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

DATE: February 5-6, 2013

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

BOARD MEMBERS PRESENT:
Stanley C. Weisser, RPh, President
Randy Kajioka, PharmD, Vice President
Ramón Castellblanch, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh
Greg Lippe, Public Member, Treasurer
Shirley Wheat, Public Member
Tappan Zee, Public Member
Amy Gutierrez, PharmD
Victor Law, PharmD

BOARD MEMBERS NOT PRESENT:
Ryan Brooks, Public Member
Albert Wong, RPh

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Robert Ratcliff, Supervising Inspector, 2/5 only
Joshua Room, Deputy Attorney General
Kristy Shellans, DCA Staff Counsel
Carolyn Klein, Legislation and Regulation Manager
Laura Hendricks, Staff Analyst

Note: The webcast for this meeting is available at:
http://www.pharmacy.ca.gov/about/meetings.shtml

Call to Order

President Weisser called the meeting to order at 9:30 a.m.

I. General Announcements

President Weisser conducted a roll call. Board members Ryan Brooks, Albert Wong and Ramón Castellblanch were absent. Mr. Castellblanch arrived at the meeting late.

President Weisser announced that licensees could be awarded 6 hours of continuing education credit for attending the meeting provided they sign in and out of the meeting.

President Weisser announced the re-appointment of Ramón Castellblanch.

II. Approval of the Full Board Meeting Minutes of October 25- 26, 2012 and December 13, 2012.

Motion: Approve the minutes of the October 25-26, 2012 meeting provided minor corrections are made.

M/S: Castellblanch /Wheat

Support: 10 Oppose: 0 Abstain: 0

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

No public comment was provided.

IV. Recognition and Celebration of Pharmacists Licensed for 50 Years In California

No 50 year pharmacist awardees in attendance.

V. Discussion on the Board of Pharmacy and Medical Board of California's Joint Forum On Appropriate Prescribing and Dispensing of Controlled Substances Scheduled for February 21 and 22, 2013

Report:

The Executive Director of the Medical Board of California, Linda Whitney, provided an update on the Joint Forum on Appropriate Prescribing and Dispensing of Controlled Substances that the Medical Board is co-sponsoring with the board. Ms. Whitney indicated that there are 500 seats available for the meeting and while they had anticipated about 200 registrants, the registration had to be closed the same day meeting was announced because it had reached capacity. She also indicated

that there are approximately 100 people on the waiting list. Depending on the success of the February, 2013 meeting the Medical Board will consider holding another forum in the Southern California area.

Discussion:

Mr. Castellblanch asked if the forum was mainly covering pain management and opioids or if it would be broader in scope.

Ms. Whitney answered that topic had been broadened to discuss appropriate prescribing.

Mr. Castellblanch asked what policy implications in addition to CURES funding would be discussed at the forum.

Ms. Whitney answered that policy implications could include the federal government putting limits on pain killers, other states implementing legislation regarding pain management drugs as well as the broader issue of how legislation could help boards enforce pain management guidelines. She indicated that while the Medical Board and Board of Pharmacy provide some funding to CURES it is not enough to run the state of the art system that is needed.

Ms. Herold commented that another topic to be discussed would be the corresponding responsibility a pharmacist must exercise prior to dispensing a controlled substance.

Ms. Whitney added that strengthening the relationship between doctors and pharmacists in regards to pain management would be discussed during the forum.

VI. Licensing Committee Report

Note: There was no Licensing Committee Meeting in the past quarter.

Report:

Licensing Committee Chair, Debbie Veale referred to the Committee Report as provided below.

A. Update on Implementation of Recently Enacted Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. AB 377 (Solorio, Chapter 687, Statutes of 2012) – Centralized Hospital Packaging Pharmacy

Background
The board currently issues licenses to hospital pharmacies as defined in Business and Professions Code section 4029 to mean and include a pharmacy licensed by the board, located within any licensed hospital, institution, or establishment that maintains and operates organized facilities for the diagnosis, care, and treatment of

human illnesses to which persons may be admitted for overnight stay and that meets all of the requirements of Pharmacy Law.

A hospital pharmacy also includes a pharmacy that may be located outside of the hospital, in another physical plant that is regulated under a hospital's consolidated license issued pursuant to Section 1250.8 of the Health and Safety Code. As a condition of licensure by the board, the pharmacy in another physical plant shall provide pharmaceutical services only to registered hospital patients who are on the premises of the same physical plant in which the pharmacy is located. The pharmacy services provided shall be directly related to the services or treatment plan administered in the physical plant.

New Specialty License

AB 377 authorizes the board as of January 1, 2013, to issue a specialty license to a pharmacy currently licensed by the board for the purpose of conducting centralized pharmacy packaging. This specialty license allows a centralized hospital packaging pharmacy to prepare medications for administration only to inpatients within its own general acute care hospital, and one or more general acute care hospitals if the hospitals are under common ownership, as defined, and within a 75-mile radius of each other.

To facilitate implementations of these new provisions, board staff developed instructions as well as an application for the new Centralized Hospital Packaging (CHP) specialty license which was posted to the board's Web site mid-December 2012. Board staff also developed the Request for Renewal of Centralized Hospital Pharmacy License. The Request for Renewal of Centralized Hospital Pharmacy License will be available as a handout at the board meeting.

Discussion:

No comments were provided by the board or public.

2. AB 1904 (Block, Chapter 399, Statutes of 2012) – Military Spouses; Expedited Licensure

AB 1904 requires the board to expedite an application for the spouse of an active duty member of the Armed Forces of the United States of America who is assigned to a duty station in California under official active duty military orders and holds a current license in another state for which the applicant seeks licensure.

The board has received five requests for expedited licensure for military spouses. However four requests did not provide the required documentation Board staff sent deficiency letters outlining the documentation required to be considered for expedited licensure.

Discussion:

No comments were provided by the board or public.

3. SB 1095 (Rubio, Chapter 454, Statutes of 2012) – Licensing: Clinics

The board currently issues clinic licenses to a variety of types of clinics as outlined in Business and Professions Code sections 4180 and 4190. AB 1904 authorizes the board to expand these provisions to additionally authorize the board to issue a clinic license to: 1) A surgical clinic licensed pursuant to paragraph (1) of subdivision (b) of Section 1204 of the Health and Safety Code; 2) An outpatient setting accredited by an accreditation agency as defined in Section 1248 of the Health and Safety Code; or 3) An ambulatory surgical center certified to participate in the Medicare Program under Title XVIII of the federal Social Security Act (42 U.S.C. Sec. 1395 et seq.).

Board staff updated the clinic applications and instructions to comply with these new provisions. The board was advised that approximately 10 ambulatory surgical clinic applications have been received.

Discussion:

No comments were provided by the board or public.

B. Competency Committee Report

1. California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Effective December 1, 2012, the board instituted a quality assurance review of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE). This process is done periodically to ensure the reliability of the examination. Based on historical patterns, the board anticipates results being released approximately February 2013. The board encourages all qualified applicants to continue to schedule and take the CPJE exam. The greater the number of applicants who take the exam during this review period, the sooner results can be released.

Discussion:

No comments were provided by the board or public.

2. Examination Development

The Competency Committee workgroups will continue to meet in the winter and spring of 2013 for examination development.

C. Second Quarterly Report on the Committee's Strategic Goals for 2012/13

The board was advised that the second quarterly report on the Licensing Committee's goals was provided in Attachment C of the meeting materials. Board staff reported on all five licensing success indicators. After review of the acceptance parameters for the licensing success indicators, the parameters were adjusted to reflect a more accurate assessment.

As demonstrated in the quarterly update, the board is meeting the acceptance parameters for Success Indicators 2C – Review Received Deficiency Items to Determine Application Completeness within Five Working Days of Receipt and 2E – Update Information Changes to Licensing Records within Five Working Days.

The board is not meeting the acceptance parameters for Success Indicators 2A – Cashier All Revenue Received within Three Working Days; 2B – Review Initial Applications within 30 Working Days; or 2D – Issue Licenses within Three Working Days of Completed Application. In all three of these success indicators, a majority of the work is completed within a time frame close to the specified indicators. For example, in Success Indicator 2D where the indicator is three days, 59% of the licenses are issued within this time frame; however, a total 88% of licenses are issued within five days or less. The board is not meeting three of the success indicators primarily due to staff vacancies.

