



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 PUBLIC MEETING
MINUTES**

DATE: September 10, 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
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Kristy Shellans, DCA Senior Staff Counsel
Joshua Room, Supervising Deputy Attorney General
Susan Cappello, Enforcement Manager
Laura Hendricks, Administrative Analyst

The meeting was called to at 9:37 a.m. Dr. Gutierrez, Chair, welcomed those in attendance. Roll call was taken and a quorum established.

I. Enforcement Matters

- a. Proposed Statutory Provisions to Prevent a Wholesaler From Purchasing Prescription Medication From a Pharmacy When the Pharmacy Did Not Purchase the Medication From the Wholesaler**

This item was not discussed.

b. Review of Walgreens' New Business Model for Pharmacies

Background

Walgreens has developed a new model for its community pharmacies where a pharmacist is located outside the normal pharmacy licensed area, so as to be more accessible to patients. This model is being rolled out nationally.

During the January 31 and February 1, 2012 Board meeting Al Carter, Pharm.D, Manager of Pharmacy Affairs for Walgreens made a presentation to the board on Walgreens new pharmacy design called "Well Experience." Dr. Carter indicated the new format, which has been implemented in several states, is designed to enhance the patient's interaction with the pharmacist.

Presentation and Discussion:

Dr. Carter, representing Walgreens, gave an overview of Walgreens new pharmacy model "Well Experience". Dr. Carter indicated Walgreens has implemented this program in four states; Illinois, Indiana, Florida and Arizona with full implementation of the technology and the use of centralization processing. Two California stores (Hollywood and Stockton) have this new design and are fully operational. There are three additional California stores that have the "Well Experience" layout and design but the technology has not been implemented. As the needs grow for the technology those stores will be implemented.

1. In 2010-2011, the executives looked back at the current practice model in community setting and wanted to look at some way to enhance that model and bring the pharmacist out front and be more accessible to the patient. Walgreens went through numerous surveys surveying patients. The centralization process would be removed from the non-resident pharmacy process to **Amend California's Compounding Regulations in Title 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.**

Mr. Lippe asked how many pharmacists are required to operate the pharmacy with this model and was advised that the current pharmacist to pharmacy technician ratio has not changed.

Mr. Lippe asked if the same pharmacist at the front desk area providing patient consultation is also the same pharmacist that verifies the prescriptions. And if so, who is going to be managing the store and monitoring the dispensing area. Dr. Carter advised that the dispensing area is being monitored by video surveillance and viewable on an iPad or a video monitor at the front desk area. The store manager and loss prevention at the district office always have access to the video surveillance at any time. The pharmacist can always go back and review the video that recorded while the pharmacist was providing patient consultation.

Dr. Kajioka commented that the Yuyama actually captures what's in the containers, what's poured in the bin and what's in the counter to be dispensed is being video captured. Dr. Kajioka asked if the pharmacist typically verifies the prescription before it goes out and was advised that the prescriptions have to be checked before it goes out. The product will be dispensed and verified before it is sold to the patient.

Dr. Kajioka asked how long is the video surveillance kept and was advised that the video surveillance is kept for about four months (180 days). To keep it longer, they'd have to upgrade their systems to keep it an additional 2 months and would be costly.

Dr. Kajioka asked if there are multiple angels going can you capture other angles while looking a one angle. The video has several angles and all are viewable at one time in a smaller frame but can be blown up to a full screen for a better look. Regardless of what angle is being viewed, everything is still being recorded.

Mr. Lippe asked if there is a possibility that someone can override the system and was advised that only the executive level has access to the video surveillance and possible override.

Ms. Hackworth asked for clarification on central processing in Florida and Arizona and was advised that when a patient drops off their prescription at the pharmacy, the prescription is scanned and sent to central processing to be inputted into the computer. The prescription is then sent back for data review at the local pharmacy and sent to the pharmacy technician to be filled and verified by the pharmacist.

Ms. Hackworth asked about the pharmacist to ancillary personnel ratio in the two California store with this model. Mr. Carter advised that the ratio is usually three ancillary personnel to one pharmacist. Ms. Hackworth wanted to know if the pharmacist was out front or behind the pharmacy counter and was advised that the pharmacist was out in the front.

Dr. Carter advised the committee that Walgreens didn't need board approval because they were in compliance with statutes and regulations. Ms. Herold advised that the board went into the stores to take a look at the model.

Dr. Gutierrez asked for clarification on the centralized processing that is in place and whether the typing was centralized or if Walgreens was filling the prescriptions centrally. Dr. Carter advised that only the typing of the prescription was being processed centrally.

Dr. Gutierrez asked how long this model has been running in the four states. Dr. Carter advised that two stores since 2011 and Indiana in 2012, and recently this model was implemented in Florida and Arizona.

