



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

Licensing Committee Report

Members:

Greg Lippe, Public Member, Chairperson

Ryan Brooks, Public Member

Rosalyn Hackworth, Public Member

Debbie Veale, PharmD

LICENSING COMMITTEE REPORT AND ACTION

Report of the Meeting Held December 14, 2011.

- a. **FOR DISCUSSION and POSSIBLE ACTION: Review of Requests and Possible Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies**

Attachment 1

Relevant Statutes

California Business and Professions Code section 4127.1 establishes a specialized category of pharmacy licensure for pharmacies that compound injectable sterile drug products and sets forth the requirements for licensure including:

1. Licensure as a pharmacy
2. Inspection by the board prior to issuance of a license and prior to renewal of a license

B&PC Section 4127.1(d) creates 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
- currently accredited by the Joint Commission on Accreditation of Healthcare Organizations or other private accreditation agencies approved by the board.

Note: an exemption from the specialty license does not exempt the pharmacy from complying with all board laws and regulations surrounding the compounding of sterile injectable products. Rather, such entities must comply with all CA laws, including the compounding regulations established by the board in 2010.

Consistent with the statute, the board has approved three accreditation agencies:

1. Accreditation Commission for Health Care, Inc (ACHC)
2. Community Health Accreditation Program (CHAP)
3. Det Norske Veritas (DNV).

Background

During the September 26, 2011 meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and representative from Pharmacy Compounding Accreditation Board (PCAB). Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Both organizations were asked to respond to the following requirements:

Survey teams will include a pharmacist.

- HFAP would need to restructure its survey teams to include a pharmacist.
- PCAB surveyor teams consist of all pharmacists.

Agency agrees to provide the board access to accreditation reports.

- HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.
- PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Agency agrees to conduct an annual inspection of each pharmacy.

- HFAP will conduct annual inspections if required by the board but routine inspections will impact efficiency and lead to additional costs for the pharmacies.
- PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

The committee requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

During the October 2011 Board Meeting, the board discussed the requests and committee recommendations. The board did not take action on this item; however it was the consensus of the board that this issue be referred back to the committee for further evaluation and consideration of requirements for accreditation agencies.

Committee Discussion

The committee discussed the requests and the results of the evaluation conducted by Supervising Inspector Dang as well as the appropriate duration of approval should the board approve the agencies. The committee determined that a two year approval is appropriate to put these agencies on the same track for reconsideration as the other three agencies.

A copy of the results of the surveys conducted by Supervising Inspector Dang as well as the information submitted by HFAP and PCAB is provided in **Attachment 1**.

Committee Recommendations

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

b. Discussion: Update on Survey Results on Manpower Assessment Data Collected from the Board's Web site as Required by the Office of Statewide Health Planning and Development

Attachment 2

Background

As part of Senate Bill 139 (Chapter 522, Statutes of 2007) the Office of Statewide Health Planning and Development (OSHPD) was directed to establish the California Healthcare Workforce Clearinghouse (Clearinghouse) to serve as the central source for collection, analysis, and distribution of information on the healthcare workforce employment and educational data trends for the state.

Specifically the bill included a provision that OSHPD work with the Employment Development Department's Labor Market Information Division, state licensing boards, and state higher education entities to collect, to the extent available, all of the following data:

- (a) The current supply of health care workers, by specialty.
- (b) The geographical distribution of health care workers, by specialty.
- (c) The diversity of the health care workforce, by specialty, including, but not necessarily limited to, data on race, ethnicity, and languages spoken.
- (d) The current and forecasted demand for health care workers, by specialty.
- (e) The educational capacity to produce trained, certified, and licensed health care workers, by specialty and by geographical distribution, including, but not necessarily limited to, the number of educational slots, the number of enrollments, the attrition rate, and wait time to enter the program of study.

DCA has been encouraging all boards to collect the necessary information to assist OSHPD in their charge to, among other items, serve as the repository for comprehensive data and standardize data collection tools and methods. In addition, as part of the board's Sunset Report, the board needs to discuss its efforts to collect the information and provide it to OSHPD.