Discussion:

No comments were provided by the board or public.

D. Licensing Statistics for July – December 2012

The board was directed to the second quarter's licensing statistics provided in the meeting materials. During the first half of the fiscal year, the board received over 8,200 applications and issued over 7,900 licenses. The number of applications received decreased almost 6% and the number of licenses issued decreased almost 7% when compared to the same time periods last fiscal year.

Discussion:
Mr. Lippe asked if the decrease was in all license types issued or if it was one specific license type.

Ms. Herold confirmed that the decrease was for the total licenses issued.

There was not additional board comments and no public comments.

VII. Communication and Public Education Committee Report

Note: There was no Communication and Public Education Committee Meeting in the past quarter.

Committee member Debbie Veale provided the report.

Report:

A. Update on New Notice to Consumers Poster, Video Display Format Option for Notice to Consumers, and Notice of Interpreter Availability

Ms. Veale stated that since the beginning of 2012, the Communication and Public Education Committee has been working on the production of a new *Notice to Consumers* poster, the *Notice to Consumer* video and the Notice for Interpreter Availability poster.

The board was advised that the new poster is currently being printed by the Office of State Printing and is scheduled to be mailed out to all pharmacies in California by the end of February, 2013. The mailing will also include the Notice of Interpreter Availability poster and a letter that explains requirements for displaying both posters.

The *Notice to Consumers* video display format has been finalized and will be available on CD for pharmacies that request it. Ms. Veale stated that the video will be available in English or Spanish. The video display was produced pursuant to 16 California Code of Regulations Section 1707.6 (below).

(a) In every pharmacy there shall be prominently posted, in a place conspicuous to and readable by a prescription drug consumer, a notice containing the text in subdivision (b). Each pharmacy shall use the standardized poster-Sized notice provided or made available by the board, unless the pharmacy has received prior approval of another format or display methodology from the board. The board may delegate authority to a committee or to the Executive Officer to give the approval. As an alternative to a printed notice, the pharmacy may also or instead display the notice on a video screen located in a place conspicuous to and readable by prescription drug consumers, so long as:

(b) The video screen is at least 24 inches, measured diagonally;

(c) The pharmacy utilizes the video image notice provided by the board;

(d) The text of the notice remains on the screen for a minimum of 60 seconds; and

(e) No more than five minutes elapses between displays of any notice on the screen, as measured between the time that a one-screen notice or the final screen of a multi-screen notice ceases to display and the time that the first or only page of that notice re-displays.

Ms. Veale noted that a pharmacy may seek approval of another format or display methodology from the board.

The Notice of Interpreter Availability poster is being printed by the Office of State Printing and will be mailed out by the end of February, 2013 with the new *Notice to Consumers Poster*. The 8.5 inch x 11 inch poster will also be available for download from the Board of Pharmacy website and will print on 8.5 inch x 11 inch paper.

Discussion:

Mr. Castellblanch clarified that the video mentioned in the report is the video that is to be displayed on a screen in a pharmacy. He also asked if the Notice of Interpreter Availability Poster was the 8.5 x 11 sign listing the different languages available for interpretation services.

Ms. Herold confirmed and indicated that it would be mailed out with the new *Notice to Consumer Posters*.

Mr. Castellblanch asked if the font size of on *The Notice to Consumer Posters* was a large enough to see from a distance.

Ms. Herold stated that the most important information was highlighted, however one would still need to be close to the poster to read all the information provided.

Mr. Castellblanch asked if it would be possible for the board to re-evaluate what language needed to be provided on the poster.

Ms. Herold responded that the board already condensed the information down from two posters to one poster and that the language could be re-evaluated in the future.

Sarah Dikeah from the California Pan Ethnic Health Network asked if any testing had been done to see if the *Notice to Consumer Poster* and Notice of Interpreter Availability Posters were understandable by members of the public.

Ms. Herold responded that both posters were displayed to the public at Committee Meetings and that the board worked with the public to make the posters as consumer friendly as possible. She stated that once the posters are mailed out the board would likely receive additional comments and the board could consider needed changes.

Ms. Herold asked if the entire board would like to review other Notice to Consumer Display methodologies submitted by pharmacies for approval.

President Weisser responded that it would be appropriate for the Communication and Public Education Committee to conduct the reviews and in the future consider delegating the review process to the Executive Officer.

B. Discussion on Securing Consumer Comments on the Board's Regulation Requirements for Patient-Centered Labels and Translations for Limited English Speaking Individuals

Report:

Ms. Veale provided that the consumer survey soliciting feedback regarding the readability of prescription drug container labels was widely distributed. An electronic version of the survey was sent to several consumer groups, who in turn distributed the survey to their ListServe contacts. The survey was also translated into Chinese and Spanish and distributed by The California Pan Ethnic Health Network (CPEHN) to the appropriate audiences. Surveys have also been collected at local Senior Scam Stopper seminars sponsored by the Contractors State Licensing Board.

Ms. Veale stated that the board has received a total of 1204 completed surveys and the results are summarized in an attachment. Individual comments are being reviewed and categorized and a summary will be made available at the next Communication and Public Education Committee meeting.

Discussion:

No comments were provided by the board or public.

C. Update on *The Script*

Ms. Veale provided that the next issue of *The Script* is currently in production. The issue will focus on application of laws and the forthcoming e-Pedigree requirements. The newsletter also lists the multiple disciplinary decisions made by the Board since the beginning of 2012.

Discussion:

No comments were provided by the board or public.

D. Public Outreach Activities Conducted by the Board October 1 – December 31, 2012

Report:

Ms. Veale reported that state government continues to be subject to a travel freeze that restricts all but the most essential travel. The Department of Consumer Affairs

must still pre-approve all travel where a travel claim will be submitted. This has restricted board operations in all areas, including public and licensee outreach. Ms. Veale indicated that despite the restrictions board staff has been able to attend some public meetings those of which have been provided below.

- October 1, 2013: Executive Officer Herold and Assistant Executive Officer Sodergren provided information about compounding issues, pharmacy laws and Board of Pharmacy issues at UCSF.
- October 9, 2012: Executive Officer Herold provides a webinar on e-pedigree pending and future regulations to attendees at LogiPharma.
- December 5, 2012: Executive Officer Herold provides an update of Board of Pharmacy issues and compounding issues to meeting of Sacramento Valley hospital pharmacists.
- December 19, 2012: Executive Officer Herold attends FDA-convened meeting on compounding issues to develop national policy involving public safety issues of compounding versus manufacturing by pharmacies.
- August 13 and 22, 2012; November 14, 2012; December 5,2012 and January 15, 2013 – Public Information Officer Jamison staffed a booth at Senior Scam Stopper seminars hosted by the Contractors State Licensing Board. Ms. Jamison collected a number of consumer surveys on the new patient-centered labels.

Discussion:

No comments were provided by the board or public.

VIII. Organizational Development Committee Report

Note: The Organizational Development Committee met December 3, 2013.

A. Budget Report for 2012/13

Report:

President Weisser provided that the budget year began July 1, 2012 and will end June 30, 2013. The board's spending authorization for the year is $15,289,000. For the first six months of the fiscal year the board has expended nearly 7 million dollars. President Weisser referenced the expenditure chart (attached) and highlighted that the largest portion of the board's expenditures is personnel services.

President Weisser reported that the board relies on the Attorney General's Office for enforcement activities. The board is projecting that it will exceed its Attorney General's budget by approximately $200,000.

President Weisser referenced the revenue chart (attached) and indicated that the board's major source of revenue is its licensing fees. These fees are the only revenue that the board can predict as the board cannot budget for cost recovery or cite and fine revenue.

Discussion:

No comments were provided by the board or the public.

B. Fund Condition Report

Report:

President Weisser reported that over the years the board's expenditures have exceeded its revenue which has prevented the board from keeping the required one year reserve. President Weisser stated that if the revenue stays the same there will continue to be a budgetary imbalance and the board will have less than 2.5 months in reserve in 2014/15, and in 2016/17 the fund will be negative.