Ms. Hackworth asked if there were any diversion or lack of pharmacist oversight over the ancillary staff and was advised that there have been no incidents of diversion and that personnel received six months of additional training. Ms. Hackworth asked if the two California stores were meeting the pharmacist to technician ratio and was advised that they were.

Ms. Hackworth asked when the two California stores were operational and was advised that the Hollywood store became operational in March 2013 but Dr. Carter wasn't sure of the exact time when the Stockton store was implemented.

Ms. Hackworth asked about the video surveillance and the time out process and was advised that the video monitor will time out one or three minutes if not "refreshed" and that the pharmacist has the capability to go back and watch previously recorded video.

Ms. Herold asked for clarification on the video surveillance footage being available for four months or 120 days and was advised that the video would be available for at least 120 days.

Ms. Herold asked if there have been an increase or decrease in medication errors and was advised that Walgreens has seen a slight decrease in medication errors but they don't really have a quantity to measure. Dr. Carter advised that there has been an increase in patient consultation and indicated that the biggest quality event was the wrong package going to the patient. Walgreens implemented a way for the patient to input digits on an iPad to ensure they receive the correct package.

Ms. Herold asked for clarification on whether the product verification was completed in the store or out of state and was advised that is verified by the pharmacist at the store.

Mr. Lippe asked about the timed out situation. Dr. Carter advised that when the screen blanks out the pharmacist still has the capability to grab that prescription and work on it as long as another pharmacist isn't working on it so that there are no two people working on the same prescription.

Ms. Herold asked whether Walgreens has done any consumer satisfaction surveys on before and after and was advised that Walgreens did do surveys and can get the board that information. Dr. Carter indicated that they've received great reviews. The biggest comment was that the consumer didn't know what to expect from the pharmacy.

Dr. Kajioka asked about data mining as far as ins and outs. Dr. Carter indicated that they've done a little as far as quality and what can be changed to be more efficient, provide more clarity, and better quality.

Dr. Gutierrez commented that the DEA has a similar concept. Dr. Carter indicated he wasn't aware that DEA has this concept. Dr. Gutierrez commented that it would be a good idea for Walgreens to look into.

Dr. Ratcliff thanked Dr. Carter for providing pictures to better understand the process. Dr. Ratcliff was involved in the Hollywood inspection which had the Yuyama machine in place. The pharmacist-in-charge was by himself concern was what happens where there is one pharmacist, pharmacist-in-charge and his personal preference tends to revert to traditional system and back behind counter. Dr. Ratcliff was impressed with the Yuyama system. There were concerns about security when the pharmacist was sitting out front, but don't really see that as a major concern. It could happen in a traditional system when the pharmacist goes out front to consult. One observation was in the facility

in San Francisco (possibly Stockton) did not toggle back and forth with consultation and video all the time. In the Hollywood store, the pharmacist had no idea that he was unaware that he could observe what was going on in the pharmacy and was under the impression that could only be viewed by loss prevention.

Dr. Ratcliff's personal concern was that the filling process is that only one prescription is filled at a time, one prescription per bag and moves down to will care area without verification by pharmacist. Everything is adjudicated through the cash register and if that prescription hasn't been verified the cash register comes to a hard halt.

There were five board inspectors there were involved in the inspections. The highlights were, they were comfortable with the system, impressed with the system, felt that medication errors, if procedures were followed, will be minimal. One of the concerns was the lack of security in being able to view the back area while having to toggle back and forth for consultation, verification, and security.

A recommendation was given to possibly using another video monitor; one screen for verification and consultation and the other for security monitor. Overall there were no problems with the system and the inspectors were very impressed with the system.

Dr. Gutierrez had a concern with only four months of security video being available.

Ms. Shellans asked if Dr. Ratcliff had any concerns of having an accurate record of the disposition of that drug if the video is destroyed within a period of time. Dr. Ratcliff indicated that the Walgreens had a system in place for when a medication error occurs the board inspectors can ask for a "board of pharmacy report" which shows the scanned image of prescription of the front and back, and shows the filling process, everyone involved in the filling process, there is a way to capture that entire video. Once a prescription is scanned, it's filed. Once a prescription is scanned, everyone works off of scan and there are no tags being put on prescriptions.

One concern was regarding controlled substances prescriptions and there being no way to tell if it was already scanned and someone removing that prescription that was already scanned somehow diverting the prescription. Walgreens instituted a system whereby controlled substances prescriptions are put the backer on the prescription to minimize diversion.

Dr. Carter advised that there is a procedure in place for the pharmacy tech to see that if a patient has multiple prescriptions and if they're ready to be picked up so that the patient doesn't have to return to the pharmacy later. The cash register will alert the pharmacy technician to check patient profile if there are other prescriptions.

