



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
LICENSING COMMITTEE MEETING
MINUTES**

DATE: December 14, 2011

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

COMMITTEE MEMBERS

PRESENT: Greg Lippe, Public Member, Chair
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

COMMITTEE MEMBERS

NOT PRESENT: Ryan Brooks, Public Member

STAFF

PRESENT: Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Greg Lippe called the meeting to order at 9:39 a.m.

Chair Lippe conducted a roll call. Board Members Hackworth and Veale were present.

Board President Stan Weisser was in attendance in the audience.

1. **Update on Survey Results on Manpower Assessment Data Collected from the Board's Website as Required by the Office of Statewide Health Planning and Development**

Report

Chair Lippe provided that after the October 2011 Board Meeting, the board placed online a survey to encourage submission of data to the California Office of Statewide

Health Planning and Development. He stated that this agency is the state's center for collection, analysis and distribution of data describing healthcare workforce employment and education.

Chair Lippe provided that a subscriber alert was sent out after this survey was added to the website, and 875 people have responded to date.

Chair Lippe advised that board staff have shared this data with the Office of Statewide Health Planning and Development.

Chair Lippe referenced the early survey results provided in the meeting materials.

There was no committee discussion or public comment.

2. Presentation by TCGRx on a Remote Tablet Packager

Presentation

James Spernow, representing TCGRx, provided a presentation on remote tablet packaging technology. Mr. Spernow reviewed capabilities of the automatic tablet packager (ATP) which facilitates the automation and verification of both unit and multi-dose packaging to be dispensed to patients in skilled nursing facilities.

Mr. Spernow discussed that although the ATP is housed inside the skilled nursing facility, the medication dispensed by the ATP is owned, controlled and managed by the pharmacy. He stated that the pharmacy is responsible for filling the canisters that will be loaded into the machine with medication and stated that a nurse and a second representative from the facility will load the canisters into the machine. Mr. Spernow reviewed safeguards, including the use of barcodes, to ensure accuracy and reduce risks such as diversion.

Mr. Spernow reviewed the packaging and labeling of the medication dispensed by the ATP and advised that the pharmacy will ensure that the medication is labeled to comply with the patient-centered requirements with the use of an auxiliary label.

Discussion

The committee discussed the ATP technology in light of pharmacy law. It was clarified that any medication that may go home with the patient must be labeled according to the patient-centered label requirements pursuant to California Code of Regulations section 1707.5.

Ms. Herold provided that if operated in California, the system must be in compliance with Business and Professions Code section 4119.1 which allows for the use of automated dispensing machines in health facilities and additional sections in the Health and Safety Code.

No public comment was provided.

Agenda items 3 and 4 were taken out of order.

4. Discussion Regarding Requests for Approval by the Board as Accreditation Agencies for Licensed Sterile Injectable Compounding Pharmacies

Discussion

Ms. Herold discussed that regulatory change is needed in order to establish specific standards for all accreditation agencies (e.g., pharmacist surveyors, annual inspections, sharing reports with the board). She stated that this process would take a minimum of one year before regulations could be in effect.

In addition to developing standards for board-approved accreditation agencies, Ms. Herold provided that the board is reviewing requests submitted by the Pharmacy Compounding Accreditation Board (PCAB) and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) to become board-approved accrediting agencies for sterile injectable compounding pharmacies. She stated that the committee may offer a recommendation to the board to approve a tentative approval at the January 2012 Board Meeting. Meanwhile, the board can work to establish standards in regulation.

Supervising Inspector Janice Dang introduced Michael Zarski and Andrew Lowe, representing HFAP, and Joe Cabaleiro, representing PCAB. She discussed that the committee and the board has reviewed the results of her evaluation of the applications submitted by the two agencies as well as the outcome of her inspections of pharmacies accredited by these two agencies.

Dr. Dang discussed that the board has requested clarification to secure that:

- Survey teams will include a pharmacist.
- An approved agency will agree to provide the board access to its accreditation reports.
- An approved agency will agree to conduct an annual inspection of each pharmacy.

Dr. Dang provided an overview of each agency's responses to these concerns as detailed in the comparison chart provided in the meeting materials.

