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

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

DATE: March 14, 2013

LOCATION: Sheraton Garden Grove
12221 Harbor Blvd.
Garden Grove, CA 92840

COMMITTEE MEMBERS PRESENT:

Randy Kajioka, PharmD, Chair
Amy Gutierrez, PharmD
Rosalyn Hackworth, Public Member
Shirley Wheat, Public Member
Tappan Zee, Public Member

STAFF PRESENT:

Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector
Kristy Shellans, DCA Senior Staff Counsel
Joshua Room, Supervising Deputy Attorney General

The meeting was called to at 9:39. Chairman Kajioka welcomed everyone, a roll call was taken and a quorum established.

I. Enforcement Committee Matters:

a. Request for Walgreens to Store Prescription Records Older than Five Years Outside a Licensed Premises.

California has requirements that all pharmacy records be readily retrievable in the licensed premises, and open to inspection by the board. These records are generally required to be retained for at least three years.

California law also permits the offsite storage of records if an offsite waiver has been approved by the board.

Al Carter, representing Walgreens provided the committee with information about the request. Mr. Carter provided an overview of the requirements for records retention to comply with CMS. Walgreens is requesting authority to store records off site after five years. The records storage is an issue because law specifies which persons have access to records, including pharmacy staff. The offsite storage vendor is not included in those authorized persons. Mr. Carter provided an overview of the proposed vendor, Iron Mountain.

Dr. Kajioka asked who would have access to the records offsite and was advised that records will be stored on a store by store basis and will only be accessed by Iron Mountain staff. Mr. Carter indicated that access to the records will be recorded.

Dr. Gutierrez ask for the timeframe Iron Mountain has to respond to a request for records and was advised that per the contract the records need to be provided within 48 hours.

Ms. Hackworth questioned the locations of the vendor and was advised that Iron Mountain have facilities throughout the state.

Ms. Herold provided an overview of the current records requirement and advised the committee that use of Iron Mountain is used as part of the offsite storage provisions. Ms. Herold indicated that the concern of the board may be the destruction of the records after the period. Mr. Carter advised Ms. Herold of the process for records destruction after the time period had elapsed. The contract specifies that the only authorized storage sites may be used and that if Walgreens fails to pay the vendor, the records would be returned to Walgreens.

Dr. Kajioka inquired is a single offsite storage waiver request could be used to facilitate approval and was advised that the request would need to be very specific. Mr. Carter indicated that Walgreens could provide a spreadsheet that includes each pharmacy and the location of the Iron Mountain facility where the records will be stored.

Motion: Approve Walgreens request.
M/S: Gutierrez/Hackworth

Public Comment

Dr. Gray advised the committee that no waiver should be required because records are only required to be maintained for three years.

SDAG Room advised the committee that while there is not requirement to obtain a waiver, Walgreens has requested one and as such should not be precluded for seeking and obtaining one.

Support: 3 Oppose: 0 Abstain: 0

b. Request from Walgreens to Establish Pharmacy Kiosks in Workplace Clinics.

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.

(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). There was no further interest pursued by Asteres after the January 2010 meeting. Materials covering some of these discussions were provided in the materials for the meeting.

Presentation and Discussion:

Mr. Carter, representing Walgreens, discussed a request that would allow for Walgreens to place kiosks in workplace clinics. Mr. Carter advised the committee that the workplace

clinic is on an employee campus serves a large volume of employees. Mr. Carter discussed the Walgreen's capability to provide pharmacy services via a kiosk. 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 kiosk would be in a secured building and advised the committee that a patient would have access to a pharmacist via a video link 24 hours a day.

Mr. Carter provided a PowerPoint presentation that walked the committee through the process from enrollment to prescription dispensing. Mr. Carter discussed who will put the medications in the machine and the safety features of the machine including barcoding. Safety features include a log-in and pin or a fingerprint scan and pin number. A camera is also used to take pictures for auditing purposes. Mr. Carter discussed the specifics of the enrollment process. Mr. Carter indicated that no refrigerated items or bulk items would be provided via this kiosk. [A copy of the PowerPoint presentation is provided at the conclusion of the meeting minutes.]

