



California State Board of Pharmacy

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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
PUBLIC BOARD MEETING
MINUTES**

DATE: December 6, 2011

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Anil Badlani, RPh
Ryan Brooks, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh
Tappan Zee, Public Member

BOARD MEMBERS

NOT PRESENT: Ramón Castellblanch, Public Member
Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

I. Closed Session

Pursuant to Government Code section 11126(c)(3), the board convened in closed session to deliberate on administrative disciplinary decisions at 9:00 a.m.

The closed session adjourned at 10:30 a.m.

General Session

President Stan Weisser called the general session meeting to order at 10:51 a.m.

President Weisser conducted a roll call. Board Members Hackworth, Veale, Lippe, Badlani, Brooks, Kajioke, and Zee were present.

II. Announcements

President Weisser recognized former Board Member Bob Graul who was in attendance in the audience.

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

Bob Gordon, representing the California LGBT Tobacco Education Partnership, requested the board's consideration to support a resolution to prohibit pharmacies from selling tobacco products.

Ron McGuff discussed the requirement pursuant to Business and Professions Code section 4162 wherein a wholesaler must submit a surety bond of one hundred thousand dollars upon the issuance or renewal of a wholesaler license. He stated that the McGuff Company submitted a request to the board to obtain the amount of funds the board has obtained pursuant to this requirement and received a response indicating that no funds have been collected as a result of enforcement action since January 1, 2006 thru May 31, 2011. Mr. McGuff requested that the board consider the removal of this requirement.

Board Member Ryan Brooks suggested that the board review its contact with Maximus, Inc., the current administrator of the Pharmacists Recovery Program. He requested that the board create a policy and a standard to allow for other potential companies to participate in this program.

President Weisser suggested that Maximus provide a presentation to the board.

Mr. Brooks requested that Executive Officer Virginia Herold send a notification to other companies that provide similar services to be provided with an opportunity to also provide a presentation.

Board Member Rosalyn Hackworth requested that the board be provided with a copy of the board's current contract with Maximus.

Mr. Brooks requested that staff review and report back to the board on the board's current surety bond requirements as well as any other requirements for fees that are being collected but are not currently being used.

President Weisser suggested that surety bond requirements be discussed at a future Licensing Committee Meeting.

IV. Discussion on the Implementation of California's Electronic Pedigree Requirements for Prescription Drugs

a. Presentation by Connie T. Jung, RPh, PhD, Acting Associate Director for Policy and Communications, Center for Drug Evaluation and Research, US Food and Drug Administration

Dr. Jung provided a presentation on the FDA's activities regarding a track and trace system for prescription medication. A copy of this presentation is attached, following this meeting summary.

Dr. Jung provided an overview of the supply chain and the many entities involved. She discussed that diversion of prescription medication can occur at any point within the chain and typically involves solid oral dosage forms.

Dr. Jung discussed risks to the drug supply including stolen and counterfeit products and provided an example of stolen insulin in June 2009. She reviewed the increase in counterfeit drug cases opened by the FDA's Office of Criminal Investigation from 1997 to 2010.

Dr. Jung discussed efforts by the FDA to develop supply chain security standards including serialization, authentication, tracking and tracing of product and transaction data, and potential models for this system. She discussed a guidance developed by the FDA and a workshop that was held in February 2011. (A summary of this workshop is available on the FDA's Web site.)

Mr. Brooks left the meeting room at 11:41 a.m. and returned at 11:55 a.m.

Discussion

The board discussed the role of the serial number identifier (SNI) in this process. It was suggested that guidelines for SNIs be developed.

Ms. Herold discussed that the FDA's guidance in this area is more specific than California's pedigree laws. She stated that effective July 1, 2017, California law will require pharmacies to have an authenticated pedigree for all drug stock. Ms. Herold indicated that the board may want to define SNI and address at what point an SNI will be retired, either at the point a drug enters a pharmacy or at the point of dispensing.

Mr. Brooks discussed that industry will need to ensure compatibility and development of standards within this system and provided an example of the cell phone industry that came together in development of Bluetooth technology.

Public Comment

George Pennebaker provided that the National Council for Prescription Drug Programs (NCPDP) is developing standards for data transmission communication in this area.

Mr. Brooks recommended that this issue be further discussed at a future board meeting.