Ms. Shellans advised that pursuant to Section 4127.1 and 4127.2, the board is required to recognize JACHO as an accreditation agency. She indicated that the board has discretion with respect to approval and the establishment of different standards for the other recognized agencies.

Ms. Herold discussed that although the board cannot establish standards for JACHO, certain standards can be recommended. She stated that the board can seek legislative

change in the event the board identifies significant deficiencies with pharmacies accredited by JACHO.

Ms. Veale suggested that the board annually request that each accreditation agency provide a list of the pharmacies that it accredits as well as copies of accreditation reports.

Chair Lippe offered support for Ms. Veale's suggestion.

It was the consensus of the committee that the responses provided by PCAB and HFAP regarding the board's concerns were acceptable.

Ms. Herold provided that the accreditation agencies currently recognized by the board were approved for three years. She stated that approving PCAB and HFAP for two years would put all accreditation agencies on the same track for reconsideration.

Ms. Shellans advised that the board should consider conditions on approval to address the changes pursuant to the board's intent to pursue regulatory change to establish standards for accreditation agencies. She recommended that the regulation address agencies that are currently recognized with respect to grandfathering, etc.

Ms. Veale offered a proposal to recommend to the board to approve PCAB and HFAP as accreditation agencies for two years.

Public Comment

A member of the public sought clarification regarding licensure requirements for pharmacies that are accredited by an agency recognized by the board.

Ms. Sodergren provided that a pharmacy that is accredited by an agency recognized by the board would not need to maintain its sterile injectable compounding license with the board.

Mr. Cabaleiro provided that PCAB has approved random surveys of five percent of the pharmacies that it accredits.

MOTION: Recommend that the board approve the Pharmacy Compounding Accreditation Board (PCAB) and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) as accreditation agencies for two years.

M/S: Veale/Hackworth

Support: 3 Oppose: 0 Abstain: 0

3. **Review and Discussion to Develop Regulation Requirements to Specify Standards for Agencies that Accredite Licensed Sterile Injectable Compounding Pharmacies (Proposed as 16 California Code of Regulations Section 1751.9)**

Report

Chair Lippe provided that California Business and Professions Code section 4127 et seq. establishes a specialized category of pharmacy licensure for pharmacies that are: 1. already licensed pharmacies, and 2. compound injectable sterile drug products. He stated that these specialized pharmacies may be either hospital pharmacies or community pharmacies. Chair Lippe advised that as a condition of licensure, these pharmacies must be inspected by the board before initial licensure and each year before renewal of the license. He indicated that this is the only category of board licensure that requires annual inspections as a condition of renewal.

Chair Lippe provided that there is an exemption in existing law from this specialty category of board licensure for pharmacies if:

the pharmacy is licensed by the board or the Department of Public Health

AND

the pharmacy is currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Discussion

Ms. Herold provided that staff has developed the following draft language of proposed regulations designed to clarify Business and Professions Code section 4127.1 based on previously proposed regulation language considered by the board and comments made during discussions on the approval of accreditation agencies over the last 18 months.

Board of Pharmacy Specific Language to Add Section 1751.9

Add Section 1751.9 to Division 17 of Title 16 of the California Code of Regulations to read as follows:

§1751.9 -Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1 or section 4127.2 shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least annually. Site inspections shall be conducted to ensure compliance with pharmacy law laws governing the compounding of sterile inject able products.

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standards-setting organizations.

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation. At least one member of the survey team must be a licensed pharmacist. All surveyors must maintain appropriate and unrestricted licensure.

(4) The accrediting agency is recognized by at least one California healthcare payor (e.g., HMOs, PPOs, PBGH, CalPERS).

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

(b) An agency seeking recognition from the board must provide the board with the following information:

1. A comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding.
2. List of employees performing survey inspections.
3. List of payors agency is recognized by.
4. List of sites currently accredited by the agency.
5. Detailed description of the process used to evaluate sites seeking accreditation or reaccreditation.