The Organizational Development Committee discussed the need for a fee increase to ensure the financial solvency of the board. The board's fees are set in statute with a minimum and a maximum. President Weisser indicated that the board's fees are currently at the statutory minimum. The Organizational Development Committee recommends that the fees should be raised to the statutory maximum. This will provide the board with an additional $3 million per year in revenue which will help rectify the structural deficit. However President Weisser indicated that a fee increase will not deal with the personnel and travel expense growth that the board will require to regulate out of state compounding pharmacies, and stated that this issue will have to be addressed at a later date. The Organizational Development Committee is recommending that staff agenize the proposed language, provided as an attachment in the meeting materials, for the next board meeting.

Discussion:

Ms. Wheat asked why the $1 million General Fund loan has not yet been paid.

Ms. Herold advised that the loan would most likely be repaid next year and is required to be repaid before a fee increase can be considered.

Ms. Wheat inquired if the fees would be increased gradually or if they would be increase all at once.

Ms. Herold answered that it will take approximately one year to get approval for the fee increases. Ms. Sodergren added that staff can provide the board with a copy of the fee audit that was conducted previously. She also stated that the proposed language would increase the fees to the maximum.

Ms. Wheat asked if the board had authority to travel out of state to regulate pharmacies.

Ms. Herold responded that part of the proposed legislation will give the board this authority and that the board would require the entities to reimburse the board for travel expenses related to inspections.

Dr. Gutierrez commented that perhaps the board should charge the out of state compounders a higher licensing fees rather than reimbursing for travel. She indicated that this would make it easier for the board to predict the revenue. Dr. Kajioka agreed on this point as long as counsel did not feel that a higher fee would create a barrier to do business in California.

Mr. Law pointed out the discrepancy between the renewal fee for a pharmacy and a wholesaler and asked how the fees were determined.

Ms. Herold responded that the fees were determined through the audit and that fees are assessed based on the amount of work it takes to license and discipline an entity, not on their ability to pay.

Motion: Instruct staff to agenize the proposed fee increase language for the next Organizational Development Committee Meeting for further discussion and review by the board.

M/S: Lippe /Veale

Support: 10 Oppose: 0 Abstain: 0

C. Update on BreEZe and DCA's Plans for a New Computer System

President Weisser reported that the board is set to release in Phase 2 of the BreEZe project and that the board will make this transition by the end of the year.

D. Reimbursement to Board Members

President Weisser referenced the reimbursement table for the board and public to review in the meeting materials.

E. Personnel Update

Ms. Herold provided the board with a personnel update as provided below.

Report:

Ramon Castellblanch was reappointment to the board by the Senate Rule Committee. The board currently has one vacancy, which is a Governor Appointment and is for a professional member representing labor.

Laura Hendricks is now serving as the administrative analyst. As part of her new role, Laura will be attending board and committee meetings and preparing minutes for the meeting. Laura will continue to coordinate board member travel and reimbursements as well.

Tessa Miller accepted a new position with the Bureau of Automotive Repair in November 2012. Inspector Cari Lee returned to the California Department of Public Health in January 2013. Inspector Sandra Fasulo resigned from the board in December 2012.

Recruitment is ongoing to fill the positions vacated by the transfers and departures. Regrettably our efforts are taking much longer than desired. Board staff is working with DCA Human Resources to facilitate more timely recruitment when DCA resources allow.

Discussion:

No comments were provided by the board or the public.

IX. Legislation and Regulation Committee Report

Note: The Legislation and Regulation Committee did not meet in the last quarter.

Legislation and Regulation Committee Chair, Greg Lippe referred to the Committee Report as provided below.

Report:

Mr. Lipped advised the board that a copy of the 2013 Tentative Legislative Calendar is provided in the meeting materials. The Legislature reconvened on January 7, 2013. The last day for member bill requests to be submitted to Legislative Counsel was January 25, 2013, and the last day for bills to be introduced is February 22, 2013. Staff is monitoring legislation to identify bills that may impact the board or the board's jurisdiction. Legislation identified is that which was introduced by January 25, 2013.

A. Legislation for 2013

1. Compounding Sterile Drug Products (Proposal)

At the October and December 2012 Board Meetings, the board discussed proposals to amend Sections 4127.1 and 4127.2 related to compounding sterile drug products. In December, the board moved to amend the draft language to include enhancements to licensing and reporting requirements, and that the final language be reviewed by the Board President and the Chair of the Legislation and Regulation Committee before it was submitted to the author. The language approved by the Board President and Committee Chair is provided in Attachment 2 and was provided to Senator Bill Emmerson, who has expressed interest in carrying this legislation.

Staff Recommendation: Ratify the language approved by the Board President and the Chair of the Legislation and Regulation Committee for sponsorship.

Discussion:

Mr. Steve Gray from Kaiser asked the board to reconsider clarifying if pharmacies can compound for outpatient clinics.

Ms. Herold asked who currently is compounding for outpatient clinics. Dr. Gray responded that currently pharmacies are compounding for them and added that the use of outpatient clinics is expected to increase.

Dr. Gray asked for clarification on the list of sterile compounded items a facility must provide to the board since their last renewal. He wanted to know if pharmacies would be required to keep a running log with the dates and times each item was compounded.

Ms. Herold responded that dates and times would not be necessary, but the number of times in the past year an item was compounded would be required. The intent is to determine if an entity is a large or small compounding facility and what type of compounding is conducted.

Dr. Gray asked if a California facility need to report if they compound items that are being shipped into, and used in other states.

Mr. Lippe and Ms. Herold confirmed that this would need to be reported to the board.

Dr. Gray asked if a California facility would need to report to the board any accrediting issues in the same way that out of state facilities are required.

Ms. Herold responded that this is not currently a requirement but that it should be included.

Ms. BJ Bartleson, Vice President of Nursing and Clinical Services at the California Hospital Association, stated that the association supports the board on its work to stringently review sterile compounding facilities. However they are worried about redundant surveys and additional workload being created. She asked if there would be an opportunity for accrediting agencies to survey to California regulations.

Ms. Herold responded that this was discussed with the accrediting agencies a year ago. However, the board's inspections are random and unannounced while inspections by accrediting agencies are relatively routine. Additionally, at the time, the accrediting agencies were unwilling to add a licensed pharmacist to their inspection teams.

Mr. Mike Cook with C.A.P.S. commented that the board should consider changing the term "sterile drug products" to "compounded sterile preparation" which has become a standard industry term.

Ms. Herold asked to clarify if currently when a clinic needs products they purchase them through a manufacturer.

Dr. Gray from Kaiser, responded that like hospitals, clinics often cannot get all the products they need from a manufacturer. If the board will not allow a sterile compounding pharmacy to serve clinics it will then require clinics to compound medications in their own facilities. He stated that clinics are often not ideal places to conduct sterile compounding. Dr. Gray recommends that the board change the language from "prescribers office use" to read "prescribers office use or use in licensed healthcare facilities."

Mr. Joshua Room commented that the clinic exception is being used to do large scale compounding that is not patient specific and that the issue should be addressed at a later time rather than trying to add it to this proposal.

Ms. Veale recommended that this item be sent back to the Compounding Subcommittee.

Ms. Herold sought to clarify if the board wanted to allow hospital accreditation.

Dr. Gutierrez added that a pharmacist is not always present during the surveys and the issues are so complex that the Joint Commission does not have the expertise necessary.

Ms. Herold asked if the board wanted to change the term "sterile drug products" to "compounded sterile preparation."

President Weisser felt the current term was adequate.

Mr. Room was not aware of any legal distinction between the two terms.

Dr. Kajioka asked if there was any need to differentiate between non-sterile to sterile compounded products and a sterile compounded product.

Mr. Mike Cook with C.A.P.S. commented that a sterile product is an approved manufactured product that is not pharmacy compounded. A terminology in any other regulations in other states or in the USP would be conflicting with the terminology proposed in California.

Mr. Ratcliff added that in USP 797 there is a distinction between the terms “product” and “preparation.”.