Dr. Kajioka asked if an authorized agent could pick up the prescription and was advised that there is a consent process in place to allow for this. The authorized agent is limited to just family members. Dr. Kajioka asked what process would occur if a pharmacist determined that consultation was required and was advised that the patient would be required to go to the pharmacy to obtain the medicine.

Mr. Room discussed some possible options the board could consider depending on the full nature of the request. Ms. Shellans indicated that her legal opinion is more limited and that current law only allows for refill prescriptions. Ms. Shellans indicated that expansion to allow for new prescriptions would require a regulatory change.

Ms. Hackworth asked what others services or items are in the room that will house the kiosk and was advised that Walgreens believes the kiosk will be the only item in the room. Ms. Hackworth also asked what payment mechanisms are accepted.

Dr. Gutierrez asked if schedule II controlled substances would be dispensed via the kiosk and was advised that Walgreens would want to include such medications if allowed by the board.

Dr. Nurse asked who would be filling the kiosk and was advised that it will be filled by pharmacists. Dr. Nurse was also advised that the prescriptions will be filled at the local Walgreens and delivered to the Kiosk, not filled by a central fill pharmacy.

Ms. Herold expressed concern about allowing a kiosk not adjacent to the facility because the board would lose control of where drugs are stored and dispensed from.

Mr. Room clarified that under the current regulation the board lacks the authority to waive the requirement that the kiosk be adjacent to a pharmacy. Further, Mr. Room noted, in response to a comment by Dr. Nurse about access by board staff for investigative purposes, that the proposed construct could be problematic.

Dr. Kajioka indicated that he believed there was not sufficient information to act at this time.

Motion: Deny request but have the board re-evaluate the regulation and determine if changes are necessary to address emerging technologies.

M/S: Gutierrez/Hackworth

Committee Member Zee suggested that perhaps Walgreens could work with counsel to develop language that could address the boards concerns as an interim solution to allow for a temporary waiver to be considered at a future committee meeting. Mr. Carter expressed a willingness to work with the board.

Mr. Carter indicated that they are aware of a few other states that allow for the use of a Kiosk as being proposed and offered to survey and provide information to the board.

Support: 5 Oppose: 0 Abstain: 0

c. Request from Kaiser for a Temporary Waiver of Secure Prescription Blank Prescribing Requirements for Controlled in a Closed Health Care System.

Background

Existing law requires the use of security prescription forms for written prescriptions for controlled substances. Security prescription forms must be printed by state-registered printers and conform to specific requirements to make forgery of these forms difficult. There are few exceptions to the use of these specialized forms when a prescriber writes a prescription.

Schedule III-V drugs may be prescribed orally; only in very limited cases, may Schedule II drugs may be orally prescribed.

In 2010, the DEA released Interim Final Rules to permit the e-prescribing of controlled substances, and all e-prescriptions for controlled substances must the DEA's regulatory

requirements, including a third-party audit of the computer application certifying that I meets the requirements of the DEA regulations.

E-prescribing is not faxing (where a prescription is actually written and signed by the prescriber, and a facsimile is transmitted to the pharmacy). Faxing is not allowed for controlled substances, although faxed prescriptions for Schedule III- V prescriptions are sometimes treated as oral prescriptions by pharmacies which if received, must verify the fax with the prescriber's office. (Note, a security prescription form, if faxed, is required to display a "VOID" impression on the faxed document, showing that the fax is not a legitimate written prescription.)

Presentation and Discussion:

Dr. Steve Gray, representing Kaiser Permanente, provided a brief overview of Kaiser Permanente including its closed integrated system. Dr. Gray provided a brief overview of the concerns with their current process and handling of schedule III and V controlled substance prescriptions. Dr. Gray indicated that the result of their current process is delays in delivering the pharmacist services, the quality of care as well as security issues. Dr. Gray indicated that the proposal would reduce drug diversion as well as diversion of security of prescription forms. Dr. Gray indicated that this temporary solution will also provide for better quality of care for patients. Dr. Gray advised the committee that the proposal was discussed with representatives of the Department of Justice. Dr. Gray indicated that the DOJ recommended that this issue be discussed by the board prior to implementation.