(c) If an accreditation agency determines, as a result of its inspection, that a sterile injectable compounding pharmacy is not in compliance with the pharmacy law, the accreditation agency may do any of the following:

1. Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the accreditation.
2. Issue a reprimand.
3. Suspend or revoke the licensed sterile injectable compounding pharmacy's accreditation.
4. The accreditation agency shall, within 24 hours, report to the board any entity issued a reprimand or any entity whose accreditation has been suspended or revoked.

(d) The board shall consider the length of time the agency has been operating as an accrediting agency.

(e) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies for a three year period.

(f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months with a notation of the outcome of each inspection.

(g) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

(h) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for

continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

(i) The board may evaluate the performance of an approved accreditation agency and may rescind its approval of the accreditation agency if the board's evaluation finds noncompliance with the standards established in this section.

Ms. Shellans shared some concerns she has with the draft language. She stated that more detail is needed to clarify the application process. Ms. Shellans discussed that the details of the application process should be specified including whether a form is needed and what information should be submitted. She also discussed that the language needs to clarify what will happen to agencies that are currently recognized by the board.

Ms. Veale stated that she believes that these agencies should have to reapply and should not be grandfathered in.

Ms. Shellans provided that the board would have to specify when these agencies would have to reapply after the regulation is adopted.

Ms. Herold spoke in opposition to grandfathering. She said that the application process and establishment of standards is important and should apply to all agencies.

Ms. Veale suggested that the agencies apply within 60 days of the adoption of the regulation.

Ms. Shellans recommended that if an agency's approval expires before the regulation is adopted, the board can extend the current approval until the board renders a decision. She discussed that if an agency is denied, the board will need to determine when the approval ceases and what notice will be provided.

Ms. Veale recommended that approval immediately cease. She stated that the board can reassess this process if problems arise.

Ms. Shellans also expressed concern that the draft language does not establish an appeal process in the event an agency is denied by the board. She recommended that applications be approved by board staff and any appeals be brought to the full board. She stated that this will eliminate the need to convene a board meeting every time an application is submitted and in order to consider renewals.

Ms. Shellans provided that for licensing cases, agencies typically have 30 days to appeal the board's decision before it becomes final.

Ms. Sodergren provided that while developing the draft language, she was informed that due process does not necessarily apply in this case as a license is not being granted.

Ms. Shellans stated that subdivision (a) should be revised to specify the application process. She stated that either a form or formal request and required documentation needs to be specified within the regulation.

Ms. Herold and Ms. Sodergren recommended that a formal request be required rather than requiring a form within the regulation.

Ms. Shellans recommended that the language in subdivision (a)(1) cross-reference the sterile compounding regulations in California Code of Regulations sections 1735 and 1751.

Ms. Shellans provided that all relative law sections should be cited throughout the regulation.

Ms. Veale agreed and directed staff to modify the language to include all relevant citations.

Ms. Shellans provided that the regulation needs to specify the nationally recognized professional or standards-setting organizations referred to in the draft language.

Ms. Shellans sought clarification regarding the intent of subdivision (d) regarding the length of time an agency has been operating as an accrediting agency.

Ms. Herold discussed that a new agency has no track record and can be a risk to the board.

Ms. Shellans recommend that this be a required element of the application.

Ms. Sodergren suggested that the board establish a minimum length of time for this requirement if the board delegates initial application approval to staff.

Chair Lippe recommended that the board establish a one year minimum for this requirement.

Ms. Veale and Ms. Hackworth recommended that the minimum be two years with a client history.

The committee discussed the suggestion to have staff approve initial applications. Ms. Veale and Chair Lippe expressed concern regarding delegating this approval to staff.

Ms. Veale provided that staff can approve renewal applications.

Ms. Shellans suggested that the board ratify all initial applications approved by staff. The committee agreed to continue its discussion and review the draft language by subdivision.

Subdivisions (a) and (a)(1)

(a) Agencies seeking to become approved accrediting agencies for pharmacies that compound sterile injectable drugs pursuant to Business and Professions Code section 4127.1 or section 4127.2 shall provide evidence satisfactory to the board that:

(1) The accrediting agency performs site inspections and re-accreditation reviews of each accredited pharmacy at least annually. Site inspections shall be conducted to ensure compliance with pharmacy law laws governing the compounding of sterile injectable products.