Mr. Room recalled that there has historically been much discussion about the correct terminology to use for the end result and that those most involved in the discussions used the term preparation.

MOTION: Ratify the language approved by the Board President and the Chair of the Legislation and Regulation Committee for sponsorship with the term “product” changed to “preparation.”

M/S: Lippe/Hackworth

Support: 10 Oppose: 0 Abstain: 0

Report:

2. SB 62 (Price) Coroners Reports; Prescription Drug Related Deaths

Under existing law, Section 802.5 of the Business and Professions Code, when a coroner receives information that a death may be the result of gross negligence or incompetence, as specified, the coroner shall file a report with the Medical Board of California and other entities. This bill would amend Section 802.5 to require that when a coroner receives information indicating that a death may be the result of prescription drug use, the coroner shall file a report with the Medical Board of California and other specified entities, ***and the California State Board of Pharmacy***. The bill specifies what information that must be reported, and further specifies that within 90 days of the initial report, the coroner’s report, autopsy protocol, and other relevant information shall follow.

Staff estimates that the receipt, review, analysis and inspection of these reports will require an additional three (3) associate analysts, and an additional six (6) inspectors to determine if there are any violations of Pharmacy Law related to the prescription drugs.

Staff Recommendation: Support SB 62 as Introduced

Discussion:

Ms. Herold indicated that this was the result of the *LA Times* article highlighting the alarming number of prescription drug deaths. The board asked the author to be included in the reporting of any prescription drug related deaths because of the value to the board to receive this information.

MOTION: Support SB 62 as introduced.

M/S: Lippe/Veale

Support: 10 Oppose: 0 Abstain: 0

b. OTHER

Report:

In addition to the above-referenced proposal and legislation, the board at prior meetings approved language to pursue statutory changes during the 2013-2014 Legislative Session as summarized below. Mr. Lippe referred the members to the relevant attachment in the meeting materials that contains draft legislative proposals that have been approved by the board, and staff will keep the board apprised of the status of these proposals.

1. Amendment to Business and Professions Code 4107 – One Site License per Premises; Exception

Business and Professions Code Section 4107 provides that the board may not issue more than one site license to a single premises, unless there is a specific exemption to do so. Following the passage of AB 377 (Hospital Central Packaging Pharmacy), the board approved language that would provide for a specific exemption to issue the central packaging pharmacy permit to a premise that also holds a hospital permit. Staff will be seeking to include this provision in an omnibus measure.

2. Addition of Business and Professions Code Section 4008.5 – Requirement to Provide Arrest and Court Documents as Requested by the Board

The board frequently has problems obtaining documents from local or state agencies for the purpose of completing an applicant or licensee investigation; these agencies cite the board's lack of authority to receive these documents. At the October 2012 Board Meeting, draft language was approved to add Section 4008.5 to provide the board with the express authority to receive certified records for this purpose.

3. Amendment to Business and Professions Code Section 4053 – Application Requirements for Licensure as a Designated Representative

Existing law specifies the requirements that must be satisfied for an applicant who applies for a designated representative license. One of those requirements is to have one year paid work experience related to the distribution or dispensing of dangerous drugs or dangerous devices, or meet other specified requirements. Pharmacy law does not specify the practice setting or types of facilities in which this one year of paid work experience must be satisfied. At the October 2012 Board Meeting, the board approved a draft amendment that would clearly specify that the one year of paid work experience shall be earned in a licensed facility, as specified.

Discussion:

Dr. Gutierrez asked if the difference between drug distributor and drug wholesaler was defined in the law.

Mr. Room answered that the intent of the language used was to address the fact that other states may use different names.

Mr. Castellblanch asked what had happened with the drug take back legislation.

Ms. Herold responded that the provision was removed from the bill in the interest of getting the bill passed.

Dr. Gray from Kaiser, expressed concerned about the language used in 4053. He suggested that the board changes the one year experience to be required for a designated representative in-charge rather than a designated representative.

Ms. Herold stated that there used to be an examination required to be licensed as a designated representative, now the board requires the one year experience in a licensed wholesaling facility.

Dr. Gray again recommended that the board reconsider what the one year experience should actually entail.

There was no additional board or public comment.

Break: 11:30 a.m.
Resume: 11:45 a.m.

B. Regulations

Legislation and Regulation Committee Chair, Greg Lippe referred the Committee Report as provided below. All attachments referenced in the Committee Report have been provided as attachments to the meeting minutes.

Report:

a. Discussion and Possible Action to Adopt Text of Previously Noticed Regulations

Combined Rulemaking: Amend Section 1745 – Partial Filling of Schedule II Controlled Substance Prescriptions; Add Section 1762 – Unprofessional Conduct; and Amend Section 1769 – Application Review / Criteria for Rehabilitation

The Board initiated a rulemaking to Amend Sections 1745 and 1769, and to Add Section 1762 to Title 16 of the California Code of Regulations. A summary of each proposal is provided below. The rulemaking was noticed on October 19, 2012, and the 45-day public comment period concluded on December 10. The board did not receive any comments related to this rulemaking during the public comment period.

Discussion:

Ms. Shellans recommended the board to strike Sub Sections A1 and A2 from 1762 so that the board can avoid having its regulatory proposal disapproved by the Office of Administrative Law. Her recommendation was based on her concern that it is duplicative of 143.5 of the Business and Professions Code which gives authority to take disciplinary action of a licensee who includes or agrees to a “gag clause” in a settlement agreement.

President Weisser commented that 1769 allows for no wiggle room and that 143.5 does not speak to unprofessional conduct and states that a person is *subject* to disciplinary action.

Ms. Shellans restated that 143.5 and 1762 both serve the same purpose and that 143.5 authorized the board to make exceptions while 1762 does not.

Mr. Room stated that he feels there are three potential advantages to keeping 1762 as written: first - there is a difference between defining something as unprofessional conduct vs. simply a basis for disciplinary action, second - 143.5 does not authorize the board to do citation and fine and third - there is a value in having all the expectations for the profession in one location.

President Weisser asked how significant it is if the OAL finds it to be duplicative. Ms. Shellans answered that the entire regulatory proposal would be disapproved and sent back to the board for correction within 120 days, causing a delay in the approval of other regulations.

Ms. Sodergren commented that when OAL reviews a packet they will often reach out informally to an agency if they have concerns and give them a chance to remove an item.

Ms. Herold expressed that it would be beneficial to have the language all in one location and either way the board would have to promulgate regulations.

Ms. Shellans recommend the board strike Subdivision B of 1762 as it defines unprofessional conduct as failure to provide a record within 15 days of the date requested, while 4105 subdivision F (enacted two years ago) requires response in 3 business days.

Dr. Gray sought to clarify who can be charged with unprofessional conduct, because often someone is not aware if there is gag clause or is able to stop a settlement agreement that includes a gag clause. He also commented, in response to the removal of Subdivision B, that often inspectors ask for documents that a pharmacist has no authority to provide.

Mr. Room noted that there is a slight difference between 1762 Subdivision B and 4105 subdivision F. Specifically, 4105 is limited to records requested from an entity and there may be occasions where a board inspector may need records held by an individual. His recommendation is to strike Subdivision B at this time but revisit the issue at a later date.

MOTION: Leave 1762 as is with the exception of the removal of Subdivision B.

M/S: Lippe/Veale

Support: 10 Oppose: 0 Abstain: 0

MOTION: Direct staff to take all steps necessary to complete the rule making process, including preparing modified text for an additional 15 day comment period which includes amendments discussed at this meeting. If after the fifteen public comment period no adverse comments are received, authorize the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt section 1745, 1762, and 1769 of the proposed regulations with the modified text.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

Report:

b. Discussion and Possible Action Regarding 15-Day Comments and Possible Action to Adopt Text

Proposal to Add New Article 5.5 to Title 16 and Add Sections 1747 and 1747.1 Pedigree Requirements

At the December 13, 2012, Board Meeting, the board discussed the board's proposed regulations related to Pedigree Requirements (SNI / Grandfathering). At that time, the board voted to modify the language at proposed Section 1747 to incorporate a reference to subdivision (d) of Section 4034 of the Business and Professions Code, and to strike and/or modify dates specified in proposed Section 1747.1.

