



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

**STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
ENFORCEMENT COMMITTEE MEETING
MINUTES**

DATE: June 4, 2013

LOCATION: DCA Headquarters
1625 N Market Blvd – Hearing Room
Sacramento, CA 95834

COMMITTEE MEMBERS

PRESENT: Amy Gutierrez, PharmD, Chair
Rosalyn Hackworth, Public Member
Randy Kajioka, PharmD
Victor Law, RPh
Gregg Lippe, Public Member

COMMITTEE MEMBERS

NOT PRESENT: Tappan Zee, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Robert Ratcliff, PharmD, Supervising Inspector
Rob Buckner, Manager, Criminal Investigations
Carolyn Klein, Manager, Legislation and Regulations
Kristy Shellans, DCA Senior Staff Counsel

The meeting was called to order at 9:30. Dr. Gutierrez, Chair, welcomed those in attendance. Roll call was taken and a quorum was established.

I. Enforcement Matters:

a. Enforcement and Compounding Committee Meeting Dates for the Remainder of 2013

Future Enforcement and Compounding Committee meetings are scheduled for September 10, 2013 and December 3, 2013. These dates are subject to change.

b. Discussion on Whether Emerging Technologies Necessitate Revisions to Title 16, Section 1713 of the California Code of Regulations

Background

Several years ago, the board promulgated regulations (16 California Code of Regulation section 1713) to allow for the use of automated delivery devices, which are markedly like vending machines, to permit the furnishing of refill medication in specified circumstances. These circumstances include, that the patient must opt in to use the machine, the medication to be refilled through the machine is appropriate. The conditions are listed below in the highlighted segment of section 1713.

1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated delivery device to deliver previously dispensed prescription medications provided:

(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.

(2) A pharmacist has determined that each patient using the device meets inclusion criteria for use of the device established by the pharmacy prior to delivery of prescription medication to that patient.

(3) The device has a means to identify each patient and only release that patient's prescription medications.

(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).

(5) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

(6) The device is located adjacent to the secure pharmacy area.

- (7) The device is secure from access and removal by unauthorized individuals.**
- (8) The pharmacy is responsible for the prescription medications stored in the device.**
- (9) Any incident involving the device where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.**
- (10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).**
- (e) Any pharmacy making use of an automated delivery device as permitted by subdivision (d) shall maintain, and on an annual basis review, written policies and procedures providing for:*
- (1) Maintaining the security of the automated delivery device and the dangerous drugs within the device.*
 - (2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the device and for which patients, including when consultation is needed. 1*
 - (3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the automated delivery device.*
 - (4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the automated delivery device.*
 - (5) Orienting participating patients on use of the automated delivery device, notifying patients when expected prescription medications are not available in the device, and ensuring that patient use of the device does not interfere with delivery of prescription medications.*
 - (6) Ensuring the delivery of medications to patients in the event the device is disabled or malfunctions.*
 - (f) Written policies and procedures shall be maintained at least three years beyond the last use of an automated delivery device.*
 - (g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.*

In 2009-10, Pharmacist Consultant Philip Burgess, on behalf of a manufacturer of one of these machines (Asteres), sought an exemption to permit the use of these machines in areas away from adjacent to the licensed pharmacy premises. The board did not approve the request, and requested more information about how and where the kiosks would be used. One concern was that the board considered that it lacked the ability to provide the exemption sought (which would have required a regulation change).

At the Committee's March 14, 2013 meeting, Mr. Carter, representing Walgreens, discussed a request that would allow for Walgreens to place kiosks in workplace clinics. Mr. Carter provided an overview of the types of services that are provided at the clinic and how Walgreens would provide medication. Mr. Carter highlighted that the kiosk would not be stored in the clinic, but would be housed across the street in a separate building. The Board did not approve the request, indicating there was insufficient evidence to act.