Dr. Kajioka asked about the consultation in the drive through service and was advised by Dr. Carter that the patient can either talk to the pharmacist on the telephone or get out of the car

Dr. Carter commented on Dr. Ratcliff's comment about using a second visual monitor at the front desk and indicated that the pharmacists complained about the strain of having to keep looking down and felt that it would be a distraction and lead to verification errors.

Ms. Hackworth asked if legal counsel had any concerns and was advised by Ms. Shellans that she had concerns about direct supervision and the control aspect with ancillary staff while out front. Ms. Shellans stated that it should be looked at it by a case by case basis but wouldn't recommend Walgreens proclaim everything compliant without looking at those case specific situations.

Mr. Room stated there is nothing in the law that prohibits the implementation of this model and that Walgreens is taking some additional risk that they're ability to exercise the same level of supervision might be impaired. Some question whether this actually having on this on video is better than standing next to somebody. Mr. Room said there is nothing in this model that violates the law or doesn't meet that requirement or at least enable the pharmacist to exercise direct supervision and control.

Mr. Lippe stated that this model would give greater opportunity for patient consultation. Mr. Room agreed with Mr. Lippe and that the board has for the last twenty years to encourage more aggressive patient consultation and for the pharmacist to be out front and this model is clearly designed to give more patient consultation.

Dr. Gutierrez feels that this model promotes the pharmacist-patient relationship and allows for the patient to ask questions.

Public Comment

Steve Gray, representing himself, has been watching this development and pointed out something that board staff is well are aware and board members discussing with the consumer groups patient centered prescription labels discussion with consumer patent center something just for that patient, only real way someone to come out front to talk to patient and see what they need. Moving the pharmacist out front to talk to patient using their professional knowledge determine what they understand lot of the problems can be and be resolved during consultation are resolved and this offers that opportunity as the pharmacist becomes more comfortable that becomes norm shown to be exactly what the consumer wants. Hope that the board allows them to go forward with this model. Half of the community pharmacy in southern California already using this model and the patients love it.

Dr. Jeff Mesaros, Vice-Chair of the Florida Board of Pharmacy has not had a long time to experience this particular model but hasn't had any increase in complaints. Florida also uses centralized processing which allows the pharmacist to be more available for the patient. There was possibly one time with a problem but Florida was able to track every step of the process in that state and out of state and had the accountability to either take discipline internally or with the other board of pharmacy.

Dr. Gutierrez asked if the central processing pharmacists are required to be licensed in Florida and was advised that the facility and pharmacists in Florida were licensed and the non-resident pharmacies were licensed in their home state.

Mr. Lippe asked if there have been an increase in complaints or positive complaints and was advised that Florida hasn't seen any complaints. Dr. Mesaros indicated that some pharmacists hated the change but after experiencing the process relive the anxiety of the process

Ms. Shellans asked how long the model in Florida has been operating and was advised by Dr. Carter that central processing center has been operational since 2006.

Dr. Gutierrez asked if the central processing center in Florida received the scanned prescription was sent to central for data entry– pharmacist verifying final. Up front piece not the end product

Ms. Herold saw the Walgreens pharmacy model operating in Chicago while standing back and watching and stated it was completing different. The pharmacist was standing at front desk, a patient, walked up to counter paid for their prescription and before walking out of the pharmacy went out of her way to say hello to the pharmacist. It was real clear she was comfortable talking to the pharmacist.

Dr. Ratcliff commented that one other observation he had regarding the security cameras was when no one was at the front counter or at the front desk there is an alarm that goes off alerting personnel that there is a patient that arrived at the counter. One advantage of this new model is that when a board investigation is taking place, a board inspector can obtain a "Board of pharmacy audit report" from any Walgreens and doesn't have to go to the actual store investigation is regarding.

Mr. Lippe asked how patient consultation was handled when the pharmacists that don't like to counsel and who are more introverts. Dr. Carter advised that this has happened and those pharmacists have been transferred to store with traditional pharmacy settings. Dr. Carter offered to provide a tour of the stores to the board members.

No further comments were received from the committee members or the public.

c. Presentation From the California Product Stewardship Council on Take Back Programs for Prescription Medications in California

Background

Heidi Sanborn, representing the California Product Stewardship Council, shared information about their bin collection program "Don't Rush to Flush, Meds in the Bin, We All Win."

Ms. Sanborn provided an overview of the Rose Foundation Grant which established six permanent pharmaceutical collection locations in Yolo and Sacramento counties. This program also educates the public and medical community about using the collection locations.

Ms. Sanborn also indicated that San Francisco and Alameda counties have piloted a program for safe medication disposal.