Discussion:

Ms. Klein noted that in accordance with the board's motion, staff issued a Notice of Modified Text on December 21, 2012. A Second Notice of Modified Text was issued on January 11, 2013, to correct an error in the *placement of* the reference to Section 4034(d) in the first sentence of Proposed Section 1747. The Second Modified Text public comment period closed on January 28, 2013.

Ms. Klein stated that the board received one comment during the First Notice of Modified Text, but the comments were unrelated to the modifications authorized by the board, however the she would provide the comment to the board so they could either accept or reject it. The comment was from Mr. Bill Connell of Maxiom Group on January 7, 2013. Ms. Klein read through the comment provided by Mr. Connell. Staff recommended that each of the points in his comment be rejected.

Ms. Shellans asked if there would be any confusion about the definition of "drug product family."

Ms. Herold answered that she has never been asked to define it by anyone in the profession.

Mr. Room stated that the statute was intented to allow for maximum flexibility to those in deriving their 50% threshold.

MOTION: Reject the comments 1-5 provided by Mr. Bill Connell.

M/S: Lippe/Law

Support: 10 Oppose: 0 Abstain: 0

MOTION: Direct staff to take all steps necessary to complete the rule making process, including the filing of the final rule making package with the Office of Administrative Law and delegate authority to the Executive Officer to make any non-substantive changes to the proposed regulations before completing the rulemaking process and adopt 1747 as noticed.

M/S Tappan/Law

Support: 10 Oppose: 0 Abstain: 0

Report:

c. Board Adopted Regulations – Undergoing Administrative Review

1. Amend Title 16, Section 1746 – Emergency Contraception Protocol

Mr. Lipped directed the board to the attachment in the meeting materials that provided the language Adopted by the board to modify its regulation at Title 16 CCR Section 1746 for the purpose of updating the Emergency Contraception Protocol, which has been approved by the Board of Pharmacy and the Medical Board of California (MBC).

This rulemaking was initiated on January 6, 2012. Modified Text was issued for a 15-day public comment period on October 30, 2012, during which time no comments to the rulemaking were received. In accordance with the motion of the board, the proposal was adopted, and the rulemaking file was completed. The Director of the Department of Consumer Affairs extended the one-year notice period, as authorized by Section 313.1(e)(1) of the Business and Professions Code.

The board received Agency approval, and delivered the rulemaking file to the Office of Administrative Law (OAL) on January 29, 2013 (Regulatory Action No. 2013-0129-04S). OAL has 30 business days in which to complete their review of the rulemaking.

Staff will keep the board apprised of the status of this rulemaking.

Report:

2. Amend Title 16, Beginning with Section 1735.1 – Compounding Drug Products

This proposal was noticed for public comment on March 9, 2012. The 45-day comment period concluded on April 23, 2012, and the Board conducted a Regulation Hearing on May 1, 2012. On May 1, the board modified the language at Section 1735.3(a)(6) to incorporate by reference USP 797 related to "Redispensed CSPs"; and also to amend Section 1751.2(d) modifying the text of the special label used for cytotoxic agents. A Notice of Modified Text was issued on July 5, and the 15-day notice period concluded on July 20, 2012.

As reported at the October 2012 Board Meeting, and in accordance with the board's motion at the July 2012 Board meeting, the Executive Officer adopted the proposed regulations and staff completed the rulemaking file. Following approval from the department and from Agency, the rulemaking was transmitted to the Office of Administrative Law (OAL) for final review on December 21, 2012 (Regulatory Action No. 2012-1221-01S). A copy of the Adopted Text is provided in the board meeting materials.

Mr. Lippe reported that OAL has 30 business days in which to complete its review. Board staff anticipates learning of the status of OAL's review the week of February 4, 2013.

Discussion:

Ms. Klein noted that OAL had contacted the board to make non-substantive changes to the rulemaking. Ms. Klein added that she had been advised that the rulemaking would be filed with the Secretary of State within the next day or two.

Report:

d. OTHER

Board Approved Regulations – Awaiting Formal Public Notice

The following is provided for information only.

Below are four board-approved regulatory proposals that have not yet been noticed for public comment. A copy of the language approved for public notice was provided in the board meeting material, and a summary of each is provided below. Staff is preparing the required notice documents and will be noticing these proposals as one combined rulemaking.

Background

Proposal to Amend Section 1732.2 – Board Accredited Continuing Education

In January 2012, the board withdrew a pending regulation to Section 1732.2 which, at that time, was pending final review at the Office of Administrative Law. Thereafter, the Licensing Committee vetted revised language which, in May 2012, was approved by the board for public notice.

Proposal to Amend Section 1732.5 – Specification of Continuing Education Credit in Specific Content Areas

In May 2012, the board approved a draft regulatory proposal for public comment to require continuing education in specific content areas. The proposed text would require six of the 30 units required of continuing education for a pharmacist renewal to be in specified content areas.

Proposal to Amend Section 1732.05 – Update Accreditation Agencies for Continuing Education

In May 2012, the board approved a draft regulatory proposal to modify Section 1732.05(a)(2) and to initiate a rulemaking. This proposal was at the request of the California Pharmacists Association, to reflect the restructuring of the Pharmacy Foundation of California and its transference of duties related to the provision of continuing education to the California Pharmacists Association.

Proposal to Add Section 1751.9 – Standards for Agencies that Accredit Sterile Injectable Compounding Pharmacies

In May 2012, the board approved for public notice a draft regulatory proposal from the Licensing Committee to add Section 1751.9 to Title 16 of the CCR for the purpose of specifying standards for agencies that accredit licensed sterile injectable compounding pharmacies.

Discussion:

Mr. Castellblanch inquired when the review of the prescription drug labels would begin.

Ms. Herold responded that the board had committed to begin the review in December of 2013, and the intent is that the Communication and Public Education Committee will undertake the review.

Dr. Gutierrez asked if the Continuing Education listed in 1732.5 were set in stone and asked if sterile compounding could be added to the list.

Mr. Steve Gray of Kaiser asked to clarify if the board's intent was to eliminate accreditation agencies for sterile injectable compounding pharmacies. Ms. Herold confirmed.

XI. ENFORCEMENT COMMITTEE REPORT

Report of the Meeting Held December 4, 2012.

Enforcement Committee Chair, Randy Kajioka referred the Committee Report as provided below.

Report:

Dr. Kajioka reported that during the December Enforcement Committee meeting, the board heard multiple very important presentations for the implementation of California's law.

During the committee meeting there was a two-hour presentation on a manufacturer to pharmacy track and trace pilot underway at the US Veterans Administration. This pilot involves the drug Humira, manufactured by Abbot Laboratories (in the future to be called AbVie), distributed through McKesson and data systems of Global Healthcare Exchange (GHX). There was considerable discussion on this pilot and the findings to date.

A presentation was also made by HP Labs on various types of technology in use worldwide for tracking and tracing, and a short demonstration of the ability of a cell phone to read bar codes, a system that could read the serialized numeric identifier on a product or case.

There was a presentation on RFID technology by Intelliflex, and a presentation by SmartRmeds on packaging technology that would facilitate aggregation and thus permit inference for downstream partners.

Discussion:

President Weisser noted that one of the presentations highlighted that you could use your cell phone as a barcode reader.

Dr. Kajioka commented that the use of simple technology such as cell phones should be considered to expedite the current 14 day turnaround time that is the current industry practice.

Ms. Veale commented that while simple technology can be used, there is still a question of security concerns.

Mr. Lippe provided that he and Ms. Wheat had the opportunity to take a tour of the CVS distribution center, and that they had learned about all that is involved with inference. He recommended that other board members take a tour to understand what is involved in the implementation of e-Pedigree.

Ms. Wheat added that the tour was very helpful to visualize the process.

Ms. Veale noted that she has taken a similar tour and she found that inference needs to be considered as part of the solution.

Ms. Herold provided that she could give the board members a list of available facilities to tour.

Report:

2. Elements for Possible Regulation Requirements to Permit Inference as Provided by California Business and Professions Code Section 4163.3.