Presentation and Discussion:

Representatives from Asteres, Inc., and Sharp HealthCare discussed the need to revise section 1713 and presented a request to allow three separate pilot studies on the campuses of Sharp, UCSD Health System and USC Hospital to review the use of automated delivery devices. Mr. Burgess, representing Asteres, Inc. reminded the Board that section 1713(b) already allows the delivery of prescriptions to employees at their worksite.

Mr. Burgess proposed to revise section 1713(d)(6) to allow for the placement of automated devices in a secure building controlled by a Board licensee at an alternate location readily accessible for Board inspection, but not adjacent to a secure pharmacy area.

Mr. Lippe and Dr. Gutierrez asked whether the devices would be on the premises of the licensee. The answer was that the devices would not have to be on the premises of a licensee but could be at corporate offices, for example, a non-licensed facility.

Mr. Burgess also proposed to revise section 1713(d) to also allow the dispensing of new prescriptions delivered from automated devices, provided consultation has taken place and proper documentation has been reviewed and saved. He explained that the Asteres system allows the ability to load filled prescriptions in the device and lock them in the device. The prescriptions would not be released to the patients until the patients had been counseled by a pharmacist via telephone (adjacent to the device). Mr. Burgess indicated the devices could also be used for prescription refills.

Mr. Burgess then provided photos of automated devices already in operation at an Air Force Base in El Segundo (Installed 2009) and St Joseph's Hospital in Phoenix, Arizona (Installed 2011) where employee utilization of the device had grown from 13 percent to 44 percent.

Mr. Lippe asked if the devices were tamper proof. The Board heard comments that security measures include a camera in the device which takes a photo of every patient, required signatures and the fact that the device itself is bolted to the floor and weighs over 1,350 pounds. More than 700,000 prescriptions have been delivered without incident. Representatives from Sharp HealthCare indicated they have seven hospitals, seven retail pharmacies and 22 clinics in San Diego serving 200,000 patients. Sharp believes the automated devices align with their vision of providing patient/employee-centered care to

the 3000 employees who work in their corporate offices. Although their pharmacy is only two miles away, getting to the pharmacy can be difficult due to work schedules and heavy traffic. She believes the automated devices would be easier and more convenient for employees to pick up their medications. Representatives from Sharp HealthCare provided photos of the proposed location for the automated device and indicated that the building in which the device would be placed has 24-hour security and requires a badge for entry.

Ms. Herold asked how a prescription gets to a pharmacy two miles away and was advised a prescription would get to the pharmacy as any other. Ms. Herold was also advised that a patient could drop off a paper prescription in a slot in the device. The paper prescription would be picked up and delivered to a pharmacy when the device is serviced during the day.

Ms. Shellans stated she did not think the Board could act on the request because current law does not allow for the storage of dangerous drugs at a location not licensed by the Board. Mr. Burgess argued that current law allows for the delivery of prescription medications to a patient at his or her office and that the Board should focus on delivery of medications as opposed to the storage of medications.

Dr. Gutierrez asked whether all seven Sharp pharmacies would be depositing prescriptions in the automated devices and was advised that it was Sharp's plan to have only one pharmacy responsible for filling and delivering prescriptions to an automated device. She also introduced another proposal in which Sharp would use the same pharmacy to deliver prescriptions to an automated device located at Sharp Memorial Hospital Campus to dispense discharge medications. Sharp envisions a patient being counseled by a Pharmacist at the bedside or over the phone, obtaining an access code, then being discharged and obtaining their prescription from the automated device. The device allows for the use of a credit or debit card for payment.

Dr. Gutierrez asked if Sharp provided mail delivery and was advised that Sharp provides next-day home delivery via mail, but prefers delivery via an automated device because the device is secure in that it allows for the tracking of who picks up their medications and who does not.

Dr. Kajioka asked how long delivery transaction data are kept on file. Mr. Burgess answered that data is kept forever and there is no purge criteria. Data includes a full audit trail which includes a photo of the person picking up the prescription and the signature log. He believes the control and accuracy associated with prescription deliveries via automated device is much better than normal.

