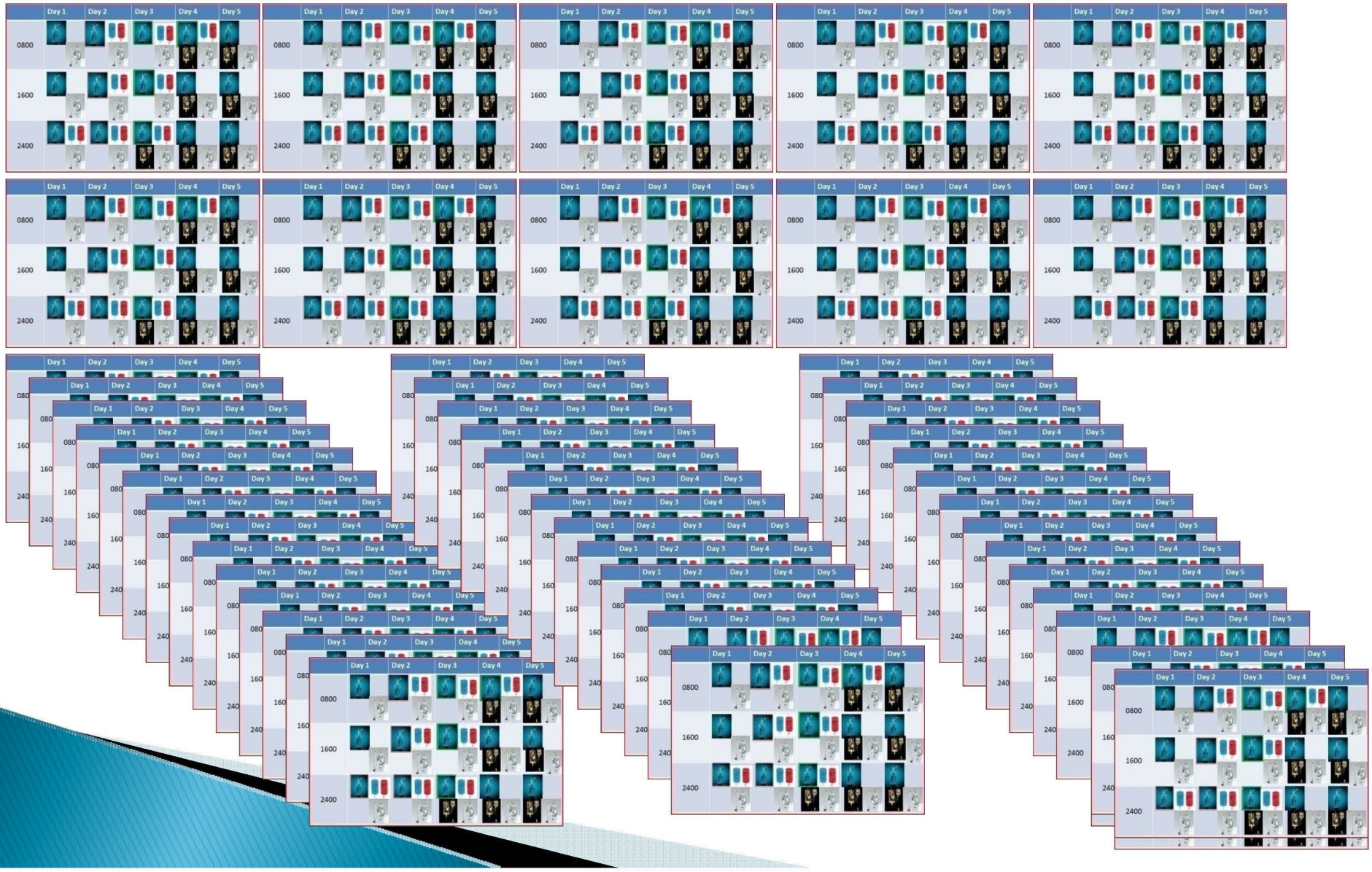
One antibiotic order for a patient for 5 days of therapy:

	Day 1	Day 2	Day 3	Day 4	Day 5
0800					
1600					
2400					

Hospitalized patients conditions change resulting in new medication orders and order modifications. Example of one patient's orders:

	Day 1	Day 2	Day 3	Day 4	Day 5
0800					
1600					
2400					

Many hospitalized patients are on multiple compounded IV medications



California Hospital Survey of Sterile Compounding Practices N=38

USP 797	• 94 % following USP 797 • 6% implemented the majority of components and working towards facility renovation
Safety Strategies	• 100% double checking of chemotherapy • Safety measures for pediatric sterile products include: certified Individuals, double checking, verifying weight based dosing
Training	• Formal Training Programs for pharmacists and technicians including ASHP training and written exam
Drug Shortages	• 100% of hospitals significantly impacted by drug shortages
Error Prevention	• Errors have been intercepted by double checks • Causes of errors include calculations, CPOE, computer system errors
Hospital Pharmacy Computer Systems	• Commercial systems do not have the ability to support documentation of lot number and manufacturer N=22

USP 797

- USP (US Pharmacopiea) Chapter 797 developed in collaboration with FDA in 2004
- Comprehensive guidelines for sterile compounding to ensure highest quality; adopted by hospital pharmacies
- Dating of sterile compounded products is defined by USP based on risk levels determined by the level of complexity of compounded products.
- CDPH Medication Error Reduction Plan Survey address USP 797

http://www.usp.org/products/797Guidebook/

Dating for Sterile Compounded Medications

USP 797 National Sterility Standards Defines storage until the IV is hung for administration *Stability is based on manuf info, published literature				CaBOP Supply Mfgr, Lot #, & Exp Date Must be Logged to Reuse Admixtures (Needles, Syringes, Tubing)
Storage Until Hanging	Room Temp	Refrig	Frozen	
Immediate Use	1 hr	1 hr	N/A	
Low Risk ≤ 2 adds; BUD<12 (non-clean room)	12 hrs	12 hrs	12 hrs	
Low Risk ≤ 2 adds (IV Clean Room)	48 hrs	14 days	45 days	Must be hung by 24 hrs No reuse
Medium Risk > 2 adds, chemo, TPN	30 hrs	9 days	45 days	Must be hung by 24 hrs No reuse
	24 hrs	3 days	45 days	Must be hung by 24 hrs No reuse

Sterile Compounding and Implications of Drug Shortages and Wastage

Approx. 900 sterile products prepared/day based on over 5000 orders/day

95 sterile products wasted per day due to 24 hour dating*

Significant environmental impact

49% of medications wasted are drugs that are in shortage

Types of drugs wasted that are on shortage: antibiotics, heart failure meds, critical care meds, chemotherapy, antivirals

Drug Shortages have a significant impact on availability of injectable drugs

184 Drug Shortages YTD of which 175 are injectable drugs

*does not include sterile products wasted in patient care areas

Challenges Associated with Quantitative and Labeled Strength Analysis (1735.8.)

- Overfill volume for commercially manufactured intravenous solutions ranges from 2%–34% (source:3 IV manufacturers)
  - Overfill varies within a batch and amongst different volumes of IV fluids
- As a result, an analysis of potency of medication will almost always be less than what is labeled

Assay of Amiodarone 500mg/500 ml D5W Effect of Overfill

DYNALABS
Innovation Accelerated®

CERTIFICATE OF ANALYSIS

SAMPLE INFORMATION

Customer:	Cedars-Sinai Medical Center	Storage:	Room Temperature
Received:	June 30, 2011	Amount / Device:	Amiodarone 500m
Description:	AMIODARONE 1MG/ML IN D5W		
Lot Number:	110629ivr03		
Sample #:	W-1-4		

RESULTS

Test	Specification	Result	Comment
Potency/Purity[1]	90.0 - 110.0 %	85.97% (0.86 mg/mL)	Amiodarone HCl calculated on actual bag volume of 551 mL is 0.9473 mg/mL 94.73%