Ms. Veale discussed that sterile injectable compounding licenses are inspected and renewed annually. She stated that this requirement for accreditation agencies would be consistent with the requirements for licensure by the board.

Chair Lippe provided that the standards for accreditation agencies should not be less stringent than the standards established for the board's licensees.

Ms. Herold clarified that this requirement is also applicable to non-resident pharmacies.

It was the consensus of the committee to maintain the language as drafted and to include the relevant law citations as previously directed.

Subdivision (a)(2)

(2) The standards for granting accreditation and scoring guidelines for those standards reflect California law and sound professional practice as established by nationally recognized professional or standards-setting organizations.

As previously advised by Ms. Shellans, the committee directed that the language be modified to specify the specific organizations.

Subdivision (a)(3)

(3) The surveyors who perform site inspections possess qualifications necessary to evaluate the professional practices subject to accreditation. At least one member of the survey team must be a licensed pharmacist. All surveyors must maintain appropriate and unrestricted licensure.

The committee discussed that it is appropriate to require that at least one member of the survey team be a licensed pharmacist. It was the consensus of the committee to maintain the language as drafted.

Subdivision (a)(4)

(4) The accrediting agency is recognized by at least one California healthcare payor (e.g., HMOs, PPOs, PBGH, CalPERS).

The committee discussed the intent of this requirement and questioned its inclusion as a requirement for the application process.

Dr. Dang provided that PCAB is recognized by organizations and not by a healthcare payor.

Public Comment

Paul Lofholm, representing PCAB, provided that, with exception of JACHO and CHAPS, he believes that there are no payors within the community practice setting that recognize any accreditation agency. He recommended that the board encourage this recognition but not require it. Mr. Lofholm suggested that the board contact payors to see whether they are interested before requiring such a requirement.

Mr. Lofholm provided that PCAB represents eight national organizations. He suggested that the American Society of Health System Pharmacists and the United States Pharmacopeia be added to subdivision (2). Mr. Lofholm referred to subdivision (a)(3) and indicated that he believes it is critical to include a pharmacist as a member of the survey team.

Chair Lippe recommended that subdivision (a)(4) be removed.

Ms. Sodergren indicated that subdivision (b)(3) also requires payor information on the application.

It was the consensus of the committee to strike subdivision (a)(4) from the draft language.

Subdivision (a)(5)

(5) The accrediting agency is able to accredit California and non-resident pharmacies.

Ms. Shellans sought clarification regarding the term “able” and asked whether this means the agency is physically capable or is authorized to accredit.

Ms. Herold clarified that the requirement ensures that the agency has sufficient personnel and resources to accredit California and non-resident pharmacies.

Ms. Veale expressed concern that the requirement is requiring agencies to accredit pharmacies outside of California.

Ms. Shellans discussed that it is important to ensure that the agency has adequate resources to perform the functions of an accreditation agency. She recommended that “and” be changed to “or.”

Ms. Sodergren provided that this provision was originally developed in 2003 as an equality issue to allow out of state pharmacies to realize the same privileges as California pharmacies.

It was the consensus of the committee to modify the language to read:

(5) The accrediting agency possesses sufficient personnel and resources to accredit California and non-resident pharmacies.

Ms. Herold provided that the term “sufficient” may need to be further clarified during the regulation process.

The committee skipped ahead to subdivisions (d) and (e) of the draft language.

Subdivisions (d) and (e)

(d) The board shall consider the length of time the agency has been operating as an accrediting agency.

(e) The board shall be able to obtain access to an approved accrediting agency's report on individual pharmacies for a three year period.

Ms. Veale recommended that subdivisions (d) and (e) be renumbered to subdivisions (a)(6) and (a)(7) respectively.

Ms. Shellans recommended that language be added to new subdivision (a)(7) to require that the report be provided to the board within 10 days after the board's request.

Dr. Dang provided that 10 days is a sufficient amount of time for this requirement.

It was the consensus of the committee to add language to new subdivision (a)(7) to require that the reports be provided to the board within 10 days after the board's request.