Ryan Jackson representing the San Francisco Department of the Environment provided an overview of San Francisco's drug take-back pilot program. One day San Francisco has thirteen pharmacies participating in the drug take-back program throughout San Francisco accepting non-controlled and over the counter prescription drugs, sharps. San Francisco Police Department volunteered to accept controlled and non-controlled substances according to their standard procedures of accepting evidence.

San Francisco has developed clear signage, available in four languages, Spanish, English, Chinese and Russian. The non-retrievable storage bins do not allow for access to the medications once placed in the bin. There is a two key system to access the bins once full, the pharmacist has possession of one key and the licensed medical waste hauler has the key and both keys are required to access the storage bin. A tracking document is given to the pharmacist and one is placed in the bin when taken by the medical waste hauler.

Angelo J. Bellomo, Director of Environmental Health, County of Los Angeles Department of Public Health, also provided an overview of their program. Los Angeles County has drop off bins, started several years ago by Los Angeles County Sheriff's Department with the support of Department of Health, to reduce crime and illicit drug use and to prevent these materials getting into the environment.

In closing, Ms. Sanborn indicated this presentation was a sampling of all the counties that are doing things and counties that have nothing. There are a lot of demands for these programs and hopes that there is a statewide sustainable solution to medication disposal. Bins would cost over \$5,000 a piece if you go into pulverization and also creates maintenance issues as well as safety issues for the pharmacist.

[A copy of the PowerPoint presentation is provided at the conclusion of the meeting minutes.]

Dr. Gutierrez asked if controlled substances are being dropped off in the bins because the average consumer really doesn't know what a controlled substance is. Mr. Jackson indicated that they do not know if this is happening as they have no access to the bins. At the pharmacies, bins are placed in the line of sight of the pharmacist, and at the point the pharmacist might say something to the consumer about which drugs are suitable for dropping in the bin and which ones need to go to the police department.

Dr. Gutierrez asked about the mail back program in Stockton and whether they provided the mail back system. Mr. Jackson indicated that the mail back envelopes only hold certain amount of medicine and were expensive and cost prohibitive and not as effective.

Dr. Kajioka asked about liquids, injectables, and ampoules in various types of vials and if those go into the bins. Mr. Jackson indicated the San Francisco consumer is instructed to tighten the lids and place the whole container in the bin. Ms. Sanborn indicated that Sacramento is also instructed to place the whole container in the bin after blacking out their personal information.

Dr. Gutierrez asked about the cost per bin. Mr. Jackson indicated that it costs approximately \$250,000 a year and includes the bins and medical waste hauler and disposal fees. Dr. Kajioka asked how many bins there are. Mr. Jackson indicated that there are thirteen pharmacies.

Ms. Herold followed up on a comment made regarding removing the container so that the names don't end in the bins but no one should be going through the bins anyway. Ms. Sanborn indicated that main reason for this was because of the space the containers take up and also they didn't want to be responsible for someone's personal information.

Ms. Herold asked if they're finding needles or syringes in the drug bins. Ms. Sanborn indicated they have not which is another reason to put it near the pharmacist so he/she can see what's going into the bins.

Dr. Gutierrez asked Mr. Jackson what the process was to select pharmacies in the San Francisco area, geographical, independent pharmacy, etc. Mr. Jackson indicated they solicited any pharmacy that wanted to participate. Thirteen pharmacies geographically made sense.

Dr. Gutierrez commented on the 2013 letter to the federal DEA and the parameters for the drug take-back programs. Dr. Gutierrez is concerned for safety in the pharmacy and the drugs in the bin. Ms. Herold indicated the issue for the Board has always been, "what happens to the drugs". The dual key lock system was an experiment that was tried a couple of years ago, it's an expensive process, the waste hauler is expensive, the pharmacist has oversight and is required to use their professional judgment on whether the drug is a controlled drug or not and the DEA decides to take action on that judgment should it be wrong.

The Board of Pharmacy is interested in working with the California Product Stewardship Council. The program should be voluntary and the pharmacy shouldn't be required to participate.

Mr. Room asked why Alameda County didn't join the others in this presentation. Ms. Sanborn indicated it was very costly per pound and inefficient. Alameda is proceeding with regulations to move forward to find a solution to begin the program.

Dr. Kajioka asked how the police department is handling the collection. The police department is destroying the drugs through their own contractor.

There were no questions or comments from the public.

d. Request from Da Vita Rx for Discussion Regarding Prescription Drugs Dispensed to Renal Clinics for Administration to Patients

Background

Representatives from Da Vita Rx sought an exemption to accept returned and reuse unused medications for renal patients that are transported and stored in accordance with state and federal laws and standards.