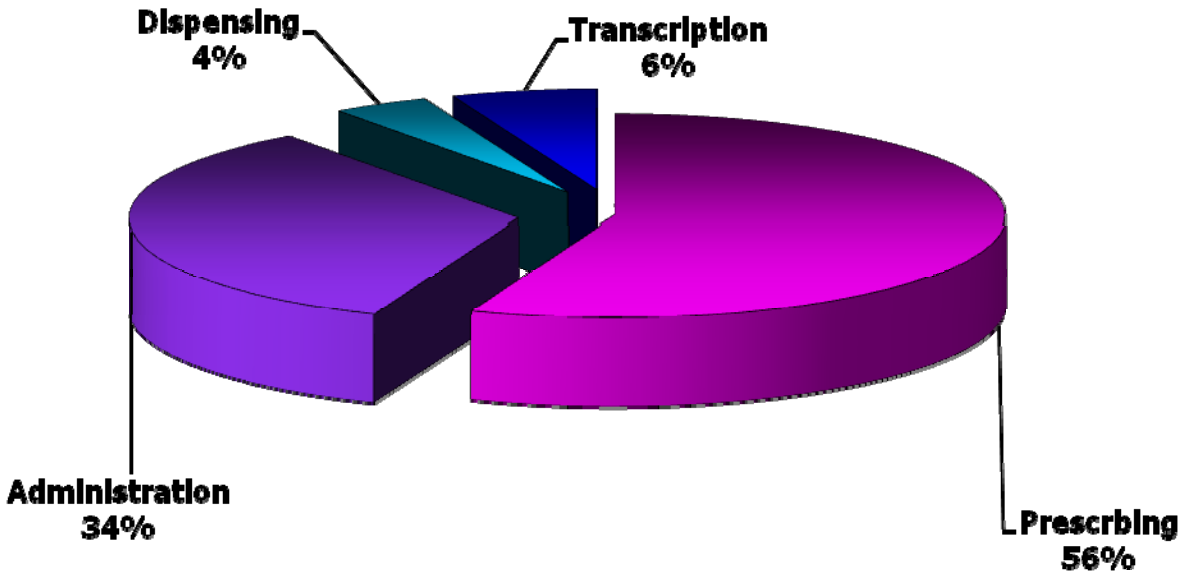
AUTHORIZATION AND WARRANTY

Medications Labeled as Chemotherapy

1751.2.d. All cytotoxic agents shall bear a label "Chemotherapy-Dispose of Properly"

Medication	Category/Use
Ganciclovir	Antiviral used for CMV prevention/treatment in transplant pts
Infliximab	Biologic used to treat Crohn's disease, rheumatoid arthritis
Flucytosine	Antifungal therapy used for meningitis
Foscarnet	Antiviral agent used for CMV retinitis and HSV
Leuprolide	Gonadotropin-releasing hormone agonist used for endometriosis
Palifermin	Keratinocyte growth factor used for oral mucositis

