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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:** September 7, 2011

**LOCATION:** Los Angeles County Health Services - Auditorium
313 North Figueroa Street
Los Angeles, CA 90012

**BOARD MEMBERS PRESENT:**
Stanley C. Weisser, President
Randy Kajioka, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Anil Badlani, RPh
Ryan Brooks, Public Member
Deborah Veale, RPh
Shirley Wheat, Public Member
Tappan Zee, Public Member

**BOARD MEMBERS NOT PRESENT:**
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member

**STAFF PRESENT:**
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Judi Nurse, Supervising Inspector
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Tessa Miller, Staff Analyst

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## ***Call to Order***

President Stanley Weisser called the meeting to order at 10:24 a.m.

President Weisser conducted a roll call. Board Members Lippe, Veale, Wheat, Badlani, and Zee were present. A quorum of the board was not present.

## I. General Announcements

President Weisser recognized former Board Members Clarence Hiura, Stanley Goldenberg, and Holly Strom who were in attendance in the audience.

## II. Discussion and Possible Action to Consider Recommendations to Initiate a Rulemaking to Amend the Board's Disciplinary Guidelines at 16 California Code of Regulations Section 1760, Including to Incorporate Recommendations of the Substance Abuse Coordination Committee (Pursuant to SB 1441, Ridley-Thomas, Chapter 548, Statutes of 2008)

Relevant Sections
California Code of Regulations Section 1760 requires the board to consider disciplinary guidelines when reaching a decision on a disciplinary action.

Business and Professions Code Section 315 established the Substance Abuse Coordination Committee (SACC) within the Department of Consumer Affairs. The committee was charged with formulating uniform and specific standards in several areas for dealing with substance-abusing licensees.

Chapter 9, Division 2, Chapter 19 (Business and Professions Code sections 4300-4315) defines disciplinary proceeding for the board as well as the grounds for taking discipline.

Discussion
Executive Officer Virginia Herold provided an overview of the board's Disciplinary Guidelines (guidelines). She discussed that the guidelines exist to ensure consistency in Board of Pharmacy disciplinary actions.

Ms. Herold provided that the board directed staff to restructure and update the guidelines and to also incorporate the Uniform Standards (standards) as finalized by the SACC. She reviewed the following proposed changes that have been identified and drafted for board consideration for incorporation into the guidelines. (Proposed changes to the guidelines are available on the board's Web site under meeting materials for this meeting.)

- Consolidation of all of the individual license types into one set of standards.
- Removal of all legal citations under each separate category of violations.
- Improved definitions and inclusion of example violations within each category of violation.
- Incorporation of SB 1441 Uniform Standards (Note: Some of the standards are not incorporated or not fully incorporated into the proposed guidelines. These standards need to be implemented through board policy and/or contract changes.)

Ms. Herold discussed that removal of the legal citations from the guidelines will increase readability and help to improve ease of use since the current lengthy lists of codes,

necessary because of the complexity of pharmacy law, make it difficult to read the standard terms for any licensee.

Ms. Herold provided that the reorganization of the guidelines will allow the board to take into consideration the severity of the violation and other specified factors when determining penalties.

Assistant Executive Officer Anne Sodergren noted that the guidelines include standard language and conditions as well as options that can be incorporated in disciplinary orders to address specific issues such as substance abuse.

Ms. Herold provided that if the board chooses to move forward with the proposed changes to the guidelines, the board will initiate the formal rulemaking process and begin a 45-day public comment period prior to a public hearing.

Ms. Herold noted that several of the standards do not need to be adopted via the regulation process as they serve as a policy guidance to the board.

Public Comment

Steve Gray, representing Kaiser Permanente, sought clarification on language added to page 16 of the guidelines regarding “disregard of drug shortages.”

Deputy Attorney Joshua Room discussed that the bulleted information in this section is meant to absorb statutes that were previously listed in the guidelines and to refer to inclusive conduct of a given category. He provided a specific example of drug hoarding during emergency conditions.

Dr. Gray provided comment on drug benefits and access to drugs during a shortage. He discussed the responsibility of pharmacists to ensure that all patients have access to their medications during a drug shortage and the possibility that patients with a drug benefit may receive less than their entitled supply during a shortage.

Ms. Herold introduced Amy Gutierrez, Director of Pharmacy Affairs, Los Angeles County Health Services, and thanked her and her staff for their accommodations with securing the meeting room.