David Kavanse, national leader and Vice President for Pharmacy Services within Kaiser, provided a powerpoint to discuss the overview of the current manual system as well as the proposal alternative process. Mr. Kavanse advised the board that they were hoping to receive guidance and feedback on the proposal. Mr. Kavanse discussed the current process for electronic prescriptions, not including controlled substances. Mr. Kavance indicated that controlled substances cannot follow the same process because of DEA rules and provided an overview of the current workflow process. Mr. Kavance indicated that the current process is extremely inefficient and briefly highlighted several options to remedy this and the basis for ruling out these other alternatives.

Mr. Kavance provided specific details for the interim solution that includes a prescriber using plain paper to prescribe the controlled III-V substance. This prescription would have a "wet" signature and date of the prescriber. This prescription would be provided to the patient who is then responsible for taking the prescription to the pharmacy. When presented to the pharmacy, the prescription would be confirmed with the electronic medical record for confirmation. If confirmed through this process, the prescription would be treated as a valid and legitimate order and the medication would be dispensed. If confirmation was not received, the pharmacy would contact the prescriber to confirm the legitimacy of the prescription prior to dispensing or the pharmacy would refuse to dispense the medicine.

Mr. Kavance indicated that the DOJ has indicated that if the board is agreeable to the proposed interim solution, the DOJ would also be agreeable to approve this process. Mr. Kavance stated that he believe Kaiser can fulfill the intent of the security paper provisions through this interim process because it is a closed healthcare system. [A copy of the powerpoint presentation is provided following these minutes.]

Dr. Kajioka asked several questions about this proposal. Dr. Kajioka asked about what notations would be made in the electronic medical record if a prescriber is contacted to confirm the legitimacy of a prescription and was advised that Kaiser would confirm how and if such information would be notated. In response to Dr. Kajioka's question about an official response from the DOJ on this proposed solution, he was advised that although DOJ cannot provide an official response on this proposal, DOJ staff did indicate that the proposal appeared to comply with the intent of the law. Dr. Gray also spoke about the security features of the Kaiser System and controls of which staff can order a prescription. Dr. Gray indicated that it this system would address the issue of someone calling in a fake oral prescription and well as the diversion of security prescription blanks.

Ms. Herold asked if oral prescriptions for schedule III-V prescriptions would still be allowed in the Kaiser system along with this proposal and was advised that Kaiser would be unable to totally eliminate oral prescriptions.

Mr. Room asked how from the prescriber's perspective how they are meeting the requirements of the Health and Safety Code as the proposed solution violates the health and safety code provisions. In response Mr. Room was advised that the question has not been considered or asked before.

When asked about the desired outcome of the presentation, the committee was advised that Kaiser was directed by the DOJ to discuss their proposal with the board to ascertain any concerns the board may have as well as guidance of the board to determine if the proposal could be implemented from the pharmacy standpoint. This information would then be brought back to the DOJ who establishes the requirement for the security prescription requirement.

A motion was made to recommend on behalf of the Enforcement Committee that in a closed loop system with electronic validation as set forth in the presentation that the Board of Pharmacy's Enforcement Committee has not objection to it provided that Kaiser works with the DOJ in terms of their administration and enforcement of the particular health and safety code. (This motion did not receive a second and was later amended.)

Dr. Kajioka indicated that two issues need to be addressed, that of the prescriber not using security paper to write a prescription as required by the health and safety code as well as the a pharmacy filling such a prescription. Dr. Kajioka indicated that the board would require documentation by the DOJ of its confirmation to waive the health and safety code provisions to address both issues.

Dr. Gray advised Dr. Kajioka that the DOJ does not have a problem with a prescriber using plain paper to prescribe schedule III-V prescriptions.

SDAG Room reiterated that he is unaware of any authorization for a prescriber to issue a prescription for a schedule III-V controlled substance other than on a secured prescription form.

Mr. Kavance acknowledged the concerns raised by the committee and indicated that the concerns would be brought to the DOJ and urged the committee members to take action on the earlier motion.

In response to a question by Dr. Gutierrez about other states that are allowing this process, she was advised that CA if the first state that has been approached in part because Kaiser does not have the same health and safety code requirements in other states. Dr. Gutierrez also sought input from enforcement staff and indicated that a person wanting to defraud the system would be able to do so. Dr. Nurse responded that one of the inherent safe guards of a security prescription is that is cannot be reproduced readily. Dr. Nurse highlighted potential ways to defraud the proposed solution.