On July 23, 2013 the board released a request for comments from interested parties on the need for inference. The solicitation request was developed by Deputy Attorney General Room and released via a subscriber alert, seeking comments from industry to gather the information the board needs to review to assess the conditions upon which inference may, or may not, be used. Provisions in Business and Professions Code section 4163.3 direct the board to balance the need for inference with the risks of permitting inference.

As explained by Deputy Attorney General Room, California statute requires every trade partner who owns the product to verify the product at the unit level. In the absence of action by the board to allow for inference, verification is required at the unit level. The board needs to have data to support what types of inference industry wants.

Initially 18 comments were received from interested parties by the initial due date of September 1, 2012. During the meeting on September 11, 2012, the committee discussed the comments received and Mr. Room emphasized that while grateful for the comments, we do not have the specificity needed to develop regulations. As such, the board released a second request for information on inference after the September Enforcement Committee Meeting. One additional comment has been received.

These comments and the specific notices seeking comments where provided in the meeting materials.

Since July, we have received comments from companies and associations representing:

- 9 manufacturers
- 5 wholesalers
- 3 pharmacies
- 1 standards setter
- 1 aggregate group of manufacturers, wholesalers, and pharmacies

At the December 2012 meeting, staff was asked to summarize the comments. These are the elements requested:

1. Identifying and contact information for the submitting person or entity.

2. A description of the submitting party's interest in this subject, including the submitting party's role, if any, in the supply chain (e.g., manufacturer, re-packager, distributor, or dispenser) or other basis for interest (e.g., vendor, consultant, standards body) and a brief description of the person, company, or other entity responsible for the submission.

3. If the submitting party is a supply chain participant, a detailed description of the means and methodology, including hardware and software specifications, processes, and data carrier(s), that the submitting party has deployed or intends to deploy to "verify and validate the delivery and receipt of dangerous drugs against [electronic] pedigrees at the unit level," including specification of the means and methodology for certification.

4. If the submitting party is seeking a regulatory allowance for inference, a specific request for same along with a detailed description of the particular circumstance(s) and/or those transaction(s) under which or pursuant to which there is a perceived need for inference. Define the requested inference(s) as specifically as possible, and where possible provide a limiting descriptor for such transaction(s) that could be used in regulatory language. In addition, provide as much data as possible regarding the factual circumstance(s) and/or transaction(s) in question, including the number and percentage of transaction(s) to which such an inference might apply, both with regard to the submitting party and in the supply chain as a whole, and any trading partners that will be involved in the inference(s).

5. If the submitting party is opposed to a regulatory allowance for inference, either generally or with regard to particular circumstances/transactions, a detailed description of same that as closely as possible meets the requirements of item 4. above.

6. The detailed reason(s) that such an inference is necessary and/or advantageous, and either decreases risk(s) of diversion or counterfeiting (or other risk(s) in the supply chain), holds risk(s) constant, or does not unacceptably increase such risk(s). Or the detailed reason(s) any inference(s) is/are unnecessary, disadvantageous, or unacceptably increase(s) risk(s).

7. Proposed SOPs that incorporate and explain the use of the inference(s), and describe the proposed process for statistical sampling to ensure the accuracy of pedigree information.

8. A proposal for the allocation of any liability that may be incurred due to use of inference.

Discussion:

Dr. Kajioka noted that the Enforcement Committee had asked on at least two occasions for public comments to help with regulatory language, but had not received any. At the last meeting the committee asked for draft regulation language to be provided to use a starting point and hopefully encourage comments.

Report:

Provided below is a general summary of the responses:

Elements Requested:

- **Means and Methodology** to be used for e-pedigree: the few responders who responded specifically to this specific element (few actually did) stated that a line of sight read would be deployed, and most specifically mentioned 2-D bar code. Hardware and software specifications were not provided, nor was information submitted regarding certification. Multiple responders identified use of GS1 standards, although not all did.

- **Inference**: All 19 responders stated that inference is necessary; no responder identified inference as unnecessary.

  Cardinal states that based on one of its pilots: 70 percent of its cases were inferred upon receipt from the manufacturer, but 98 percent of the items were actually shipped by Cardinal as individual units – they explained it is because they tend to sell product in the smallest quantity possible (and instead do multiple deliveries each day).

  The Generic Pharmaceutical Association states that 75-90 percent of all cases it ships to a wholesaler are opened by the wholesaler at some point after receipt of a case by the wholesaler (or 10 -15 percent of the cases its members ship to a wholesaler are NOT opened by the wholesaler and shipped directly as an unopened case to the buyer (a pharmacy or pharmacy distribution center).

- **Detailed reasons for Inference:**
  The board received multiple reasons from responders, most lacking quantification, of why they needed inference. Most stated that opening each container to do line of sight reads of each saleable unit of a product would greatly increase the opportunity to expose products to possible diversion, eliminate covert and overt packaging by the manufacturer to protect products, permit adulteration and greatly slow the receipt and delivery of pharmaceuticals to downstream partners and patients.

- **Standard Operating Procedures:**
  Generally, no standard operating procedures were provided. At least two responders indicated they could not develop operating procedures until they routinely start receiving serialized product. Cardinal does discuss procedures on how it would ensure a manufacturer's product has been accurately aggregated.

- **Assessing Liability:**
  Again, the specific responses are not responsive to the level of information sought or hoped for by the board in seeking industry comments on liability. When a responder addressed this issue, manufacturers generally indicated that they could be responsible for the product until it reaches the wholesaler -- then it was no longer within their control. Wholesalers generally responded each trading partner must be responsible for the information the partner represents as true, and for consequences that result from false or erroneous information. Pharmacies stated liability has little usefulness in the area of inference, and pharmacies should not be held responsible for the mistakes of wholesalers and manufacturers. They requested implementation of the law first, and then the board should address the issue of liability in response to the problems that arise.

Discussion:

Ms. Herold drafted the elements for regulation. She noted that it is not in regulatory language and will be modified and provided at the next Enforcement Committee Meeting. The draft elements for regulation were provided by Ms. Herold as follows: a homogeneous case from the manufacturer that consists of the same product with the same NCD code can be inferred by the wholesaler if the manufacturer provides advanced notice of the serialized products linking the "eaches" to the box and if it goes further, the boxes to the case, the case to the pallet. There must be a business relationship between the manufacturer and the wholesaler for inbound inference to occur. If a case is opened by a wholesaler then the products inside the case would have to be scanned at the time the box was opened. If the case is shipped straight through, never being opened, then it can be shipped without scanning each unit. The allocation of liability if a pedigree does not match will have to be discussed further by the board, particularly when a case is shipped straight through without being opened. If a wholesaler discovers a problem with a case the wholesaler will have to resolve the issue with the manufacturer.

Mr. Lippe asked if a distributor, who only distributes to their own company would be considered a closed system.

Ms. Herold confirmed that it would be considered a closed system and they would not have to append the pedigree because there would be no change in ownership.

Ms. Veale commented that a lot of brand drugs go from the manufacturer to the wholesaler, then to the chain warehouse - while generic drugs do not go through the wholesaler.

Dr. Kajioka commented that at some point before it is dispensed a case will have to be broken down to the smallest sellable unit to be scanned to validate its pedigree.

Ms. Wheat asked if when a distribution center opened the case they would have to scan each individual unit and if when the retailer received the case they would *again* have to scan each unit.

Ms. Herold responded that if it was a chain retailer they would not have to rescan because it is a closed system, however they can choose to do so because it would provide them with a lot of information to manage their drug products.

Ms. Wheat asked when the change of ownership occurs.

Mr. Room answered that the change of ownership happens at the point the pharmacy's warehouse takes ownership of the product.

Mr. Room clarified that there are two inferences in what Ms. Herold had provided in the draft elements of regulation, and they both relate to homogeneous, sealed cases. The first is inbound inference -if anyone receives a homogeneous, unopened case they can infer upon receipt that case identifier accurately populates the database with the individual unit identifiers. The second inference is - if wholesalers and distributors want to move the unopened product along they can also rely on that inference. However, for both of the inferences there will have to be validation once the case is finally opened, by whoever opens it. If the inference is found to be incorrect when the case is finally opened, there will have to be standard operating procedures in place to correct the problem.