Presentation and Discussion

Ned Milenkovich stated that Da Vita Rx is a full service pharmacy specializing in renal care. All medications are sent to the dialysis centers in a controlled locked box and the medication rests in a sealed tamper-proof evident packaging. In many cases the medication is returned to the pharmacy for various reasons and this medication is then destroyed and not reused. These medications could be reprocessed when received back in the pharmacy. The integrity of the medication is maintained throughout each step of the delivery process and DaVita Rx is confident that the medication has never been received or administered to the patient nor left the tamper evident packaging. This is similar to what happens in a pharmacy when the patient never picks up their medications and the medication is put back on the shelf. These medications would then be reused. This medication maintains its integrity and not touched by the original patient and hasn't been opened. Mr. Milenkovich also indicated that Florida and Texas currently allows this activity to occur.

Mr. Milenkovich is requesting to work with California and to understand whether Da Vita Rx can reprocess the unused medications that were properly handled and returned to the pharmacy and use on other patients in the future. Da Vita Rx see this as a very important step in making sure that maximizing economics in terms of waste in healthcare payers paying for these medications unnecessarily and having to throw them away without using them on other patients so that they're not paying for something that is being thrown away.

Dr. Gutierrez asked for clarification on the type of medications to be reprocessed and whether they are oral medications, sterile compounds, or solutions and was advised that these were primarily manufactured sealed containers. Dr. Gutierrez ask if these were patient specific bottles with the patient name, counted and recorded on the amber via and was advised that in this case it would be prescriptions in a manufacturers container.

Mr. Milenkovich stated that currently Da Vita Rx is operating in Florida, Texas and California and that Florida and Texas permits this activity. Mr. Milenkovich stated that the definition of dispensed is whether the patient received the medication or didn't receive the medication, that if the patient didn't receive the medication then the prescription wasn't dispensed.

Mr. Room asked if Da Vita Rx is in some ways in which Da Vita is running up against caps for a patient, third party billing– would this enable patients to receive medications that they would otherwise not being able to get.

Dr. Gutierrez asked where the California pharmacy was located and was advised that there is one pharmacy located in San Bruno and dispense about 4,000 – 5,000 prescriptions a day.

Dr. Gutierrez asked legal counsel whether this was legal. Ms. Shellans stated that the issue is not the dispensing part of it but what the board has usually dealt with is whether you can restock them and resale them. There is no assurance that the drug is adulterated. The law states you cannot transfer a drug, and cannot return drug products. The pharmacist can no longer be assured the integrity of the drugs. Ms. Shellans does not recommend that returning and restocking of those drugs. The board is never going to know if the drugs have been adulterated. Ms. Shellans stated that the board has published this topic in the January 2007 and March 2013 issues of the Script.

Mr. Lippe asked if there is some ability to verify if the drug was not adulterated. Mr. Room commented that you can never be sure that the drugs weren't adulterated.

Mr. Room stated that the board cannot bless this practice but stated that Da Vita Rx is on the hook if there is actual patient harm or a patient receiving adulterated drugs.

Dr. Kajioka stated that the integrity of transportation device and once it leaves the pharmacist hands that are where the validation needs to be controlled.

Mr. Room applauded the general thinking and benefit to the healthcare system but reserves the right if something goes wrong the pharmacy and pharmacist-in-charge are going to be on the hook going into it. Mr. Room cautioned the board in blessing this practice as the board can't say if those drugs have been adulterated.

Mr. Milenkovich stated that the definition of dispensing means furnishing of drugs or a device and what does furnishing mean. Mr. Milenkovich maintains that the patient would never receive the medication and would always be in a tamper resistant pouch. He feels that it doesn't sound like the board is saying it's not permitted but proceed with caution and we'll fall on the merits on how they handle themselves.

Ms. Herold sought clarification on who are the licensed professionals that were handling the medications. Mr. Milenkovich indicated that the medications are handled by the pharmacist, pharmacy technician, physicians, nurses, social workers, and FedEx.

Mr. Lippe asked if the drugs were temperature controlled and was advised that they were.

Ms. Shellans asked if they have received feedback from FDA and was advised that they aren't aware of any requirements that FDA has regarding returned and reuse of medications. Ms. Shellans suggested that they look at FDA compliance guidelines section 7132.09.

Mr. Milenkovich offered to bring this to the full board along with the facility administrator so that the board can ask any questions they may have.

Ms. Shellans stated that the Health and Safety Code prohibits someone from holding a drug that is adulterated and it really about whether the drug is adulterated or not. Ms. Shellans stated that the general guidance and position of the board is to say that you shouldn't return and reuse.

Mr. Milenkovich asked the committee members what the next step would be and was advised that he could provide additional information.

Mr. Room stated that there is no action the board can or should take. This topic will come to the board by way of the Enforcement Chair's report to the board at the October Board Meeting.

Ms. Hackworth asked what the mechanism is for tracking the drugs when going back to the pharmacy and was advised by Rick Hagan, pharmacist-in-charge of Da Vita Rx, the medication goes back to the pharmacy and restocked. Mr. Milenkovich stated that they would ensure the accuracy of the tracking when returned.