Stanley Goldenberg provided comment on the challenges retail pharmacies face when dealing with third parties and adherence to pharmacy law. He recommended that the board address these challenges.

The board recessed for a break at 10:42 a.m.

The board reconvened at 10:56 a.m. Board Members Brooks and Kajioka were present. A quorum of the board was established.

Additional Discussion

Board Member Tappan Zee offered a proposal to initiate a rulemaking to amend the guidelines as proposed.

DCA Staff Counsel Kristy Shellans recommended to the board that the legal citations under each separate category of violations be retained within the guidelines. She discussed that these citations are present in the guidelines of other healing arts boards and provide guidance with respect to the recommended minimum and maximum penalties.

Board Member Deborah Veale sought clarification regarding the removal of the citations.

Mr. Room discussed that he does not find this information to be very useful when he uses the guidelines. He explained that the same citations are listed in multiple categories and are essentially a list of the titles of the various statutes. Mr. Room stated that these titles provide limited information to individuals, such as administrative law judges (ALJ), who are unfamiliar with pharmacy law. Mr. Room indicated that the current listing has been often ignored by ALJs and does not reflect the gradation of seriousness between the various categories. He explained that the proposed guidelines now include bullet points to provide descriptions of the citations that have been removed providing more meaningful information.

Mr. Room advised that although there is a possibility that this modification could result in concerns with the rulemaking package, this change is worthwhile.

Ms. Herold discussed that the guidelines are intended to assist the board. She stated that the current format of the guidelines was difficult for the board to follow when determining a disciplinary decision. Ms. Herold suggested that the citations be provided as an adjunct document, but not as one of the main organizations of the disciplinary provisions.

Ms. Shellans referred to language within the proposed guidelines regarding the precedence of category III over category II on page 16. She advised that this language is subjective and provides a lack of clarity.

Board Members Veale and Lippe offered support for the proposed changes to the guidelines.

Additional Public Comment

Stanley Goldenberg suggested that a future edition of *the Script* include a summary of the changes to the guidelines upon finalization of the rulemaking. He discussed that the changes may create anxiety among licensees.

Mr. Room offered to provide a prosecutor's summary of the amended guidelines to be shared in *the Script*.

**MOTION:** Direct staff to take all steps necessary to initiate the formal rulemaking process to amend the text of Title 16 California Code of Regulations at Section 1760 as proposed, and to modify the Disciplinary Guidelines, which are incorporated by reference in that section, as proposed; authorize the executive officer to make any non-substantive changes to the rulemaking package; provide the proposed language and Disciplinary Guidelines for a 45-day public comment period; and set a public hearing for the rulemaking.

M/S: Zee/Wheat

Support: 7 Oppose: 0 Abstain: 1

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

### a. Overview of the Law

Ms. Herold and Mr. Room provided a presentation on California's Electronic Pedigree (E-pedigree) Law.

Ms. Herold discussed that pedigree is an important part of a series of provisions intended to address threats to the prescription drug supply from counterfeit, misbranded, adulterated or diverted drugs. She explained that the overall intent is to secure the drug distribution system and sustain and increase confidence in authenticity of prescription drugs in California.

Mr. Room provided an overview of E-pedigree and a review of the current statutes. He discussed that California's E-pedigree law was first enacted in 2004, with an initial effective date of January 1, 2007, and then modified through several amendments to staggered implementation from 2015 to July of 2017.

Other topics of discussion during the presentation included the pharmaceutical supply chain, recalls, industry readiness to meet the 2015-17 deadline for implementation, and future areas to be addressed by the board.

Mr. Zee left the meeting room at 11:43 a.m. and returned at 11:48 a.m.

Mr. Brooks left the meeting room at 11:50 a.m.

Mr. Room stated that the board will regularly address E-pedigree as the 2015-17 deadline approaches.

Ms. Herold encouraged licensees and other interested parties to register to the board's subscriber alert to receive updates regarding future E-pedigree meetings, which will be held as part of future Enforcement Committee Meetings.

Discussion

Board Member Shirley Wheat asked whether specified technology is required by the E-pedigree law.

Mr. Room provided that the law does not specify a carrier or technology to be used. He discussed that industry has indicated greater use of 2-D matrix bar coding over RFID technology. Mr. Room discussed that there has been technology advances since the last amendment to the law.

Ms. Wheat sought clarification regarding industry readiness in 2008.

Mr. Room provided that many wholesalers and manufacturers indicated that they could have been ready by 2011.