Deputy Attorney General Joshua Room asked whether Mr. Brooks is seeking a possible regulation to define communication standards and data standards that will be implemented for purposes of the pedigree statutes.

Mr. Brooks provided that he personally doesn't believe that government should make this definition. He stated that he wants to ensure there is a standard for data transmission communication.

Mr. Pennebaker discussed that the new systems discussed during Dr. Jung's presentation will present a challenging transition for the 6,000 pharmacies in California. He suggested that there be a phased implementation for new requirements in this area.

Dr. Jung discussed that the FDA is cognizant and will be mindful of the challenges that these systems will present for pharmacies as well as for all parties involved in the supply chain.

Mr. Pennebaker asked whether batch numbers and expiration dates will be incorporated into SNIs.

Dr. Jung discussed that the FDA is recommending that the SNI be limited to the National Drug Code (NDC) and the serial number. She stated that considering the capabilities of data carriers, these additional elements could be incorporated.

Bryce Docherty asked whether there will be a uniform federal standard implemented by the FDA that would exempt the California ePedigree requirements.

Dr. Jung provided that the FDA is aware of California's deadline for ePedigree and will make their standards available as soon as they are finalized.

Gayle Shields, representing the California Department of Corrections and Rehabilitation, sought clarification regarding the tracking of repackaged bingo cards that will be dispensed directly to the patient.

Ms. Herold provided that the pharmacy is required to track and serialize the medication when it enters the pharmacy and does not need to serialize the bingo card when it is

dispensed to the patient. She stated that wholesalers and manufacturers must create a new serialized number for repackaged products.

Dr. Jung provided that this is consistent with the FDA guidance for repackagers.

Ron McGuff provided comment on data integrity and duplicate SNIs and possible problems in these areas.

Dr. Jung provided that the FDA is addressing these issues.

The board recessed for a lunch break at 12:37 p.m. and reconvened at 2:12 p.m.

b. Presentations and Questions from the Pharmaceutical Supply Chain

Presentation

Supervising Inspector Judi Nurse discussed that complex drug distribution makes investigation involving diversion and counterfeiting difficult. She provided an example based on a board investigation in which a patient received a drug containing two different AIDs medications that originated from an unlicensed California wholesaler broker entity that disperses drugs through many different wholesalers and pharmacies. Dr. Nurse stated that ePedigree will drastically benefit the board's investigation of such cases and will help to ensure patient safety.

Discussion

Ms. Herold discussed that pharmacies are not permitted to sell back drugs to any wholesaler other than the wholesaler in which the drugs were purchased. She stated that the wholesaler surety bond requirement is another such safeguard which allows the board to claim against the bond if a licensee fails to pay a fine issued for failure to pass a pedigree.

Mr. Brooks asked for information regarding the types of drugs that are counterfeited.

Dr. Nurse explained that all types of drugs are counterfeited

Ms. Herold discussed that price drives the entire counterfeit process.

Dr. Jung discussed that over-the-counter medication is also being counterfeited.

Presentation

Elizabeth Fallenagh, representing the Healthcare Distribution Management Association (HDMA), provided a presentation on the distribution of healthcare products within the supply chain. A copy of this presentation is attached, following this meeting summary.

Ms. Fallenagh provided an overview on HDMA as well as background information regarding pedigree.

Mr. Brooks left the meeting room at 2:38 p.m. and returned at 2:41 p.m.

Ms. Fallenagh reviewed other states that have adopted pedigree legislation or have pending legislation. She stated that California is the only state that starts the pedigree requirements at the manufacturer and explicitly includes the serialization requirement.

Ms. Fallenagh encouraged the board to participate in a tour of a distribution center.

Ms. Fallenagh reviewed results from a track and trace survey conducted by HDMA in late 2010. She stated that the survey identified that manufacturers are fully aware of track and trace programs being implemented within the healthcare industry, but pharmaceutical dispensers, particularly hospitals and independents, are not.

Ms. Fallenagh reviewed California issues in this area including grandfathering, drop ship, inference, and decommissioning.

Discussion

Dr. Jung provided comment on the international tracking of prescription drugs. She stated that Turkey is currently working on implementation of a track and trace system.

Mr. Room asked whether there is a different context for implementation now compared to in 2008.