Dr. Kajioka commented that this ensures that at some point before a product has been dispensed to a patient it will have been scanned and the pedigree ensured.

Report:

b. FOR DISCUSSION AND POSSIBLE ACTION: US DEA Notice of Proposed Rulemaking Related to Disposal of Controlled Substances, and Opportunity for Comment

One of the causes mentioned for the growing incidence of prescription drug abuse is lack of appropriate methods for patients and others to dispose of unwanted or no longer needed prescription medication, specifically controlled substances. Existing law offers few options for proper disposal of controlled drugs.

Since 2008, the board has been working with various agencies on drug take back programs. Currently, California has guidelines for how these programs should work. These guidelines were developed through the work of multiple agencies. However, they are only guidelines; there are no requirements specified in law or regulation for drug take back programs.

Part of the complexity to adopting rules or specific requirements for drug take back programs was waiting for the federal Drug Enforcement Administration to determine how federal law should be amended to permit the return and destruction of unwanted controlled substances. In mid December 2012, after a number of years of waiting, the federal Drug Enforcement Administration released the long-awaited proposal for drug take back and disposal of controlled substances.

Given the high demand and street value of controlled substances, the growing number of prescription drug caused deaths, when coupled with the fact that the board regulates pharmacies and reverse distributors who would be permitted to establish prescription drug take back programs, staff believe that the board should provide comments regarding the provisions. Staff will seek the board's authorization to work with President Weisser on comments to this proposal based on California's current guidelines for disposal of unwanted pharmaceuticals.

Discussion:

Dr. Gutierrez asked how common it is for pharmacies to have take back services offered in their facility.

Dr. Kajioka answered that he believes there is a web site that provides a list of chains have the program.

Ms. Herold answered that outside of Marin County there are few facilities with the program.

Ms. Herold commented that the board is concerned about long term care facilities being allowed to have a drug take back program and that unless the drugs are pulverized there is a concern for drug diversion and abuse.

Dr. Kajioka commented that currently pharmacies are not allowed to take back controlled substances, only law enforcement agencies can do so.

Mr. Castellblanch asked when the comments are due to the DEA, and if they would have another opportunity to make additional comments.

Ms. Herold answered that all comments are due by February 19, 2013 and confirmed that the board would have other opportunities for input.

Mr. Steve Gray from Kaiser recommended that the board work with the Medical Board, Hospital Association and county government to create the comments.

MOTION: Allow the board president to work with board staff on developing and making comments on California's current guidelines for the DEA proposed rulemaking and ask for an extension on the due date to submit comments.

M/S: Kajioka/Law

Support: 10 Oppose: 0 Abstain: 0

c. FOR INFORMATION: Future Meeting Dates Proposed for the Enforcement Committee

March 14, 2013 – Southern California
June 4, 2013
September 10, 2013
December 3, 2013

d. FOR INFORMATION: Enforcement Statistics

Dr. Kajioka referenced the Enforcement Statistics attachment provided in the board meeting packet. No public or board comment was provided.

e. FOR INFORMATION: Second Quarterly Report on the Committee's Goals

Dr. Kajioka referenced the Quarterly Report attachment provided in the board meeting packet. No public or board comment was provided.

The board recessed for a lunch break at 1:04 p.m. and reconvened at 2:03 p.m.

XII. COMPOUNDING SUBCOMMITTE FORMATION AND UPDATE

Compounding Subcommittee Chair, Amy Gutierrez referred to the Committee Report as provided below.

Report:

Dr. Gutierrez reported that the board's public protection mandate specifies that protection of the public shall be the highest priority for the board in exercising its licensing, regulatory, and disciplinary functions.

Since the beginning of October 2012, the country has become aware of the dangers contaminated compounded medication pose to the public health.

In California, existing law requires either an additional specialty license issued by the board or specific accreditation for any pharmacy that compounds sterile injectable products within, or ships such products into, California. These statutory requirements were developed in 2001 following the deaths of three patients in the Bay Area who had received injections of contaminated compounded medication. Following this enactment, the board has developed regulations that sterile injectable compounding pharmacies must follow whether specially licensed with the board or whether accredited. The board has also developed regulation requirements for any pharmacy that does general compounding.

In June 2012, the board issued a cease and desist order to a California-licensed nonresident sterile injectable pharmacy located in Florida because it had shipped contaminated product into California. Issuing such a cease and desist order is an act authorized in the 2001 legislation. In October, the board issued another cease and desist order against the California-licensed New England Compounding Center once it was confirmed they had shipped potentially contaminated product into California and contaminated products into other states.

The more recent emergency involving the New England Compounding Center and the pharmacy in Florida that distributed contaminated sterile injectable product to California physician offices requires that the board reevaluate its regulation program in this area to ensure it provides optimal public protection.

Since late October 2012 the board has issued three additional cease and desists orders – two pharmacies, and one pharmacist for violations involving sterile injectable compounding.

During both the October and December 2012 board meetings, the board discussed these incidents where consumers were harmed because of compromised compounded drug product. The results of these discussions yielded both a legislative proposal that will be sponsored by the board this year as well as the creation of a new compounding subcommittee.

Since the last board meeting President Weisser appointed Dr. Gutierrez and Dr. Kajioka to serve on this committee. There has been no public meeting of this committee yet.

In early January 2013, Board Members Gutierrez and Kajioka discussed with staff topics for the subcommittee's review. During this meeting, the subcommittee members were updated on the status of board-sponsored legislation that will strengthen the board's regulation over pharmacies that compound sterile drug products. Subcommittee members requested that staff prepare a comparison of the

board's current regulations versus the compounding requirements of USP 797. In addition the subcommittee requested an analysis of the board's inspection findings of pharmacies that compound sterile injectable products as well as a comparison of the licensure requirements with other states. Work on these items is ongoing and should be completed in advance of the first public subcommittee meeting, which will be convened before the April, 2013 board meeting.

Also in mid December, Executive Officer Herold attended an FDA forum on compounding practices at the state level. Representatives from all 50 states were present and asked to provide comments on four inquiries regarding compounding; specifically:

- Given existing authorities and resources, are the states currently able to provide the needed oversight of pharmacy compounding and consumer protection?
- What should the federal role be in regulating higher-risk pharmacy compounding such as compounding high volumes of drugs for interstate distribution?
- Is there a way to rebalance federal and state participation in the regulations of pharmacy compounding that would better protect the public health? What strategies should be developed to further strengthen federal/state communications?
- Do you see a role for the states in enforcing a feral standard for "non-traditional" compounding? If so, what role? What factors would affect a decision by your state to take on such responsibility?

The board does not believe that FDA has released its response to the comments provided yet.

Discussion:

Mr. Castellblanch asked what outcomes the subcommittee anticipated seeing in the coming year.

Dr. Gutierrez answered that she expects to see the board re-evaluate the current standards, address the issue of out of state pharmacies that are compounding products and bringing them into California, to look for ways to strengthen our laws, and look to see how other states are moving forward.

Mr. Castellblanch asked if there was an agency they could work with to see how other states are addressing the problem.

Dr. Gutierrez responded that they would have to go state by state.

Mr. Room asked if the board had heard anything back from the senate regarding federal vs. state compounding laws.

Ms. Herold answered that the board had provided a report to the Senate, on all disciplinary actions the board had taken against compounders.

Ms. Herold commented that the board works with the FDA when it feels that a facility is manufacturing rather than compounding. However, often the FDA does not share the same concern as the board. The board is working towards strengthening its relationship with the FDA to improve consumer protection.

Ms. Herold provided that is was only luck that California escaped having deaths caused by sterile injectable compounded drugs. Therefore the board is moving forward with multiple items to prevent this from happening. One of the things the board did was create a list of sterile compounding pharmacies that the board suspected are doing a large volume of compounding. The board sent a group of inspectors to these facilities to conduct inspections and collect data which would be provided to the board by Dr. Jeff Smith.