As the board has neither a statutory or regulatory mandate to collect this data, nor are licensees required to provide this information as a condition of licensure or renewal, implementation efforts are limited. Previously members were advised that the department was working with OSHPD on the development of a survey and that the board could provide a link via our website; however, board staff was later advised that the department is no longer moving towards such implementation.

Recent Update

After the October Board Meeting, the board placed online a survey to encourage submission of data. A subscriber alert was sent out after this survey was added to the website, and 897 people have responded to date.

Board staff is working with OSHPD on the appropriate means to share this information.

For your information **Attachment 2** contains the early results obtained from the survey.

The survey can be accessed by going to www.pharmacy.ca.gov and clicking on information for “Licensees.” The manpower survey is listed there.

c. FOR INFORMATION: Summary of a Presentation to the Committee by TCGRx on a Remote Tablet Packager

Presentation

James Spernow, representing TCGRx, provided a presentation to the committee on remote tablet packaging technology. Mr. Spernow reviewed the 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 labels are configurable to comply with California’s labeling requirements.

Committee 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. The committee was advised that if the system operated in California, it must be done in compliance with Business and Professions Code section 4119.1, which allows for the use of automated dispensing machines in health facilities.

d. FOR INFORMATION: Summary of 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)

Relevant Statutes

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. These specialized pharmacies may be either hospital pharmacies or community pharmacies. As a condition of licensure, these pharmacies must be

inspected by the board before initial licensure and each year before renewal of the license. This is the only category of board licensure that requires annual inspections as a condition of renewal.

However, 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.

Background

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors. Provided below is the general criteria the board initially established in 2003.

1. **Periodic inspection** -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** -The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** -The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payers** -Recognition of the accrediting agency by major California payers (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** -The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

Over the past two years the board has reviewed and approved several new accreditation agencies. During the course of its discussion and evaluation, the board has expressed some hesitation in the approval of accreditation agencies that do not incorporate the following items:

1. A pharmacist as a member of the survey team
2. Perform annual inspections

3. Willingness to share information with the board on findings
4. Ensuring conformance with California's requirements for LSCs

To facilitate implementation of these requirements, regulation language needs to be approved and ultimately adopted by the board.

Committee Discussion

The committee discussed the draft language provided as well as comments made by committee members, staff, and counsel. In addition the committee discussed the process for implementing the regulations once approved by the board and if current agencies should be grandfathered in. Several changes were requested to the current draft of regulation. The committee requested that the changes be incorporated and brought back to the committee for additional consideration and possible action.

e. FOR DISCUSSION and POSSIBLE ACTION: Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Relevant Statutes

Business and Professions Code section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Business and Professions Code section 4232 specifies that content of courses that will be acceptable including the following:

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

Background

For some months at meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn CE in specific subject matter areas. To establish such a requirement would take either a legislative or regulation change.

Prior discussions have included possible mandatory CE in emergency/disaster response, patient consultation, drug abuse or in maintaining control of a pharmacy's drug inventory. Any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

During the October 2011 Board Meeting, the board directed the committee to continue its discussion about such a requirement and specified that if the recommendation is approved, to authorize staff to investigate implementation.

Committee Discussion

During the meeting the committee spoke generally about the board's current policy to award continuing education for attending board and committee meetings. In addition, the committee discussed the proposal to require continuing education in specific content areas.

Committee Recommendations

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.

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

f. **FOR INFORMATION: Implementation of AB 2699 (Bass, Chapter 270, Statutes of 2010) on the Board of Pharmacy and Discussion to Develop Regulation Requirements**

Attachment 3

Relevant Statutes

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

Committee Discussion

The committee discussed some of the challenges including 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. Additional information will be obtained about the intent of the legislation and the role board licensees would have at such events. This additional information will be brought back to the committee for future discussion and possible action. The committee did not take action on this item.

Attachment 3 contains a copy of the legislation.

g. FOR DISCUSSION: Competency Committee Report

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

The board instituted a quality assurance review of the CPJE effective December 1, 2011. This process is done periodically to ensure the reliability of the examination. On January 4, 2012, the quality assurance review was removed and results have been released.

Examination Development

Competency Committee workgroup will continue to meet in the spring of 2012 for examination development.