Subdivisions (b) and (b)(1)

(b) An agency seeking recognition from the board must provide the board with the following information:

1. A comparison of the agency's sterile compounding standards with each of the components of this article and other California law regarding sterile injectable compounding.

Ms. Sodergren provided that this section specifies components of the application. She stated that staff will revise the language to specify that applicants must include all essential information including company name and contact information, etc.

Ms. Shellans recommended that the term “recognition” be changed to “approval” in subdivision (b).

Subdivision (b)(2)

2. List of employees performing survey inspections.

Ms. Sodergren provided that this section will be amended to require name, title, and license status of the employees performing survey inspections.

Subdivision (b)(3)

3. List of payors agency is recognized by.

The committee discussed that the agency may or may not be recognized by a payor. It was the consensus of the committee to maintain the language as drafted.

Subdivision (b)(4)

4. List of sites currently accredited by the agency.

Ms. Sodergren suggested that this section be amended to include the name, location, and license number.

Subdivision (b)(5)

5. Detailed description of the process used to evaluate sites seeking accreditation or reaccreditation.

It was the consensus of the board to maintain the language as drafted.

Subdivision (c)

(c) If an accreditation agency determines, as a result of its inspection, that a sterile injectable compounding pharmacy is not in compliance with the pharmacy law, the accreditation agency may do any of the following:

1. Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the accreditation.
2. Issue a reprimand.
3. Suspend or revoke the licensed sterile injectable compounding pharmacy's accreditation.
4. The accreditation agency shall, within 24 hours, report to the board any entity issued a reprimand or any entity whose accreditation has been suspended or revoked.

Ms. Shellans expressed concern regarding this provision and stated that the board may not have this authority. She suggested that the language be amended to require that the agency establish standards for requiring correction.

Ms. Sodergren discussed that the language is intended to establish expectations for the accreditation agencies.

Ms. Shellans provided that it may be acceptable to set a performance standard that agencies have a process in place to address non-compliance that may include paragraphs 1-4 as listed in the draft language.

Ms. Herold suggested that subdivision (c)(4) be renumbered to new subdivision (d). She also suggested that subdivision (c) be amended to read:

(c) An approved accreditation agency has a process to address non-compliance that may include any or all of the following:

1. Require correction of any identified deficiencies within a set timeframe. Failure to comply shall result in the accrediting agency issuing a reprimand or suspending or revoking the accreditation.
2. Issue a reprimand.
3. Suspend or revoke the licensed sterile injectable compounding pharmacy's accreditation.
4. The accreditation agency shall, within 24 hours, report to the board any entity issued a reprimand or any entity whose accreditation has been suspended or revoked.

It was the consensus of the committee to approve the changes as suggested by Ms. Herold.

Subdivision (f)

(f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that have been accredited during the past 12 months with a notation of the outcome of each inspection.

Ms. Veale recommended that the report should list all current board-licensed facilities as well as board-licensed facilities that have been accredited during the past 12 months.

It was the consensus of the committee to amend subdivision (f) to read:

(f) On an annual basis, no later than July 1 of each year, an approved accrediting agency shall submit a report to the board listing all board-licensed facilities that are currently accredited and have been accredited during the past 12 months with a notation of the outcome of each inspection.

Subdivision (g)

(g) The board may conduct unannounced inspections of accredited sites to determine if the licensed facility is in compliance with California law and good professional practice.

Ms. Sodergren asked Ms. Shellans whether or not this language is needed.

Ms. Shellans indicated that she will evaluate the language and report back to the committee.

No changes were made to the language.

Subdivision (h)

(h) This approval shall be good for a period of three years. Three months before the end of the approval period, an approved accrediting agency must submit a reapplication to the board for continued recognition as an approved accrediting agency. The Board of Pharmacy shall take action on a completed application at a scheduled board meeting.

Ms. Shellans recommended that language regarding due process and details on reapplication be added to this section.

The committee again discussed the application approval process as well as a possible appeal process.

Ms. Shellans again recommended that applications be approved by board staff and any appeals be brought to the full board. She stated that this will eliminate the need to convene a board meeting every time an application is submitted.

