



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: November 14, 2013

LOCATION: Department of Consumer Affairs
First Floor Hearing Room
1625 North Market Blvd.
Sacramento, Ca 95834

BOARD MEMBERS

PRESENT: Stanley C. Weisser, President
Amy Gutierrez, PharmD, Vice President
Greg Lippe, Public Member, Treasurer
Victor Law, RPh
Ramón Castellblanch, PhD, Public Member
Rosalyn Hackworth, Public Member
Albert Wong, PharmD
Deborah Veale, RPh
Lavanza Butler, PharmD
Randy Kajioka, PharmD

**BOARD MEMBERS
NOT PRESENT:** Tappan Zee, Public Member
Ryan Brooks, Public Member
Shirley Wheat, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Joshua Room, Supervising Deputy Attorney General
Michael Santiago, DCA Staff Counsel
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, SSM2
Laura Hendricks, Staff Analyst

Note: A webcast of this meeting can be found at:

<http://www.youtube.com/watch?v=qYdu8wkvEgo&feature=youtu.be&noredirect=1>

CALL TO ORDER

President Weisser called the meeting to order at 10:00 a.m.

I. GENERAL ANNOUNCEMENTS

President Weisser conducted a roll call. Board members present: Randy Kajioka, Gregg Lippe, Rosalyn Hackworth, Debbie Veale, Lavanza Butler and Victor Law.

Note: Albert Wong arrived at 10:10 a.m., Amy Gutierrez arrived at 10:24 a.m. and Ramon Castellblanch arrived at 10:42 a.m.

III. DISCUSSION AND POSSIBLE ACTION TO INITIATE A RULEMAKING TO AMEND TITLE 16 CALIFORNIA CODE OF REGULATIONS SECTIONS 1715, 1735.2 AND 1784, TO UPDATE THE SELF-ASSESSMENT FORMS FOR PHARMACIES, HOSPITALS, WHOLESALERS AND COMPOUNDING PHARMACIES

Background

Pharmacy Law requires pharmacies and wholesalers to conduct self-assessments on or before July 1 of each odd-numbered year to promote compliance with various federal and state laws and regulations through self-examination and education. Self-assessment forms also serve as an easy reference guide for a Pharmacist-in-Charge (PIC) or a Designated Representative-in-Charge (DRIC). A self-assessment is required any time there is a change in the PIC or DRIC, when a new permit/license is issued; or (for a wholesaler) when there is a change of address.

Several new laws went into effect in 2013, and many of the changes to the self-assessment forms reflect these new laws:

- AB 377 – c. 687, Statutes 2012, Centralized Packaging Pharmacy
- SB 41 – c. 738, Statutes 2011, Hypodermic needles and syringes
- SB 360 – c. 418, Statutes 2011, Pharmacies: access to CURES reports
- SB 431 – c. 646, Statutes 2011, Pharmacies: regulation (mandated reporting to the board of theft, diversion or self-use of dangerous drugs by a licensee)
- SB 1301 – c. 709, statutes 2012, Prescription drugs: 90-day supply
- SB 1329 – c. 709, Statutes 2012, Prescription Drugs: collection and distribution program
- SB 1481 – c. 874, Statutes 2012, Clinical laboratories: community pharmacies

Additional changes were added where references to (existing) statutes provided clarity. For example, where the Community Pharmacy Self-Assessment addressed controlled substances

inventory (Section 19 of Form 17M-13), a new item is proposed to provide a reference to existing federal regulation that requires the inventory record indicate if the inventory was taken at the “open of business” or the “close of business.”

Title 16 CCR § 1715 incorporates two self-assessment forms:

Form 17M-13 – Community Pharmacy Self-Assessment; Hospital Outpatient Self-Assessment

Form 17M-14 – Hospital Self-Assessment

Title 16 CCR § 1735.2 incorporates one self-assessment form:

Form 17M-39 – Compounding Self-Assessment

Note: The proposed changes to Section 1735.2 and to the self-assessment do not reflect the current discussions of the Enforcement/Compounding Committee and the board related to the implementation of recently-enacted legislation (SB 294 and AB 1045) related to compounding and non-resident compounding pharmacies. The majority of the changes to Form 17M-39 reflect new items that reference requirements for a centralized hospital packaging pharmacy (as a result of AB 377, c. 687 statutes 2012).

Title 16 CCR § 1784 incorporates one self-assessment form:

17M-26 – Wholesaler Self-Assessment

The meeting materials contained the proposed regulatory text to amend Title 16 California Code of Regulations Sections 1715, 1735.2 and 1784. Also attached are proposed amendments to the four self-assessment forms, which are incorporated by reference in these sections (all with proposed revision dates of “11/13”).

Staff is not recommending that a regulation hearing be conducted on this regulatory action, unless one is requested

Discussion

Carolyn Klein provided an overview of the rulemaking and directed the board and the public to the meeting materials to view the entire rulemaking.