There were no comments received by the public.

No action was taken by the board.

e. Review and Discussion of Federal Government Accountability Office Report on the Difficulties of Regulating Internet Pharmacies

Background

The Federal Government Accountability Office (GAO) issued a report on July 8, 2013 which focused on the difficulties of regulating rogue internet pharmacies that are often complex, global operations composed of thousands of related websites. The report found that, despite challenges, state and federal agencies have taken actions to combat and disrupt internet pharmacy operations through convictions, asset seizure and public education.

In an attempt to combat these sites, the National Association of Boards of Pharmacy (NABP) sought formal approval last year to be able to approve anyone using the general top level domain (gTLD) of .pharmacy. Generic top level domains are the suffix part of a Web site address (e.g., .com, .org, .edu). According to 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 U.S. pharmacy laws and practice standards established to protect patients. 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 intent is to have the parameters for the .pharmacy gTLD in place by the end of 2013.

Discussion

Mr. Room clarified that there were two issues; 1) international internet pharmacies; and 2) internet providers (domain) that are being used and have relationships with brick and mortar pharmacies. The international pharmacies can't be touched as they are out of the country and the other being an internet domain.

There were no questions or comments from the committee or public on this item.

f. Role of a Pharmacist's Corresponding Responsibility in the Dispensing of Controlled Substances

Background

Federal and state law both require a pharmacist to use corresponding responsibility when dispensing a prescription. Specifically:

- California Business and Professions Code section 4306.5 provides:

4306.5.

Unprofessional conduct for a pharmacist may include any of the following:

- (a) Acts or omissions that involve, in whole or in part, the inappropriate exercise of his or her education, training, or experience as a pharmacist, whether or not the act or omission arises in the course of the practice of pharmacy or the ownership, management, administration, or operation of a pharmacy or other entity licensed by the board.
- (b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services.
- (c) Acts or omissions that involve, in whole or in part, the failure to consult appropriate patient, prescription, and other records pertaining to the performance of any pharmacy function.
- (d) Acts or omissions that involve, in whole or in part, the failure to fully maintain and retain appropriate patient-specific information pertaining to the performance of any pharmacy function.

(Amended by Stats. 2006, Ch. 777, Sec. 11. Effective January 1, 2007.)

- And California Health and Safety Code section 11153 provides:

11153.

- (a) A prescription for a controlled substance shall only be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his or her professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. Except as authorized by this division, the following are not legal prescriptions: (1) an order purporting to be a prescription which is issued not in the usual course of professional treatment or in legitimate and authorized

research; or (2) an order for an addict or habitual user of controlled substances, which is issued not in the course of professional treatment or as part of an authorized narcotic treatment program, for the purpose of providing the user with controlled substances, sufficient to keep him or her comfortable by maintaining customary use.

- (b) Any person who knowingly violates this section shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the Penal Code, or in a county jail not exceeding one year, or by a fine not exceeding twenty thousand dollars (\$20,000), or by both that fine and imprisonment.
- (c) No provision of the amendments to this section enacted during the second year of the 1981–82 Regular Session shall be construed as expanding the scope of practice of a pharmacist.

(Amended by Stats. 2011, Ch. 15, Sec. 148. Effective April 4, 2011. Operative October 1, 2011, by Sec. 636 of Ch. 15, as amended by Stats. 2011, Ch. 39, Sec. 68.)

Dr. Gutierrez provided an overview of the pharmacist’s corresponding responsibility and the board’s efforts in educating California pharmacists, the board’s recent adoption of a precedential decision involving a pharmacist’s corresponding responsibility and the six one-day sessions on a pharmacist’s role in dispensing controlled substances and using corresponding responsibility.

Mr. Room briefly described the violations that occurred in the precedential decision and that this decision could be relied upon by the board in future cases.

Ms. Sodergren commented that is a good opportunity for the board to reach out to the prescriber communities that this precedential decision highlights many of the red flags that a pharmacist needs to consider and hopefully that will minimize the pushback the pharmacist receives when calling the prescribers offices to exercise their due diligence with respect to corresponding responsibility.

Public Comment

Jonathan Nelson, representing California Society of Health System Pharmacists, stated that it can be difficult for their members in the pharmacy community to know if they’re on the right side or the wrong side of law or appropriate regulations. Mr. Nelson indicated that anything the board can do to offer clarification or education is always very much appreciated. The feedback from the members has been very positive.

Tony Park, CPhA, stated the association has taken this decision to heart and has offered two one-day long education seminars.

Ms. Herold indicated that the board has offered to put on seminars on pharmacist’s role in dispensing controlled substances and using corresponding responsibility.