Mr. Burgess stated UC San Diego and USC couldn't appear at the meeting, but would like to appear at the full Board meeting in July to discuss proposed changes to section 1713.

Dr. Gutierrez advised the presenters to create a formal proposal for the Board to review.

Ms. Herold indicated Board would also need to see some parameters from the school explaining parts such as what measurements they would take and how long the pilot study

would last. Ms. Herold stated that the UC San Diego conducted the initial pilot and that contacting them might be helpful. Also, because the requirements and concerns raised varied due to whether a proposed location was licensed or not, Ms. Herold advised the presenters to break up their proposals so the Board could address each individually.

Ms. Herold stated that the Board has limited authority to waive a regulation based on an experimental program pursuant to the requirements listed in section California Code of Regulations Section 1706.5. The results of the experimental program would have to demonstrate to the Board that the automated device is safe and that a regulation revision would be advantageous.

Motion: Recommend to Board that it consider moving forward with an experimental program/research study once UC San Diego and USC can develop and submit a specific proposal.

M/S: Lippe/Hackworth

Support: 5 Oppose: 0 Abstain: 0

c. Request from California Society of Health-System Pharmacists to Discuss Drug Shortages

Background

At the March 13, 2013, Committee meeting, Jonathon Nelson, representing the California Society of Health-System Pharmacists (CSHP), addressed the Committee to discuss the drug shortages and requested the topic be discussed at a future meeting.

Presentation and Discussion

Jonathan Nelson, representing CSHP, thanked the Committee for giving him the opportunity to discuss the crisis of drug shortages. He shared an article from the Washingtonian Magazine which detailed rationing, hoarding and bartering of medications in Washington area hospitals.

Maria Serpa, a Pharmacist at Sutter Medical Center, Sacramento, addressed the Committee and shared her experiences with drug shortages and how they are impacting patients everyday. She and her team monitor and anticipate drug shortages, constantly look for alternative drug sources and medications, create back orders with wholesalers, and when necessary, begin rationing. She provided examples of times when her team has sent drugs to other healthcare centers that were completely out of specific drugs. The shortages have created an informal bartering system where healthcare centers share drugs with each other.

Dr. Serpa also shared a recent New England Journal article that outlined a study in which first line standard treatments for cancer became a drug shortage problem. Researchers

switched the patients to an equivalent treatment to deal with the shortage. When researchers reviewed the results of the alternative equivalent therapies, they found that patients had a significant increase in cancer recurrence.

Mr. Lippe asked why there are shortages now. Dr. Serpa answered that there are multiple reasons including financial decisions which result in a dropped product line; drugs dropped from the market due to regulatory issues; and short supplies of raw product used in drug production.

Dr. Gutierrez stated that President Obama issued an Executive Order in 2011 to have the FDA begin tackling the issue of drug shortages. Mr. Nelson indicated the Food and Drug Administration (FDA) is working with manufacturers to identify the reasons for drug shortages and address those issues.

Mr. Lippe asked whether a database could be created so healthcare centers would more easily locate other healthcare centers with a surplus of the specific drug. Ms. Herold stated brokering drugs between facilities on a large scale would require a license to prevent people from moving drugs through the gray market. A pharmacy, for instance, is only allowed to sell drugs back to the wholesaler with some limited exceptions, one of which being drug shortages.

Mr. Herold stated she was not sure what the Board could do to address the problem. Dr. Serpa suggested the Board, as well as other associations, could provide information regarding the seriousness of the problem and different methods of dealing with drug shortages before and after they arise.