Chair Lippe recommended that staff review all new applications and make a recommendation for board approval.

Ms. Sodergren discussed that applications will be denied when the minimum standards established by this regulation are not met. She stated that the board would not override a denied application that does not meet the minimum standards as established in the regulation.

Ms. Herold cautioned the board from establishing a licensing program. She stated that this is not the intent of this regulation.

Ms. Shellans discussed that staff typically review and approve these types of applications as the standards are established by the board in regulation.

Ms. Herold provided that staff can provide an annual report to the board on the approval statistics for accreditation agencies.

Ms. Veale provided that considering the importance of sterile compounding, initial applications that meet the standards should be forwarded to the board for approval. She stated that renewal applications can be approved by staff.

The committee agreed with Ms. Veale's comments.

Ms. Sodergren indicated that she will meet with Ms. Shellans to make the modifications to this subdivision as suggested by the committee.

Ms. Shellans provided that she will also work on development of an appeal process.

Subdivision (i)

- (i) The board may evaluate the performance of an approved accreditation agency and may rescind its approval of the accreditation agency if the board's evaluation finds noncompliance with the standards established in this section.

Ms. Shellans discussed that the regulations needs to specify how the board's approval of any agency can be rescinded. She stated that the only grounds for the approval to be rescinded in the current draft language is if the agency violates standards established in this particular section.

Ms. Herold suggested that the language be modified to clarify that the board may rescind its approval of the accreditation agency for failure to conform with California pharmacy law, standards, and specific relevant code sections.

The committee agreed and directed staff to make modifications to the draft language as discussed.

No public comment was provided.

MOTION: Direct staff to revise the draft language as discussed for committee consideration.

M/S: Veale/Hackworth

Support: 3 Oppose: 0 Abstain: 0

5. Discussion on a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Report

Chair Lippe provided that the committee has discussed at length a requirement for pharmacists to earn CE in specific subject areas. He stated that the committee is to evaluate and establish the specific subject areas to be recommended to the board.

Chair Lippe provided that Business and Professions Code section 4232 specifies the current content of courses that are acceptable include the following:

- Pharmacology
- Biochemistry
- Physiology
- Pharmaceutical chemistry
- Pharmacy Administration
- Pharmacy Jurisprudence
- Public health and communicable diseases
- Professional practice management
- Anatomy
- Histology

Chair Lippe provided that the committee has considered the following additional subject areas for the potential requirement:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse
- Defined Content Areas
- Certification in a pharmacist specialty by a accreditation agency

Chair Lippe provided that the committee has also heard comments about content specific course mandates and CE in general, and whether a portion of CE be obtained in a specific manner (e.g. live, web-based, journal, etc.).

Discussion

Ms. Shellans provided that she had previously recommended that the board pursue legislation in this area. She discussed that in light of the Governor's recent veto of a similar CE bill, she now recommends that the board pursue a regulation.

Chair Lippe suggested that the committee recommend that the board pursue a regulation to establish specific content areas for CE.

Ms. Veale suggested that the committee also discuss the amount of CE that can be awarded for attendance at meetings of the board. She recommended that the current amount of six hours per year be modified to three hours per year for attendance at board meetings. Ms. Veale also recommended that CE hours should not be offered for attendance at committee meetings.

Chair Lippe and Ms. Hackworth discussed that the current amount of six hours is appropriate considering the travel that may be required in order to attend a board meeting.

Ms. Veale offered a proposal to modify the current amount of CE awarded for board meeting attendance to six hours per renewal period. She stated that no CE credit will be offered for attendance at committee meetings.

Ms. Shellans sought clarification regarding the pending regulation change to California Code of Regulations section 1732.2 regarding board accredited continuing education.

Ms. Herold provided that there is currently a 90-day extension for this regulation change. She stated that the regulation is likely to die and the board will most likely have the opportunity to initiate a new rulemaking. Ms. Herold advised that more information will be available at the January 2012 Board Meeting.

Ms. Herold suggested that the proposed 6 hours of CE also be awarded to pharmacy technicians.

No public comment was provided.