Ms. Herold indicated that she firmly believes that the board lacks the authority to act on this proposal. Ms. Herold indicated that DOJ also lacks the authority to accept this waiver as well. Ms. Herold reminded the committee that unless the law authorizes something, it cannot be done. Ms. Herold indicated that she would strongly advise the board to not consider this waiver until the statute is amended. Ms. Herold discussed some of the challenges with the current motion including the fact that it could apply to any HMO. Ms. Herold reminded the committee that the board is awash in drug diversion cases and indicated that this proposal is very dangerous.

Dr. Gray advised the committee that the DOJ has indicated that they do not believe that the Health and Safety Code does not prohibit this and that the DOJ could exercise some enforcement discretion.

SDAG Room indicated that he does not believe this proposal is allowed under current law and indicated that he would need to discuss this proposal with colleagues the DOJ to determine if the law is in fact flexible enough to allow the proposal without a statutory change. Mr. Room advised the committee that he can convene a meeting within the DOJ to ensure everyone within the DOJ is in agreement on this issue.

Tappan suggested that there are two issues. This is a regulatory enforcement issue that is under the purview of the DOJ. Mr. Zee indicated that it appears that the DOJ is hesitant to take action without some input from the Board of Pharmacy.

Motion: Move that the board recommend to the DOJ that the board does not have an objection to the plan as set forth by Kaiser a closed system to use plain paper with the caveat that Kaiser counsel meet with DOJ to discuss the enforcement issues.

M/S: Zee/Wheat

Mr. Room clarified that this would serve as a policy statement that would be made consistent with the law.

Ms. Hackworth indicated that she does not believe that a motion is necessary given that the DOJ could always have internal discussions.

Support: 3 Oppose: 2 Abstain: 0

d. Board Comments Submitted in Response to the Federal Department of Justice, Drug Enforcement Administration's Notice of Proposed Rulemaking Related to Disposal of Controlled Substances [Docket No. DEA-316]

Background

In 2009, California adopted guidelines for the take back and destruction of unwanted pharmaceuticals from the public so they could be appropriately destroyed and not misused by others or flushed down the drain. However, the guidelines were only guidelines until the FDA promulgated regulations to deal with the collection and destruction of controlled substances.

The DEA developed proposed regulations to deal with the take back and destruction of controlled substances and released them for comment in December 2012, with a final comment date of February 19, 2013. At the February Board Meeting, the board directed that comments be submitted to conform to board policy and California's guidelines in this area.

Discussion:

Dr. Kajioka provided an overview of this issue and discussed the information about drug take back and the comments submitted in response to the DEA's request for comments on the proposed rule change. Dr. Kajioka reviewed the preferred method the board is advocating for drug take back to reduce the diversion of such items.

There was no committee or public comment.

e. 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

Prior to discussion on this issue Mr. Room provided a cautionary note about the topic to be discussed. Mr. Room advised the committee that the discussion needs to remain very general in nature and should not include the names of any businesses, etc.

Discussion:

Ms. Herold provided an overview of the issue and referenced materials in the committee materials. Ms. Herold indicated that under investigation is a wholesaler that is purchasing drugs from nonresident pharmacies, drugs that are short supply. Ms. Herold referenced a congressional report that was provided in meeting materials on this issue.

Ms. Herold provided an explanation for the legislative proposal that would prohibit a CA licensed wholesaler from purchasing drugs from a nonresident pharmacy. Such a prohibition currently exists for CA pharmacies however the law does not appear to explicitly prohibit such a transaction when the pharmacy involved in the transaction is not located within CA.

Ms. Herold reviewed the legislative proposal. [A copy of the language is provided as an attachment to the meeting summary.]

Mr. Room discussed the intent of the legislative proposal and outlined the current law relating to this area. The prohibition currently only applies to CA pharmacies however there is no similar provision for nonresident pharmacies.

Ms. Shellans advised the committee that there are other provisions in pharmacy law that may also need to be changed if the board is interested in doing policy changes in this area.

MOTION: To make a recommendation to forward the legislative framework to the full board for consideration along with any other statutory amendments that may be necessary to accomplish the goal.

M/S: Hackworth/Kajioka

Note: The committee did not vote on the prior motion and no action was taken on this item.

Public Comment

Dr. Gray suggested that the topic warrants more discussion and sought clarification on the intent.