Public Comment

The Board heard public comment regarding a pending law which will create a Compounded Manufacturing License issued by the FDA. The Board also heard public comment regarding the possibility of relying more on compounding pharmacies to fill the need during times of drug shortages as well as the need for state and federal government to oversee the safety of compounding manufacturing while also allowing flexibility in allowing compounding manufacturers to fill an important need.

d. Implementation of Penal Code section 11105 – Board Requirement to Provide Criminal Offender Record Information to an Applicant or Licensee When the Information is Used as the Basis for a Licensing Decision

Background

As part of its licensing process, the Board is required to conduct a criminal background check to determine whether an applicant has committed acts that would constitute grounds for denial of a license. Applicants must submit their fingerprints to the California

Department of Justice (DOJ) who then matches the fingerprints against state and federal criminal history databases. The DOJ provides the results of the background check to the Board who uses the information to help determine the suitability of the applicant for licensure. The Board also receives a notice from the DOJ when a licensee is arrested in California subsequent to initial licensure.

Penal Code section 11105 authorizes the DOJ to release criminal offender record information (CORI) to law enforcement and other authorized agencies such as the Board. The Board cannot share criminal offender record information (CORI), including responses that indicates no criminal history exists, with anyone unless expressly authorized. Individuals have the right to request a copy of their own criminal history record from the DOJ to review for accuracy and completeness, but CORI is not subject to disclosure under the Public Records Act. Release of information to unauthorized individuals can result in civil or criminal penalties pursuant to Penal Code sections 11142 and 11143.

Effective January 1, 2013, however, Penal Code section 11105 (Amended by Stats. 2012, c. 256, A.B. 2343) requires authorized agencies to expeditiously furnish a copy of CORI to the person to whom the information relates if the information is the basis for an adverse employment, licensing or certification decision.

The Board implemented procedures on January 1, 2013, to comply with this new requirement and since that time has provided a copy of the CORI to every applicant who has been denied and every licensee who has received a Letter of Admonishment, Citation or has been referred to the Attorney General's office for disciplinary action based, to some degree, on information contained in the CORI.

Discussion and Comment

Chair Gutierrez provided information on the new law and the board's implementation. There were no questions or comments from the Committee or public.

e. National Association of Boards of Pharmacy Report on Sales of Fake and Substandard Medications

Background

The National Association of Boards of Pharmacy (NABP) issued a report on April 26, 2013 which focused on the global distribution of counterfeit and substandard medications. The report found that the proliferation of these medications was primarily due to illegal distribution by internet pharmacies operating out of compliance with US pharmacy laws. A copy of the report was provided in the meeting materials, and can also be found on the NAB website at:

https://awarerx.s3.amazonaws.com/system/redactor_assets/documents/179/NABP_Internet_Drug_Outlet_Report_Apr2013.pdf

Discussion:

Ms. Herold stated the Board has a very limited role in regulating internet pharmacies short of disciplining people or businesses for unlicensed activity. Ms. Herold described the video on the Board's website that educates and warns the public about the appropriate way to deal with internet pharmacies. She stated the Board rarely gets complaints regarding internet pharmacies because the people using them are happy to get their drugs without a prescription or without having to see a prescriber. The Board generally receives complaints only when there's a problem regarding continuing shipping or billing and identity fraud. When the Board receives complaints, they are generally referred to the National Association of Boards of Pharmacy and the FDA.

Dr. Gutierrez mentioned consumers can look for **Verified Internet Pharmacy Practice Sites (VIPPS)** symbol on the website which indicates that the internet pharmacy has completed the NABP accreditation classes and is licensed in the state in which they're located.

Public Comment

There were no questions or comments from the public.

f. NABP Announces Development of Standards for the .pharmacy Generic Top Level Domain for Internet Pharmacy Web Sites

Background

According to the NABP, which monitors Web sites selling prescription drugs among its various programs, 97 percent of the 10,300 Internet drug outlets it has reviewed are out of compliance with pharmacy laws and practice standards in the US established to protect patients. Correspondingly, NABP has labeled as "Not Recommended" 10,082 Web sites; nearly half of these are offering foreign or non-FDA approved drugs, and many include counterfeits.

Generic top level domains are the suffix part of a Web site address (e.g., .com, .org, .edu). Late last year, the NABP sought the formal approval to be able to approve anyone using the general top level domain (gTLD) of .pharmacy. Earlier this year, an international group of experts were convened by the NABP to develop parameters for anyone that would be able to use the .pharmacy gTLD. The board's executive officer was one of the individuals who participated in this process, and the intent is to have the parameters for the .pharmacy gTLD in place by the end of 2013. A copy of the NABP press release issued May 21, 2013 was provided in the meeting materials.