Dr. Jeff Smith provided the board with a report on what was found during the survey of the 40 high volume sterile compounding pharmacies. The list was created through input from board inspectors and lists from accreditation agencies. The goal of the survey was to determine what kind of compounding was being done, at what volume, and if they where shipping products outside of California. Of the 40 facilities selected to be part of the survey only 35 could actually be surveyed due to various mitigating circumstances. The results of the survey are listed below.

- 29 facilities had sterile compounding licenses, 6 did not have a license but where accredited
- 30 facilities reported themselves to be USP 797 compliant
- 21 facilities conducted high risk compounding
- 13 facilities shipped products out of state
- 16 facilities compounded products that were not patient specific labeled
- 31 facilities did hood certification every 6 months
- 3 facilities did annual hood certification
- 1 facility did quarterly hood certification
- 21 facilities did viable air organism sampling
- 11 facilities did surface testing
- 10 facilities did fingertip testing
- 30 facilities did sterility testing
- 34 facilities did pyrogen testing
- 11 minor citations were issued
- 12 major citations were issued
- 1 cease and desist was issued
- 1 case was opened and sent directly to the Attorney General’s Office

Ms. Hackworth asked what some of the minor citations were issued for.

Dr. Smith answered minor citations were issued for things such as not having a self assessment for sterile compounding and not having documentation that every compounding employee had done a process validation.

Dr. Smith noted that the cease and desist and the AG case where both the result of a facility having more than 5 major issues, such as not doing any kind of testing on their products, not putting expiration dates on their products and not documenting expiration dates in their compounding records.

Mr. Lippe asked if any tainted products had been found.

Dr. Smith answered that products where not sent out for testing.

Dr. Gutierrez asked if either of the two facilities that had major violations were accredited.

Dr. Smith answered that one was accredited and one was a licensed sterile compounding pharmacy with the board.

Dr. Smith noted that data was collected on how many high risk products where compounded at each facility. The numbers ranged from the hundreds to the tens of thousands. One pharmacy compounded 19,000 doses of high risk product in a three month period and was licensed in about 40 other states.

President Weisser asked if some of the pharmacies visited during the survey should have been licensed as a manufacturer rather than a compounding pharmacy.

Dr. Smith answered that in his opinion, yes, but it is hard to make that distinction.

President Weisser asked what the first step would be when a facility that is possibly manufacturing is found.

Dr. Smith answered that a supervisor would be contacted and then the Food and Drug Branch would be contacted.

Ms. Herold noted that the board is perusing disciplinary action against three pharmacies the board believes are manufacturing.

Mr. Lippe asked what some of the high risk products where.

Dr. Smith answered that he did not know the products off the top of his head but there would be a lot of injectable, steroid products.

Dr. Gutierrez asked if more facilities would be inspected.

Ms. Herold answered that with the limited inspector staff the board is not able to conduct the routine inspections of pharmacies at the rate it would like.

Mr. Lippe asked if insurance companies required inspections of facilities and if the board could use those inspections.

Ms. Herold responded that she did not know what type of inspections insurance companies would require. She noted that when the board does routine inspections about 10% result in a case being opened.

President Weisser asked if the board could contract out for inspection services.

Ms. Sodergren answered that it would be difficult to have other organizations inspect up to the boards standards. Ms. Sodergren noted that based on the findings of the survey the board will be expanding the types of facilities inspected. Additionally the board will be partnering with the FDA to leverage their inspector staff more effectively.

Mr. Castellblanch asked if the findings of this survey would be provided in a written report with some commentary.

Ms. Herold answered that the statistics would be provided in the meeting minutes and would also be presented at the subcommittee meeting.

Ms. Herold commented that the reality is inspectors are not in pharmacies as often as the board would like. Ms. Herold asked Mr. Law when the last time his pharmacy was inspected. Mr. Law answered that it had been between five and eight years.

Dr. Gutierrez asked if there was a way to look at purchases made by a facility to determine if they where manufacturing high risk products.

Dr. Smith answered that purchasing reports can be requested from any wholesaler, however when a facility purchased directly from manufactures it makes it more difficult to obtain purchasing reports.

Ms. Herold commented, in response to President Weisser's earlier question, that if the board had the money to contract for inspectors they would, but currently there are not the resources to do so.

Ms. Shellans provided that contracting for inspectors could cause a conflict with the civil service act which requires state government agencies to first, hire a state worker and it could also cause problems when it comes to prosecution.

Mr. Lippe asked if the board could follow a model similar to the Accountancy Board and require all pharmacies to conduct, and pay for a review.

Ms. Herold responded that it may be something the board would like to consider in the future.

Dr. Gutierrez asked if the board had ever considered requiring pharmacies to submit the self assessment forms to the board for review, rather than just being kept at the pharmacies.

Mr. Ratcliff commented that the volume of paperwork that would be received by the board would make it very difficult.

Mr. Room added that perhaps the self assessment paper form could be converted into a web based form.

Dr. Gutierrez suggested that the data could then be searched for key areas that could indicate there may be a problem.

Ms. Herold asked Mr. Ratcliff if when inspectors go into pharmacies and review the self assessment forms, they ever find that a pharmacy has self reported that they are not in compliance.

Mr. Ratcliff confirmed that they do find pharmacies that indicate they are not compliant in a certain area. This leads to a discussion with the inspector about how to come into compliance and the creation of a plan to ensure they come into compliance.

Ms. Herold asked if they ever see a pharmacy indicate they are compliant in an area and upon inspection find that they are, in fact, not in compliance.

Mr. Ratcliff answered that inspectors will take the self assessment form, and observe the pharmacy's practices to confirm that they really are in compliance.

Dr. Gutierrez asked what the purpose of the self assessment form is if they are not being monitored by the board.

Ms. Herold answered that the form is to allow a pharmacy to self-inspect and to come into compliance with the law because board inspectors cannot come to inspect pharmacies often enough.

President Weisser asked Dr. Smith if he had anything else to add in regards to the agenda item.

Dr. Smith answered that he had been reviewing USP to see if there were any opportunities for the board to improve its regulations, and that in the future he would like to provide his findings.

Mr. Lee Worth, senior pharmacist for Medical's Integrity Unit, from the Department of Health Care Services commented that their field inspectors have seen more problems with compounding pharmacies recently and offered to partner with the board on this issue.

Ms. Mendez-Harper, from Prime Therapeutics and board member for the New Mexico Board of Pharmacy, commented that since the deaths related to sterile compounding Prime Therapeutics has been contacted by at least 10 states asking for their practices and asked if the California board had considered doing the same thing.

Ms. Herold commented that it would be the role of the committee to decide if the board would issue a questionnaire and if so, what would be asked.

XIII. CLOSED SESSION

Meeting adjourned to closed session at 2:45 p.m.

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

ADJOURNMENT FOR THE DAY

Wednesday, February 6, 2013

XIV. CLOSED SESSION

No closed session items.

CALL TO ORDER – RESUMPTION OF THE OPEN SESSION

President Weisser called the meeting to order at 9:32 a.m.

President Weisser conducted a roll call. Board members present were: Stanley C. Weisser, President; Randy Kajioka, PharmD; Vice President, Ramón Castellblanch, Public Member; Rosalyn Hackworth, Public Member; Deborah Veale, RPh; Greg Lippe, Public Member, Treasurer; Tappan Zee, Public Member; Amy Gutierrez, RPh; Victor Law, RPh; Shirley Wheat, Public Member.

XV. PETITION FOR EARLY TERMINATION OF PROBATION

The following petitioners where presented for early termination of probation:

a. **Gene Kim, RPH 43406**
b. **Wayne Fujitaki, RPH 31483**

XVI. PETITION FOR REINSTATEMENT

The following petitioners where presented for reinstatement:

a. Renee Voshake, RPH 45674

XVII. CLOSED SESSION

President Weisser adjourned the meeting to closed session at 1:02 p.m.

Pursuant to Government Code Section 11126(c)(3), the Board Will Convene in Closed Session to Deliberate on the Petitions for Early Termination of Probation and to Deliberate on Disciplinary Matters.

ADJOURNMENT

The meeting was adjourned at 1:51 p.m.