No further comments were provided from the committee or public.

Dr. Gutierrez recessed for lunch at 12:20

The meeting reconvened at 1:06 p.m.

II. Compounding Matters

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

Background

The board drafted proposed legislation late last year following two large-scale public health emergencies in which contaminated products compounded by two out-of-state pharmacies were shipped nationwide. Senator Emmerson has authored Senate Bill 294 (SB 294) to carry the 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 – following a board-performed inspection – from this board. It will also eliminate accreditation by designated agencies as an alternative to licensure.

Assembly Member Quirk-Silva authored AB 1045 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.

Dr. Gutierrez provided an overview of Assembly Bill 1045 and Senate Bill 294. A prescriber alert would be sent out by the board on recalls.

Ms. Sodergren indicated that Assembly Bill 1045 was signed by the Governor and Senate Bill 294 was sent back to the Senate for concurrence.

Public Comment

Mr. Nelson commented that CSHP supports the bill because in the last few days he has lost track of how many recalls have been received from the FDA and that clearly there is a need. Dr. Gutierrez thanks CSHP's support.

No further comments were received from the committee or public.

b. Update on Proposed Federal Legislation on Compounding

Background

Pending at the federal level is possible legislation that would establish stronger federal requirements for pharmacies that compound sterile medications, particularly for those pharmacies that compound medications in large quantities and without a patient-specific prescription. However, the status of enactment of such a proposal at this time is a bit uncertain.

The Senate has a draft proposal pending and the House is working on its own version of compounding provisions. The belief is that compounding legislation may be combined with requirements for national track and trace provisions for medications (possibly to preempt California's e-pedigree requirements). However, the House has already passed its own version of a track and trace system, without the corresponding piece. The Senate track and trace provisions do have a compounding piece but this bill has not yet been passed by the Senate.

If the Senate bill is passed by the Senate, both the House and the Senate bills will go to a conference committee to rectify the provisions into a single piece of legislation. This could occur in the fall.

In early August the GAO issued a report on compounding by pharmacies. The report is attached, and can also be accessed on the GAO's website at: <http://www.gao.gov/assets/660/656388.pdf>

From the Executive Summary is the following:

The authority of the Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), to oversee drug compounding is unclear. Two federal circuit court decisions have resulted in differing FDA authority in different parts of the country.

According to FDA officials, these inconsistent decisions and the agency's limited inspection authority over pharmacies have created challenges in FDA's ability to inspect and take enforcement action against entities engaging in drug compounding. For example, from 2002 through 2012, in order to inspect some facilities engaged in drug compounding, FDA officials said they had to obtain 11 warrants to gain access to drug compounders' facilities that had challenged FDA's inspection authority. GAO also found that while FDA and national pharmacy organization officials generally agreed that states regulate the practice of pharmacy and FDA

regulates drug manufacturing, there was no consensus on whether compounding drugs in large quantities—in anticipation of individual prescriptions or without prescriptions—and selling those drugs across state lines falls within the practice of pharmacy or is a type of drug manufacturing that should be overseen by FDA. This lack of consensus and differing FDA authority to oversee compounded drugs across the country has resulted in gaps in oversight of drug compounding.

FDA lacks timely and reliable information to oversee the entities that compound drugs, but has found problems through its limited oversight. Specifically, FDA's inspection database cannot identify all of the agency's inspections of compounding pharmacies, or the final classification of inspection results, for all of the inspections. Until 2013, FDA limited its inspections of compounding pharmacies to those conducted in response to complaints or adverse events. However, the agency recently inspected compounding pharmacies that it identified as posing a significant threat to public health from poor sterile drug production practices in the past and found problems, such as concerns about a lack of sterility, which resulted in recalls of compounded drugs. In addition, drug manufacturers are required to register with FDA and are subject to FDA's inspection and drug approval processes; pharmacies meeting certain requirements are generally exempt from registration. However, some compounding pharmacies may have registered with FDA to market themselves as "FDA-registered" which may lead some purchasers to assume that FDA has inspected or approved their compounded drugs; whereas, according to FDA officials, this is generally not the case.

The states GAO reviewed—California, Connecticut, Florida, and Iowa—have each taken actions to enhance their oversight of drug compounding. For example, Florida required all pharmacies—both those located in the state and out-of-state that sell drugs in Florida—to notify the board of their compounding activities. In addition, national pharmacy organizations have undertaken efforts to help states oversee drug compounding. For example, a national pharmacy organization is working with Iowa to inspect out-of-state pharmacies that ship drugs into the state. However, according to national pharmacy organizations and officials from state boards of pharmacy, some states do not have the resources to inspect pharmacies on a regular basis. Instead, these states inspect pharmacies only in response to a complaint or a reported adverse drug event.