Ms. Klein noted that three *minor* changes had been made to the rulemaking document since the meeting materials were released. Copies of the updated language were provided to the board members and the public. Ms. Klein reported that all of the changes were about the community pharmacy self-assessment forms. Ms. Klein walked through each minor change and highlighted that none of the changes were substantive, the changes were designed to have the form better reflect the statutory language. Ms. Klein also explained that many of the changes to the forms are the result of feedback from the board inspectors on common violations they encountered.

Ms. Klein informed the board that each change was provided to legal for review to ensure the changes accurately reflect statute.

President Weisser walked the board and the public through each change on the community self-assessment form to allow for board and public comment. No comments were received from the board or from the public.

Community Pharmacy Self-Assessment

Motion: Approve the changes to the Community Pharmacy Self-Assessment Form.

M/S: Lippe/Hackworth

Support: 7 Oppose: 0 Abstain: 0

Hospital Pharmacy Self-Assessment

Motion: Approve the changes to the Hospital Pharmacy Self-Assessment Form.

M/S: Lippe/Hackworth

Support: 7 Oppose: 0 Abstain: 1

Wholesaler Self-Assessment

Motion: Approve the changes to the Wholesaler Self-Assessment Form.

M/S: Lippe/Gutierrez

Support: 9 Oppose: 0 Abstain: 0

Compounding Self-Assessment Form

Dr. Gutierrez asked if the self-assessment forms will be updated as the new compounding regulations are implemented. Ms. Herold and Mr. Room confirmed that this document will be updated as changes occur.

Motion: Approve the changes to the Compounding Self-Assessment Form

M/s: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

Motion: Direct staff to initiate the formal rulemaking process to amend the text of 16 CCR Sections 1715, 1735.2 and 1784 and the Self-Assessment Forms incorporated by reference in those sections, as proposed at this meeting. Authorize the Executive Officer to make any non-substantive changes to the rulemaking package, and provide a 45-day public comment period. If no negative comments are received, direct staff to take all steps necessary to complete the rulemaking process, including the filing of the final rulemaking package with the Office of Administrative Law, delegate to the Executive Officer the authority to make any

non-substantive changes to the proposed regulations before completing the rulemaking process, and adopt the proposed regulations at Sections 1715, 1735.2 and 1784 as described in the notice.

M/S: Lippe/Hackworth

Support: 9 Oppose: 0 Abstain: 0

IV. REGULATION REPORT

Background

Status of the Board's Proposal to Add Title 16, California Code of Regulations, Sections 1747 and 1747.1 Related to E-Pedigree – Serialized Numeric Identifiers, Specification of Pedigreed Dangerous Drugs in California by January 1, 2015 and January 2016, Identification of Non-serialized Stock Remaining After E-Pedigree Implementation (Grandfathering)

As discussed at the board meeting held October 29, 2013, the board received verbal notification on October 18, 2013, that the Office of Administrative Law (OAL) would be disapproving the board's proposed rulemaking to add Title 16, California Code of Regulations (CCR) Sections 1747 and 1747.1 related to E-Pedigree. A formal Notice of disapproval was issued thereafter on October 25, 2013.

On October 31, 2013, the board received a **Disapproval Decision** from OAL. A copy of the Disapproval Decision was provided in the meeting materials. The regulation text itself was not questioned by OAL. The basis of OAL's disapproval was discussed in length in the Disapproval Decision, and are briefly summarized below.

First, OAL determined that the "necessity standard" was not met as it relates to the requirement that certain declarations (required by 1747.1) be made under penalty of perjury. OAL stated that because the Initial Statement of Reasons did not include statement as to the specific purpose of requiring a declaration be made under penalty of perjury, nor address why this provision was necessary, the board did not meet the "necessity standard" for these declarations.

Second, OAL determined that the board's economic impact assessment did not meet the requirements of Government Code section 11346.3(b)(1) which requires an agency to assess whether and to what extent the rule would affect the following:

- The creation of or elimination of jobs within the state;
- The creation of new businesses or the elimination of existing businesses in the state;
- The expansion of businesses currently doing business within the state, and
- The benefits of the regulation to the health and welfare of California residents, worker safety and the state's environment.

Following a disapproval, the board has 120 days to correct the items identified in OAL's Disapproval Decision and resubmit the file to OAL for review. The Disapproval Decision was issued on October 31, 2013; thus, the file must be resubmitted to OAL no later than February 28, 2014.

To correct the deficiencies outlined in the Disapproval Decision, staff is preparing an *Addendum to the Initial Statement of Reasons* to address the "necessity standard" as it relates to the board's requirement that declarations be made under penalty of perjury.

Likewise, staff is preparing an *Addendum to the Economic Impact Statement* to address whether and to what extent the rule will affect the items outlined in Government Code section 11346.3(b)(1).