Ms. Wheat sought clarification regarding penalties imposed on licensees who distribute or dispense counterfeit drugs.

Ms. Herold discussed challenges in identifying the source of drugs within a pharmacy. She reviewed a case in which a pharmacy failed to identify counterfeit medication that was dispensed to a patient. Ms. Herold indicated that both the pharmacy and the wholesaler involved in this case were cited and fined.

Mr. Room discussed that the board's ability to investigate and trace where drugs come from is reliant upon paper invoices. He stated that California's pedigree law will certify the point of entry of a drug into the supply chain and impose stronger criminal penalties for confirmed violations.

President Weisser sought clarification regarding the current status and security of the supply chain.

Ms. Herold discussed that diversion and losses of drugs from California pharmacies is up 45 percent over the past two years. She explained that this increase indicates a significant problem within the supply chain. Ms. Herold provided that the board is conducting opening inspections of new pharmacies now to address this and other fraudulent activity.

Mr. Brooks returned to the meeting room at 12:09 p.m.

Board Member Anil Badlani provided comment on the diverse technology that can be used for E-pedigree.

Mr. Room discussed that just as in all matters, the board typically provides flexibility to allow for advances in technology.

## b. Comments of the FDA

Connie Jung, Acting Associate Director for Policy and Communications, Office of Drug Security, Integrity and Recalls, U.S. Food and Drug Administration (FDA), provided a presentation via conference call on recent track and trace efforts by the FDA. A copy of this presentation is attached, following this meeting summary.

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 reviewed standards for securing the supply chain including serialization, authentication, and the tracking and tracing of product and transaction data. She provided an overview of recent efforts by the FDA in this area including the development of a guidance for industry and a public workshop that was held in February 2011. (A summary of this workshop is available on the FDA's Web site.) Dr. Jung advised that the FDA published a Federal Register Notice to open a public docket to solicit comments from stakeholders regarding this issue.

Dr. Jung provided that California's E-pedigree law is in line with the FDA's mission of a safe and secure prescription drug supply chain and to promote and protect the public health. She indicated that the FDA will continue to work with the board to pursue and maintain this goal.

Discussion

Mr. Room asked when it is anticipated that a response to the comments received in the docket from the Track and Trace Conference will be released.

Dr. Jung stated that the comments are currently under review for consideration. She indicated that the release date has not yet been set.

No public comment was provided.

The board recessed for a lunch break at 12:30 p.m.

The board reconvened at 1:55 p.m. Mr. Zee was not present.

President Weisser recognized Stan Goldbenberg for his dedication towards the development of California's E-pedigree law.

## c. Presentations and Questions from the Pharmaceutical Supply Chain

Bob Celeste, representing GS1, provided an update on GS1's development in serialization and track and trace. He reviewed the complexity of the supply chain and the challenges with tracking and tracing products as they change dispositions throughout the system. Mr. Celeste provided comment on other complexities and challenges impacting the supply chain including authenticity verification and disaster response and recovery.

Mr. Celeste discussed that serialization will benefit the supply chain and the recall and expiration management systems by allowing access to information electronically.

Mr. Celeste provided that GS1 will be holding a series of meetings and webinars with industry to discuss models that have been identified to secure both the product and the communication path of the information related to the product. He discussed that GS1 is also in development for pilot programs to test components of the supply chain process as well as draft implementation guidelines for track and trace.

Mr. Celeste discussed the use of barcodes in the supply chain process. He reviewed factors such as handling that may damage the integrity of the barcode during the supply chain process.

<u>Discussion</u>
Mr. Brooks asked whether the barcodes used by UPS have been considered as models in this area.

Mr. Celeste indicated that UPS barcodes are proprietary information. He stated that UPS is working with GS1 on the development of barcode standardization in this area.

Discussion continued regarding the use of barcodes and the development of standards in this area. Mr. Brooks suggested consideration for legislation to standardize barcode information for the industry.

Ms. Herold discussed that pharmacies are required to provide information regarding the source of their medications and how they acquired them when inspected by the board.

Mr. Room provided that a pharmacy in possession of a drug for which there is no pedigree or chain of custody document will be held responsible for receiving a drug without pedigree. He stated that education, compliance, and enforcement should help to deter pharmacies from receiving products without pedigree.

There were no additional presentations or comments provided.

### d. General Discussion

There was no additional discussion.

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

No public comment was provided.

The meeting was adjourned at 2:40 p.m.