Discussion

Dr. Gutierrez provided an overview of the GAO report on compounding by pharmacies. Ms. Herold indicated that the board is working closely with FDA on inspections and testing some of the products. The board and FDA are trying to work together on the training that FDA provides to their staff and is available to board staff. FDA also wants to know what California is doing.

Mr. Room thought it was interesting that where entities are cross registered as both pharmacy and manufacture and that the FDA was exercising some type of oversight and the GAO report makes it clear that the FDA is doing no such oversight. The FDA made no effort to inspect those entities that were registered as manufacturers. In pharmacies that have never been inspected the FDA went in and found huge problems.

There were no further questions or comments from the committee or public on this item.

c. Subcommittee Recommendation: Amend California’s Compounding Regulations in 16 California Code of Regulations Sections 1735 et seq. and 1751 et seq.

Background

As part of the board’s efforts to strengthen the board’s regulation and enforcement of pharmacies that compound sterile drug products, the board in 2012 established a Compounding Subcommittee for the purpose of conducting an in-depth review of the board’s regulations of sterile compounding pharmacies. At the December 2012 Board Meeting, President Weisser appointed Dr. Gutierrez and Dr. Kajioka to serve on the committee.

The subcommittee first met in January 2013, which resulted in the subcommittee’s request that staff prepare a comparison of the board’s current regulations versus the compounding requirements of USP 797. This ‘crosswalk’ comparison was provided and discussed at the April 2013 Board Meeting and June 2013 Enforcement and Compounding meeting.

Committee Recommendation: Amend entire Section 1735 to strike “injectible” as the board is looking at sterile compounding overall and not just injectibles and strike “expiration date” and replace with “beyond use date” from the entire Section 1735 language.

Ms. Shellans asked Dr. Ratcliff to explain the difference between the expiration date and the beyond use date. Dr. Ratcliff indicated that the beyond use date is the expiration date of any of the

components in the compounded products whichever comes first. Ms. Shellans suggested that the definition of “beyond use date” be included in the language to help with clarity and Office of Administrative Law.

Committee Recommendation:

1735.3. Recordkeeping of Compounded Drug Product

(c) Chemicals, bulk drug substances, and drug products, ~~and components~~ used to compound drug products shall be obtained from reliable FDA-registered suppliers. The pharmacy shall acquire and retain ~~any available~~ certificates of purity or analysis for chemicals and bulk drug substances, ~~drug products, and components~~ used in compounding. Certificates of purity or analysis are to be matched to the product received. ~~Certificates of purity or analysis are not required for products that are approved by the Food and Drug Administration.~~

Public comments suggested that the board remove the FDA-registered requirement and taking a look at the USP guidelines.

Committee Recommendation:

1735.3. Recordkeeping of Compounded Drug Product

(d) After receipt by the pharmacy, packages of ingredients that lack a supplier’s expiration date cannot be used after one (1) year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in compounded sterile products.

Public comment asked about the one year requirement and whether it was an arbitrary date used.

Committee Recommendation: Amend Section 1751(b)(6) to specify ISO Class 5 hood and would read as follows:

1751(b)(6) A sink shall be included in accordance in Section 490A.3.4 Title 24, Part 2, Chapter 4A of the California Code of Regulations. Sinks and drains shall not be present in ISO Class 5 cleanrooms nor adjacent to the ISO Class 5 hood in a segregated compounding area.

M/S: Lippe/Hackworth

Support: 4 Oppose: Abstain: 0

d. Recalls of Compounded Drugs Throughout the United States

Background

Between May 21, 2013 and August 26, 2013, the Board posted two 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.

- Specialty Compounding, LLC, in Cesar Park, Texas, voluntarily recalled all sterile medication that had not yet reached its expiration date. The recall was initiated after reports of bacterial infections affecting 15 patients at two Texas hospitals.
- The U.S. Food and Drug Administration advised pharmacies of concerns about the adequacy of testing performed by Front Range Laboratories, Inc., in Loveland, Colorado following FDA investigator's observations of methods used by Front Range to assess sterility, strength and stability for compounding pharmacies. This was an alert only. No products were recalled.
- Olympia Compounding Pharmacy, in Orlando Florida, was issued a cease and desist order on May 30, 2013, for any and all sterile compounded drug products.
- Specialty Compounding, LLC, of Cedar Park, Texas was issued a cease and desist order on August 9, 2013, from furnishing sterile compounded products in California. This action was based on their voluntary recall noted above. The board has since entered into a stipulated agreement extending the agreement longer than 30 days

III. Future Meeting Dates

The committee will meet on December 3, 2013

IV. Closing Comments

V. Public Comment on Items Not on the Agenda/Agenda Items For Future Meetings

Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code Sections 11125, 11125.7(a)]

ADJOURN

5:13 p.m.