MOTION: Modify the current amount of continuing education awarded to a pharmacist or pharmacy technician for attendance at a full day board meeting to six hours per renewal period. No continuing education credit will be offered for attendance at committee meetings.

M/S: Veale/Hackworth

Support: 3 Oppose: 0 Abstain: 0

The committee continued its discussion of specific content areas.

Ms. Veale offered a proposal to recommend that the board move forward with a rulemaking to require mandatory CE in specific content areas including the following:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse

Ms. Veale also proposed that the requirement specify that 6 hours of CE will be earned in one of the aforementioned areas per renewal period. She discussed that two 3-hour classes in one of these areas would satisfy this requirement.

Public Comment

A member of the public spoke in opposition to the proposal. He discussed that this requirement may not necessarily meet the needs of pharmacists. He recommended that the board ensure that there are available CE courses in these specified areas. He also discussed that he believes that the California Pharmacists Association (CPhA) does not support requiring CE in specific areas.

The committee discussed that the proposed content areas are applicable to pharmacists in all practice settings and also address many of the issues concerning the board's discipline cases. It was also discussed that course providers will create courses in this area to meet the demand for this new requirement.

MOTION: Recommend that the board move forward with a rulemaking to require six hours of mandatory CE per renewal period in the following specific content areas:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Ethics
- Drug Abuse

M/S: Veale/Hackworth

Support: 3 Oppose: 0 Abstain: 0

6. **Discussion on Implementation of AB 2699 (Bass, Chapter 270, Statutes of 2010) on the Board of Pharmacy and Discussion to Develop Regulations Requirements**

Report

Chair Lippe provided that Business and Professions Code section 901 provides the statutory framework for health care offering free care to uninsured or underinsured individuals. He stated that included in this authority is the ability for health care practitioners licensed in another state to provide services in CA for such events. Chair Lippe advised that these provisions were incorporated into SB 2699 (Bass, Chapter 270, Statutes of 2010) and took effect January 1, 2011. He provided that the provisions will sunset January 1, 2014, unless a later enacted statute extends this section. He stated that while it appeared initially that pharmacists would not be participating in such events, recent information received indicates otherwise.

Chair Lippe provided that the statute only provides the statutory framework. He stated that for these provisions to be fully implemented, the board must adopt regulations to define the parameters under which a pharmacist licensed in another state can participate in these health care events.

Discussion

Ms. Shellans provided comment on some challenges with these provisions. She stated that the board will need to evaluate the scope of an out-of-state pharmacist's participation in health care events as dangerous drugs and controlled substances must be maintained in a licensed pharmacy.

Ms. Herold provided comment regarding a recent event that was brought to her attention in which students were asked to work in a dispensary at a health care event. She discussed that the board initially took the position that these new requirements do not affect the board's licensees. Ms. Herold recommended that the board now reconsider this position.

The committee further discussed this issue. Ms. Herold offered to speak to the Medical Board as well as the bill's author to obtain additional information for the committee.

Public Comment

Paul Lofholm, representing the Pharmacy Compounding Accreditation Board (PCAB), provided that he would assume that physicians brought the drugs to the event Ms. Herold discussed. He stated that this is a common practice wherein the students act as an agent of the physician. Mr. Lofholm recommended that Ms. Herold speak with the bill's author on this issue.

7. Competency Committee Report

Report

Chair Lippe provided that each Competency Committee workgroup met once in the fall of 2011 for examination development purposes. He stated that the workgroups will resume examination development meetings in 2012.

Chair Lippe provided that SB 541 (Price, Chapter 339, Statutes of 2011), authorizes the board to enter into an agreement with subject matter experts to assist in examination development. He advised that beginning in January 1, 2012, consistent with the department's plan for implementation of these provisions, the board will contract with each of the members of the examination committee. Chair Lippe stated that these contracts will ensure the board continues to have members on the committee to assist in all activities related to examination development.

There was no committee discussion or public comment.

8. Licensing Statistics

Chair Lippe referenced the licensing statistics provided in the meeting materials.

There was no committee discussion or public comment.

9. Public Comment for Items Not on the Agenda

No public comment was provided.

The meeting was adjourned at 12:41 p.m.