Discussion

Ms. Herold stated the Board was one of two state Boards of Pharmacy invited was to participate in the development of the .pharmacy internet domain.

Public Comment

There were no questions or comments from the public.

Break for lunch 11:30 – 12:32

II. Compounding Matters

a. Discussion on Pending California Legislation on Sterile Compounding: Senate Bill 294 (Emmerson) and Assembly Bill 1045 (Quirk-Silva)

Background

Following two large-scale public health emergencies last year in which dangerous products compounded by two out-of-state pharmacies were shipped nationwide, staff suggested modifying existing sterile compounding requirements in California. As a result, Senator Emmerson has authored Senate Bill 294 (SB 294) to carry this Board-sponsored legislation.

Senate Bill 294 will strengthen the Board's ability to regulate and monitor pharmacies that compound sterile drug products. This legislation would prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding pharmacy license from the board.

Additionally, on April 22, 2013, Assembly Member Quirk-Silva amended Assembly Bill 1045 to carry provisions that would amend existing law to allow the Board to suspend or revoke a nonresident pharmacy's license if its license is suspended or revoked in the pharmacy's home state. It would also require resident and nonresident pharmacies that issue a recall notice regarding a sterile compounded drug to contact the recipient pharmacy, prescriber or patient of the recalled drug and the Board within 24 hours of the recall notice if use of or exposure to the recalled drug may cause serious adverse health consequences or death and if the recalled drug was dispensed or is intended for use in this state.

Discussion

There were no Committee comments.

Public Comment

The Committee heard public comment asking about current licensing requirements. With regard to AB 1045, Ms. Herold clarified that the qualifying method for someone to become licensed as a non-resident pharmacy in California is for the pharmacy to be licensed in the home state. If the license in the home state is revoked, suspended or cancelled for any reason, the California license will correspondingly be revoked, suspended or cancelled by operation of law. Ms. Herold also clarified that the California license could still be disciplined whether or not the license is disciplined in the home state.

b. Discussion of Recent Federal Reports and Articles Relating to Compounding Pharmacies

1. FDA's oversight of NECC and Ameridose: A history of missed opportunities
2. Office of the Inspector General Memorandum Report: High-Risk Sterile Preparations and Outsourcing by Hospitals That Use Them, OEI-01-013-00150
3. ASHP Guidelines on Outsourcing Sterile Compounding Services
4. FDA's Guidance for FDA Staff and Industry – Marketed Unapproved Drugs , Compliance Policy Guide
5. U.S. Senate Health, Education and Pensions Committee Report: The Case for Clarifying FDA Authority: Large-Scale Drug Compounding and the Ongoing Risk to Public Health
6. Miscellaneous Articles

Background

Full articles were provided in the meeting materials.

Discussion

Dr. Gutierrez provided some background and a brief overview of each report and article. There were no questions or comments from the Committee.

Public Comment

There were no questions or comments from the public.

c. Proposed Federal Legislation on Compounding Introduced by the U.S. Senate (S. 959)

Background

On May 22, 2013, the United States Senate Committee on Health Education Labor & Pensions passed S. 959, the *Pharmaceutical Compounding Quality and Accountability Act*. A copy of a statement from Senator Harkin made Wednesday, May 22, 2013, was provided in the meeting materials.

Discussion

Ms. Herold stated the pending Senate legislation is currently linked with the supply chain security provisions which would preempt California's e-pedigree law if enacted. There is competing legislation for the e-pedigree law which just passed the House.

Regarding compounding, non-patient specific drugs moving across state lines into a state would be regulated by the FDA and drugs within a state would be regulated by the state Board. For the most part, the federal legislation is on the same path as California's e-pedigree law.