When finalized, staff will prepare a "Notice of Documents Added To The Rulemaking File" and issue the notice for a 15-day comment period. In accordance with the board's motion on October 29, 2013, if no negative comments are received, staff will complete the rulemaking process and resubmit the rulemaking package with OAL prior to the expiration of the 120-day period.

If comments are received related to the items outlined in the Notice, the board will need to review and accept or reject comments prior to resubmitting the file to OAL.

Discussion

Ms. Klein reported that staff is currently working on the addendum.

Ms. Shellans reported that she had provided staff with case law that illustrates why "under penalty of perjury" is important to use on forms.

V. PRESENTATION ON A PHARMACIST'S CORRESPONDING RESPONSIBILITY UNDER CALIFORNIA LAW BY BOARD STAFF

Background

In a Decision and Order initially effective June 3, 2012 (after the lapse of a 30-day stay from its initial effective date of May 4, 2012), and made a precedential decision of the Board effective August 9, 2013, the Board of Pharmacy revoked the licenses issued by the Board to Pacifica Pharmacy, PHY 46715, a pharmacy licensee, and Thang Q. Tran, RPH 41172, a pharmacist licensee, based on allegations and proof that respondents engaged in unprofessional conduct including failures to exercise the "corresponding responsibility" a pharmacy/pharmacist owes under California law to determine the legitimate medical purpose of controlled substance prescriptions before dispensing, under Health and Safety Code section 11153, subdivision (a).

The entire precedential decision, as well as a two page summary, can be found at:

<http://www.pharmacy.ca.gov/enforcement/precedential.shtml>

Discussion

President Weisser asked Mr. Room to briefly review the board's precedential decision on the Pacifica Pharmacy case.

Mr. Room commented that many pharmacists only look at each *individual* prescription and validate its legitimacy. What this decision indicates - and what the board has been trying to promote - is that a pharmacist needs to look at the patient's entire prescription profile, as well as their patient population as a whole, to identify patterns that may raise suspicion.

Mr. Room identified several "red flags" that should give a pharmacy / pharmacist the inkling of a potential problem with prescriptions and invoke in them a duty of inquiry:

- Irregularities on the face of the prescription itself
- Nervous patient demeanor
- Age or presentation of patient (e.g., youthful patients seeking chronic pain medications)
- Multiple patients at the same address(es)
- Cash payments
- Requests for early refills of prescriptions
- Prescriptions written for an unusually large quantity of drugs
- Prescriptions written for potentially duplicative drugs
- The same combinations of drugs prescribed for multiple patients
- Initial prescriptions written for stronger opiates (e.g., OxyContin 80mg)
- Long distances traveled from the patient's home to the prescriber's office or pharmacy
- Irregularities in the prescriber's qualifications in relation to the medication(s) prescribed
- Prescriptions that are written outside of the prescriber's medical specialty
- Prescriptions for medications with no logical connection to diagnosis or treatment

Mr. Room noted that pharmacists need to start thinking of themselves as potential targets for illegitimately issued prescriptions, doctor shopping, prescription fraud, drug diversion, etc.

Mr. Lippe noted that the board often sees "cocktails" of Hydrocodone, Xanax and Soma being written illegitimately for patients who had no medical need for them. Mr. Lippe asked if there is ever a legitimate purpose for these three drugs to be prescribed together for a patient. Mr. Room responded that you cannot rule out that there may be rare circumstances that would require a prescription for these drugs together. However, if a pharmacist sees multiple patients coming in with prescriptions for these drugs, especially if the prescriptions are all from the same prescriber, the pharmacist should be suspicious.

Mr. Kajioka commented that law enforcement refers to this drug combination (Hydrocodone, Xanax and Soma) as the “holy trinity.” Ms. Herold added that seeing the three of these drugs prescribed at the same time is not itself a violation, but it should raise a red flag for the pharmacist, especially if a pattern emerges.

Dr. Wong commented that prescribers need to be held responsible for overprescribing.

President Weisser commented that the board has a newly created subcommittee, chaired by Ramon Castellblanch, which deals exclusively with prescription drug abuse.

Dr. Castellblanch commented that the subcommittee is updating the website with more current information on prescription drug abuse, monitoring the implementation of the new CURES system and looking for ways to educate pharmacists on corresponding responsibility and their role in preventing prescription drug abuse.

Dr. Gutierrez asked that education for pharmacists on corresponding responsibility be agenzized for the next Prescription Drug Abuse Subcommittee meeting.

Ms. Herold provided a presentation on “Pharmaceutical Supply Chain Thefts Reporting and Prevention and Corresponding Responsibility.” The slides are included immediately following the minutes.

The board recessed to closed session at 11:29 a.m.

VI. CLOSED SESSION

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on Disciplinary Matters

ADJOURNMENT