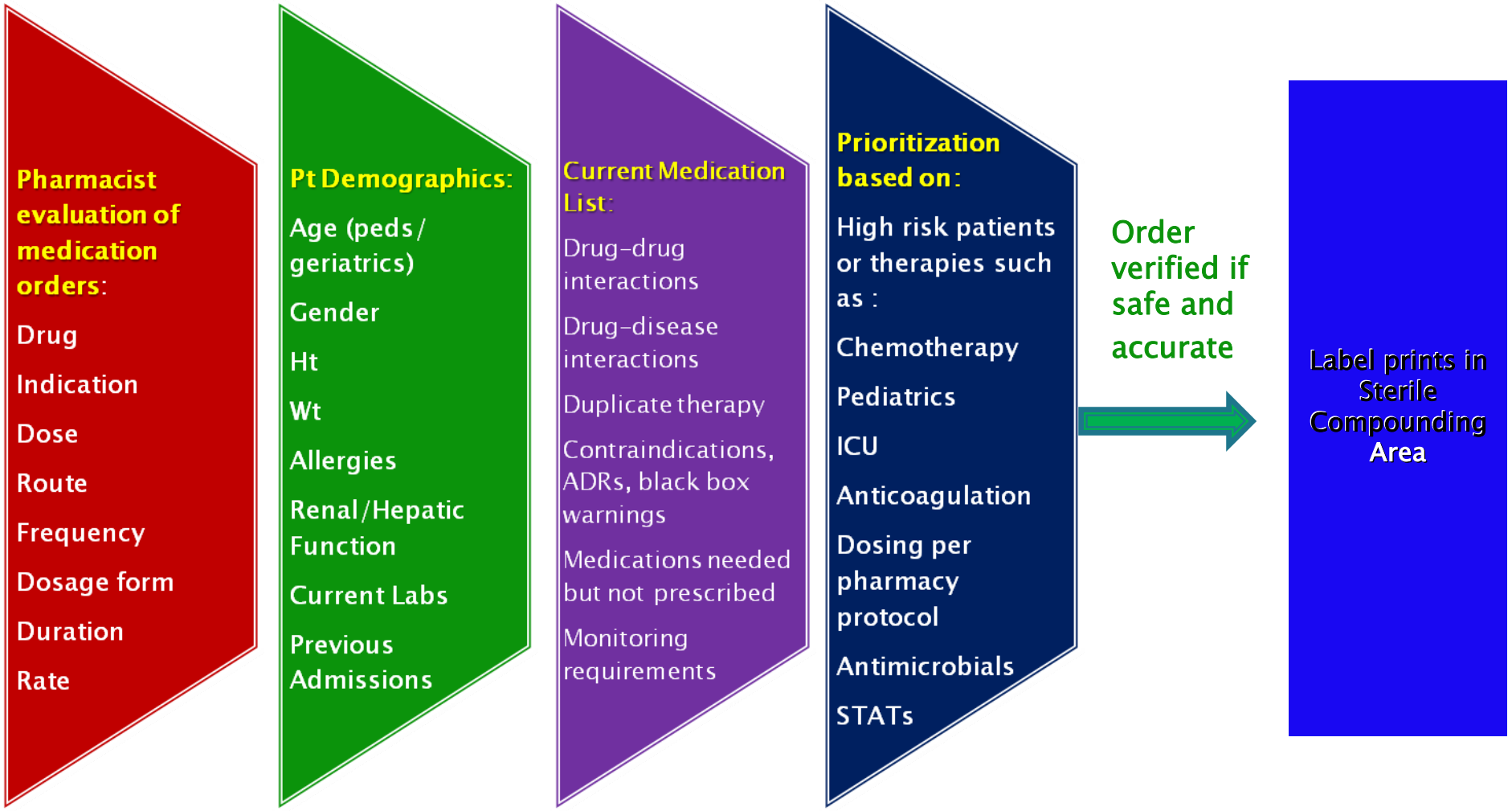
The Origin of Errors
Preventable Adverse Drug Events in Hospitals



53 prescribing errors/1000 medication orders (prescriptions)

Sources: Bates, et al. *JAMA* (1995)
Institute of Medicine 2006

Hospital Pharmacist Evaluation of Medication Orders



Patient Specific-Medication Considerations

- **Patient-specific medications should not require the recording of manufacturer and lot numbers for the following reasons:**
  1. Handwritten documentation for **patient-specific medications delays prompt delivery** of critical medications.
  2. Harmful events related to sterile compounding **have not been shown to result from drug recalls** but rather from contamination and errors.
  3. Critical medications **in the face of shortages are being discarded** even though considered sterile and stable based on national standards.
  4. Quarantining **all** recalled products would ensure **patient safety** and **timely follow-up and action.**
- **Medications prepared and not administered** due to changes in patients' condition **could be dispensed if stability and sterility standards are met.**

Hospital Recommendations-Part 1

1. Interpretation of "Component" &"Equipment" 1735.3. (a) (5)-(7)
   a. "Component": Medications used to compound sterile products (excludes needles, syringes, etc).
   b. "Equipment": list of items used in compounding to ensure medications are accurately and safely prepared which are documented on the Master Formula Record.

2. Interpretation of "Hospital Patient-Specific Compounded Medications"
   a. "Hospital Patient-Specific Compounded Medications": Medications compounded using sterile products for an individual patient based on a physician order (prescription) intended to be given within 24 hours.
   b. Documentation of manufacturer and lot number for medications should only be required for batches and non-sterile compounded products.
   c. Hospital Patient-Specific Compounded Medications would not require documentation of manufacturer and lot number.

Hospital Recommendations–Part 2

3. **Requirements for Quantitative Analysis**
   a. Reserve for hospital high-risk medications that can be quantitatively assayed by current assay technology
   b. Conduct periodic evaluations to ensure potency and labeled strength

4. **Labeling of Cytotoxic Agents as "Chemotherapy"**
   a. All cytotoxic agents shall bear a label which states "cytotoxic" rather than "chemotherapy" as currently stated in Compounding Regulations. 1751.2.(d)