Mr. Room indicated that under current law, a pharmacy is allowed to sell a drug that is currently in stock to a wholesaler to alleviate a shortage, however the law does not allow a pharmacy can purchase drugs in short supply and then resale it.

Mr. Room indicated that three conditions must be met to allow for a sale from a pharmacy to a wholesaler from other than that from which they originally purchased the drugs.

1. The pharmacy already has it in stock
2. The drug is a shortage and
3. A person will be denied health care

Dr. Nurse discussed some of the history of the current law and the problems that the board is currently encountering. Further Mr. Room clarified that the board has the authority to

Gil Carpenter expressed concern over the legislative proposal that would limit the ability for pharmacies and wholesalers to conduct business relationships that ensure patients receive their medications when a shortage occurs. Mr. Carpenter discussed the type of business he currently operates that allows him to fill a given order for a drug in short supply through a network of wholesalers and serves as a clearinghouse to ensure patients receive the medications they need.

The committee discussed the issue and the issues surrounding the practices of primary and secondary wholesalers.

Dr. Kajioka indicated that this discussion may be premature until the board has the opportunity to understand more about the case currently pending.

Tony Park, CPhA indicated that several pharmacies are confused about what the preconditions are for transactions to occur. He recommended that the board should provide clarity on these issues.

The committee did not vote on the prior motion and no action was taken on this item. The item will be discussed by the committee after further information is provided.

II. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Medication

a. Update on the Status of Proposed Regulations to Implement Serialized Numeric Identifiers, Grandfathering and Manufacturer Reporting of How the 50 Percent Threshold of Serialized Products on January 1, 2015. (Proposal to Add Title 16, California Code of Regulations Section 1747 and 1747.1)

Discussion:

Ms. Herold provided an update on the regulation package undergoing promulgation relating to the SNI requirements as well as the grandfathering provisions. There were no committee or public comments on this item.

b. Presentation and Questions from the Pharmaceutical Supply Chain on Their Readiness to Meet California's Staggered E-Pedigree Implementation Schedule

Presentation by Bob Celeste

The committee heard a presentation from Mr. Bob Celeste representing GS1. Mr. Celeste provided information the GS1 Track and Trace document. Mr. Celeste indicated that the document is a preliminary document at this point. The document is being used by some companies to move forward with pilots, but may change as a result of pilot projects as well as further review of the overall process. [A copy of the presentation as well as the referenced GS1 Track and Trace and document is attached to these minutes.]

Mr. Celeste provided an overview of the document as well as how to use the materials. Mr. Celeste noted that as companies gain experience with pilots it is assumed that the document will change dramatically. The standards are designed with three primary functions: identify necessary elements, capture data and sharing data with trading partners and the document is formatted following those three functions.

At the conclusion of his presentation Mr. Celeste advised those in attendance that GS1 is working with manufacturers to ensure that they have a properly encoded and well defined barcode. GSI is also offering workshops to take people through the document, dedicating a day to going through the details. These workshops also provide a forum for individuals to discuss their particular implementations and any questions they may have.

Mr. Room questioned Mr. Celeste about the use of the EPCIS standard to develop another fashion to comply with the board's law noting that is appears to be possible to build such a standard. Mr. Celeste indicated that there is a general belief that at minimum the standard

could meet the intent of the e-pedigree requirements using the EPCIS model. Mr. Celeste noted that the EPCIS model is more flexible. Mr. Celeste indicated that there are some issues surrounding the architecture of the system. Mr. Celeste discussed some of the rules in place for a distributed model and some of the challenges using of the centralized model because of the issues of data governance and who will have access to view and see information. Mr. Celeste discussed one of the general concepts of the guidance document is of the movement of product through the supply chain involved two trading partners both reporting the transaction.

There was no additional committee or public comment.

Presentation by Liz Gallenagh & John Howells (HDMA) Drop Shipment PPT

The committee heard a presentation from Liz Gallenagh and John Howells representing HDMA. The presentation focused on the use of drop shipments by members of the supply chain. [A copy of the presentation is attached to these minutes.]

Dr. Room asked at what point the distributor is advised of the transaction and was advised that it varies and was provided with several difference scenarios.

Ms. Herold asked about how brokering by a wholesaler would fall into this model and was advised that the information being provided does not include brokering, rather is limited to just drop shipment information.