Public Comment

The Committee heard a public question on whether out-of-state pharmacies are able to ship high-risk sterile injectable compounded drugs. Ms. Herold answered that an out-of-state pharmacy would have to hold a California specialty license or be accredited by one of the accrediting agencies. Further, Ms. Herold indicated that as she reads the Senate Bill, non-patient specific shipping across state lines would cease if the Bill passes.

d. Discussion Regarding USP's 797 Standards and Regulation Requirements of the Board of Pharmacy

Background

For a number of years, California has had its own statutory and regulation requirements for those pharmacies that compound medication or perform parenteral compounding. Since 2001, again through legislation as well as through regulations, the board has several times developed additional requirements to respond to emergent public health or regulatory concerns.

Many states rely upon USP 797 components to regulate compounding activities. California, instead, relies on its own standards for compounders and sterile compounding.

During this segment of the meeting, the Committee will review the components in a crosswalk comparing the two sets of requirements. This crosswalk has been prepared by the Los Angeles County Department of Health Services, and was provided in the meeting materials.

Discussion and Comment

Dr. Ratcliff and Dr. Smith presented the crosswalk and the Committee reviewed and compared the two sets of requirements. Ms. Herold advised that the Committee make sure all the requirements in USP 797 eventually be included in the Board's regulation and that the regulations be written as clearly and concisely as possible for the benefit of everyone.

The Committee and public made several comments regarding the best process for making sure the Board's regulations are inclusive of the requirements in USP 797. In addition the committee heard comments and suggestion regarding the best path forward in its review and recommendations as well as the need to keep in mind that there are instances, therapies, formulations, and practice settings that don't fit into the norm.

Motion: Form subcommittee to work with staff to create third column on crosswalk with proposed regulation changes for public comment.

M/S: Kajioka/Law

Support: 5 Oppose: 0 Abstain: 0

e. **Discussion Regarding "Batches"**

Background

Board regulations related to compounding are found in Title 16 of the California Code of Regulations, Article 4.5 (all compounding) and Article 7 (related to sterile injectable compounding). On April 1, 2013, regulation changes went into effect that apply to compounding definitions, expiration dating, recordkeeping requirements, and labeling of cytotoxic agents. During this rulemaking, the board was asked what the board's definition of "batch" is, and what requirements apply to batching – but these topics were not within the scope of the regulation change.

At this meeting, the Committee will initiate a new discussion of "batch." The following references are provided for the Committee's information.

Existing Board Regulation

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

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

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

United States Pharmacopeial Convention (USP)

"Batch" – More than 25 units

¹**American Society of Health System Pharmacists (ASHP)**

Excerpt:

Risk Level 2.

Risk level 2 sterile products exhibit characteristic 1, 2, or 3, stated below. All risk level 2 products should be prepared with sterile equipment, sterile ingredients and solutions, and sterile contact surfaces for the final product and with closed-system transfer methods.

¹ American Society of Health-System Pharmacists. ASHP Guidelines on Quality Assurance for Pharmacy-Prepared Sterile Products. *Am J Health-Syst Pharm.* 2000; 57:1150-69. Available at <http://www.ashp.org>

Risk level 2 includes the following:

1. Products stored beyond 7 days under refrigeration, stored beyond 30 days frozen, or administered beyond 28 hours after preparation and storage at room temperature.
2. **Batch-prepared products without preservatives** (e.g., epidural products) that are intended for use by more than one patient. (Note: Batch-prepared products without preservatives that will be administered to multiple patients carry a greater risk to the patients than products prepared for a single patient because of the potential effect of inaccurate ingredients or product contamination on the health and well-being of a larger patient group.)
3. Products compounded by complex or numerous manipulations of sterile ingredients obtained from licensed manufacturers in a sterile container or reservoir obtained from a licensed manufacturer by using closed-system aseptic transfer; for example, TPN solutions prepared with an automated compounder. (Note: So many risks have been associated with automated compounding of TPN solutions that its complexity requires risk level 2 procedures.)