Ms. Fallenagh provided that there is a different context now as the industry is more educated about the capabilities and problems in this area. She discussed that there is an emphasis at both the process and technological level.

No public comment was provided.

c. General Discussion

There was no discussion on this item.

d. Discussion about Future Rulemakings to Implement California's Requirement

Ms. Herold requested direction from the board regarding development of regulations in this area.

Ms. Herold recommend that the board start this process now and focus on the more straightforward issues including grandfathering and what type of electronic signature will be appended to the pedigree.

Ms. Herold discussed that the board will have to promulgate regulations to implement some of the provisions in the law. Regulations will be required for:

- Inference
Inference allows a unique identifier to be applied to a case, pallet or other “aggregate” without individually reading each serialized unit. The law specifies that manufacturers, wholesalers and pharmacies distribute and receive electronic pedigrees, and verify and validate pedigrees at the unit level except where efficiency and safety can be secured through inference.
- Decommissioning
When the medication within a serialized container has been dispensed, there needs to be a process to close out the e-pedigree. Also involved in this is outdated medication or recalled medication that cannot be dispensed.
- Drop Shipment Pedigree
Drop shipping occurs when products are shipped from manufacturer directly to the pharmacy; however, ownership (and hence the need to append the pedigree) needs to track and certify ownership as it moves from the manufacturer to wholesaler to pharmacy, even though the wholesaler never possesses the medication. There will need to be a rule to describe what must occur in these situations.
- Linkage between invoice and shipping notice
Invoices are typically sent after drugs are delivered. Shipping notices accompany the shipment. The pedigree requires annotation to the pedigree before the product is sold to another entity – this could occur before the invoice arrives. However, documenting the sale is an important part of the chain of custody created with the e-pedigree system.
- Grandfathering Lists
The board is required to establish a process for manufacturers, wholesalers and pharmacies to designate drugs already in their possession when pedigree requirements kick in, and exempts these listed drugs from pedigree requirements. The law requires that the drugs be described in written lists submitted to board and specifies that these lists are confidential.

Ms. Herold suggested that the board direct staff to draft an order for these issues to help guide the board at a future meeting. She discussed that it will take some time in order for the board to address these issues and solicit input from the industry to develop adequate language.

Mr. Brooks discussed that input from both the industry and advocates will be needed during this process.

No public comment was provided.

e. Future Meeting Dates to Discuss Electronic Pedigree

Ms. Herold reviewed the following meeting dates for 2012:

- March 13
- June 12
- Sept. 11
- Dec. 4

Ms. Herold stated that the March 13 meeting will be rescheduled due to a conflict with an HDMA conference (representing large drug wholesalers) conference on the East Coast. The confirmed date will be posted on the board's Web site.

There was no board discussion or public comment.

V. Discussion Regarding the Board's 2011 Sunset Report

Mr. Herold stated that the Board's 2011 Sunset Report is complete. She indicated that there will be a hearing for this review in February or March 2012.

There was no board discussion or public comment.

VI. Executive Officer's Report

Ms. Herold reviewed the following upcoming meeting dates:

- Board Meeting – October 16 and 17, 2012 (TO BE RECHEDULED for October 18 and 19, 2012)
- Communication and Public Education Committee Meeting – January 19, 2012
- Compounding Subcommittee Meeting – January 4, 2012

Ms. Herold provided that the board has secured additional office space across from the board's current suite. She stated that the board's licensing staff will be moving to this new space.

Ms. Herold provided that the board is no longer subject to the hiring freeze and reviewed the current vacancies and recent hires.

Ms. Herold provided that President Weisser and Vice President Kajioka met with the contracted consultant to finalize the board's Strategic Plan. She stated that the plan will be presented to the board at the January 2012 Board Meeting.

Ms. Herold provided that as requested by Board Member Zee, staff will begin reporting mail vote statistics to the board.

There was no board discussion or public comment.

VII. Update on the Process for Evaluation of Board Executive Officers

President Weisser provided that the evaluation form will be sent to the board members in the next few days. He requested that the forms be completed and returned to him by January 15, 2012. President Weisser stated that Executive Officer Herold will be completing an evaluation of herself and the board will review the evaluation at the January 2012 Board Meeting.

There was no board discussion or public comment.

The meeting was adjourned at 3:28 p.m.