The committee discussed some of the parameters of brokering and how it may work as well as if the possibility exists for a broker to leverage the drop shipment model to compromise the pedigree process. The committee was advised of some of the changes between the brokering model versus the drop ship model.

Mr. Room pointed out that the manufacturer designee drop ship model described would not realized the benefits of a regulation in this area because it does not comply with section 4163.1.

Mr. Room discussed possible regulatory language on inference, certification and expectations on how to access data for purposes of inspections. (Draft language was made available and those in attendance were advised that the language was also posted on the board's web site.

Mr. Room provided an overview of the concept of certification and what is required.

Public Comment on draft regulation:

HDMA sought clarification on some of the terms used in the language.

Dr. Gray provided some other information for consideration (need to take from webcast) SDAG indicated that there does not appear to be robust security features on the shipment of cases and pallets and as such the language is narrowly drafted.

Representatives from Walgreens provided information on the case size. They indicated that the number of units varies based on the size of the units and can range from 39 to 144. Walgreens offered to provide the board with information on the number of units in a case. Walgreens spoke in need of inference in their distribution center. When asked what percentage of cases go through their distribution center without being broken down, Walgreens indicated that an unsealed case going through to their pharmacies would be an exception.

SDAG asked for the percentage of cases that will move through the system without being opened. This information is necessary to assess the risk of allowing items to move using inference.

Public comment from another individual indicated that it may be a challenge to define a case because it is continually changing. Perhaps the solution would be to rely on the case security such as tamper evidence tape etc. The individual indicated that provided extra seals would not provide any greater level of security and also expressed concern about treating different cases differently.

Ms. Herold underscored the need for the board to have comments on the draft language to ensure that the regulation is appropriate, ensures the necessary protections are in place but does not prevent the flow of drugs through the supply chain.

Dr. Gutierrez indicated that a case should really be something some can pick up and suggested perhaps rather than specifying a number of units contained in the cases as a definition to rather a weight limit.

c. Discussion on the Use of Drop Shipments in an E-Pedigree System

Discussion:

The committee was advised that board staff released a solicitation request through the board's email notification system that the board was seeking information on drop shipments from members of the supply.

The committee heard comments from John Valencia, representing a number of clients. Mr. Valencia indicated that a number of the clients he represents need guidance for drop shipments. Mr. Valencia spoke about a drop ship model that is used for some specialty

products. He referenced comments submitted and detailed some changes between the HDMA model discussed earlier in the meeting and the proposed solution being offered by his clients. Mr. Valencia urged the committee to discuss the issue and move forward the language for discussion as it will solve a real dilemma for a small but specialized area.

Mr. Room clarified that the proposal appears to specify that there would be a direct connection between the manufacturer and the physician's office or clinic. Mr. Room noted that the proposed solution would work for their business model, but not for all.

Mr. Valencia indicated that his clients need to be in some place of certainty to ensure businesses know how to move forward as the implementation date moves closer. Mr. Valencia reminded the committee that the billing relationship is not what is important in tracking a pedigree.

Mr. Room indicated that he did not have any concerns from a legal perspective with the draft language.

Ms. Herold again requested information from industry to ensure that the board has the necessary information to ensure the development of the language is appropriate.

Committee Member Wheat requested information about the possibility of splitting the committee and was advised that this should be discussed by the board. Ms. Wheat indicated that it is very hard to make decisions on information that is provided to the committee members during the meeting.

Dr. Gutierrez asked if it was possible to maintain the committee meeting so it would be back to back meetings.

III. Public Comment on Items Not on the Agenda/Agenda Items for Future Meetings.

Discussion

Dr. Kajioka requested comments for public comment for items not on the agenda.

Jonathon Nelson, CSHP addressed the committee to discuss drug shortages and requested that this topic be discussed by the board at a future board meeting.

Douglas Barcon, representing CSHP and as an individual, addressed the committee to discuss the issue of drug returns from skilled nursing facilities. Pharmacist Barcon indicated that USP Section 1196 prohibits the de-blistering of a returned medication to be reused. He expressed concerned about the process to handle a drug returned from the skilled nursing

facility to a drug repository and encouraged the board to look at the issue of drug repositories and how to manage this.

Dr. Kajioka adjourned the meeting at 2:11 p.m.