Discussion

Dr. Ratcliff stated that the term “batch” is defined as 25 more or by USP 797 and as 10 or more by ASHP. Dr. Ratcliff stated he believed the two numbers were arbitrary and there was no scientific evidence to support either. He has advised that, in the interest of public safety, the batch should be defined as affecting more than one patient.

Dr. Gutierrez stated the Board should adopt the definition of a batch from the CGMP (Current Good Manufacturing Practices from the federal register) which doesn't have a number associated with it. She also said she believed the reason USP came up with 25 was because that's the smallest amount you can sample and actually have any useful data.

Public Comment

The Committee heard another comment that if you're talking about batching, you need to talk about sampling, processes, and process validation.

f. Discussion on the Board of Pharmacy's Questions and Answers Document on Compounding

Background

To provide guidance to pharmacies and others, the board has various "Questions and Answers" on its website in response to questions from practitioners. To reflect recent changes in the board's compounding regulations which took effect April 1, 2013, the Board is in the process of amending some of its "Questions and Answers."

Discussion

There were no questions or comments from the Committee.

Public Comment

The Committee heard one comment in appreciation of the Board's efforts in this area.

g. Outcomes of Recent Sterile Compounding Inspections

Presentation and Discussion

Dr. Ratcliff provided the Committee with a summary of outcomes from recent board inspections of sterile compounding pharmacies. Between January 1, 2013 and mid-May 2013, staff completed 87 inspections. See attached graphs and charts for more specific information.

Public Comment

The Committee heard clarifying questions from the public.

h. Recalls of Compounded Drugs Throughout the United States

Background

Between April 11, 2013 and May 20, 2013, the Board posted seven subscriber alerts related to compounding drug recalls and two subscriber alerts related to cease and desist orders issued. A summary of the alerts are listed below.

- Green Valley Drugs in Henderson, Nevada, voluntarily recalled all lots of sterile products compounded, repackaged, and distributed by the pharmacy due to lack of sterility assurance and concerns associated with the quality control processes.

- ApotheCure, Inc. recalled all lots of sterile products compounded by the pharmacy that are not expired to the user. The recall was initiated due to lack of sterility assurance and concerns associated with the quality control processes.
- NuVision Pharmacy recalled all unexpired lots of lyophilized compounds of HcG 5000IU-5ml and Sermorelin/GHRH6-5ml to the user. The recall was initiated due to the lack of sterility assurance and concerns associated with the quality control processes identified during a FDA inspection.
- Balances Solutions Compounding Pharmacy, LLC recalled all lots of sterile products compounded by the pharmacy that were not expired. The recall was initiated due to concerns associated with quality control processes, which present a lack of sterility assurance.
- Nora Apothecary & alternative Therapies recalled a multi-state recall of all sterile drug products compounded by the pharmacy that have not reached the expiration date listed on the product. The compounded products that are subject to the recall were products within their expiration date that were compounded and dispensed by the pharmacy on or before Friday, April 19, 2013. The recall was initiated due to concerns associated with quality control processes that present a lack of sterility assurance and were observed during a recent FDA inspection.
- The U.S. Food and Drug Administration alerted health care providers, hospital supply managers, and pharmacists that the FDA's preliminary findings of practices at The Compounding Shop of St. Petersburg, Florida, raised concerns about a lack of sterility assurance for sterile drugs produced at and distributed from this site.
- Pentec Health, Inc. initiated a limited recall of in-date nutritional prescriptions for renal patients due to lack of sterility assurance associated with one of its laminar flow hoods used in compounding.
- Southern California Compounding Pharmacy, LLC was issued a cease and desist order on April 19, 2013, for any and all non-sterile compounding.
- Advance Outcome Management Pharmacy Services was issued a cease and desist order on April 29, 2013, from furnishing sterile injectable compounded products.

Discussion and Comment

Chair Gutierrez presented information on the recalls and Board actions. There were no questions or comments from the Committee or public.

Chair Gutierrez adjourned the meeting at 2:42 p.m.