Also, 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. 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. These contracts will ensure the board continues to have members on the committee to assist in all activities related to examination development.

h. FOR INFORMATION: Licensing Statistics

Attachment 4

Attachment 4 includes the licensing statistics for the second quarter of 2011/12.

i. FOR INFORMATION: Workload and Processing Statistics

As we continue to fill vacant positions, we anticipate a reduction in processing times. During the meeting board members will be provided with the current processing times for various license applications. We will continue to document our progress in reducing backlogs and processing times.

j. FOR INFORMATION: Minutes of the Meeting Held December 14, 2011

Attachment 5

Attachment 5 contains the minutes from the meeting.

k. FOR INFORMATION: Second Quarterly Report on the Committee's Goals for 2011/12

Attachment 6

The second quarterly report on the Licensing Committee's goals is provided at the back of the tab section in **Attachment 6**.

New Licensing Committee Items Not Discussed During the December 14, 2011 Meeting

I. FOR INFORMATION and POSSIBLE ACTION: Discussion on Implementation of AB 1424 (Perea, Chapter 455, Statutes of 2011) Regarding Franchise Tax Board and New Requirements for Denying or Suspending a Licensing for Delinquent Tax Debt

Attachment 7

Background

This bill requires the State Board of Equalization and the Franchise Tax Board to each make available a list of the 500 largest tax delinquencies described above at least twice each calendar year. This bill requires the Franchise Tax Board to include additional information on the list with respect to each delinquency, including the type, status, and license number of any occupational or professional license held by the person or persons liable for payment of the tax and the names and titles of the principal officers of the person liable for payment of the tax if that person is a limited liability company or corporation. This bill specifies that a license may be suspended for failure to pay tax delinquencies.

Implementation Efforts

The bill included notice requirements advising applicants and licensees of these provisions. As of December 31, 2011, the below language was inserted into all the board's site and individual initial and renewal applications on the board's web site with the exception of the pharmacy technician initial application, which has a separate notice between the instructions and the first page of the application. This language is also included as an insert to the renewal application mailed to all licensees.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

For Action

The pharmacy technician application is incorporated by reference into California Code of Regulation section 1793.5. To include the above notice in the application, a Section 100 regulation change must be pursued.

The proposed language and amended application form are provided in **Attachment 7**.

m. FOR DISCUSSION: Selection of Meeting Dates for 2012.

Committee members are encouraged to be prepared to set committee dates for the remainder of 2012. Below are proposed dates for committee consideration.

- April 16, 17 or 19, 2012
- July 12 or 13, 2012
- November 27, 28, or 29, 2012



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

December 9, 2011

To: Members, Licensing Committee

Subject: Agenda Item 4: Review of Requests for Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies

Earlier this year, the board received requests from two additional organizations seeking to become board-approved accrediting agencies for sterile injectable compounding pharmacies. The two agencies are the Pharmacy Compounding Accreditation Board (PCAB) and the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP). These applications were reviewed at the September Licensing Committee Meeting, and brought to the October Board Meeting with a recommendation from the committee to approve their applications.

However, during discussion at the board meeting, the board focused on the need to develop stronger standards for all accrediting agencies instead.

Staff is bringing this request to the committee to evaluate whether the board will accept these two agencies as accreditation agencies provisionally, while the board establishes stronger standards for all accreditation agencies (e.g., pharmacist surveyors, annual inspections, sharing reports).

Representatives of both agencies will attend this meeting, as will Supervising Inspector Janice Dang.

Following this page is her comparison chart of the pharmacy inspections conducted of several pharmacies accredited by the board's approved accrediting agencies and those of pending PCAB and HFAP (**Attachment 4 a and b**).

EXCERPT FROM THE OCTOBER 2011 BOARD MEETING MINUTES

Mr. Lippe provided that during the Licensing Committee Meeting, the committee heard presentations from representatives of the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP) and representative from Pharmacy Compounding Accreditation Board (PCAB). He stated that Supervising Inspector Janice Dang provided the results of her evaluation of the applications submitted by the two agencies as well as the outcomes of her inspections of pharmacies accredited by these two agencies.

Mr. Lippe provided that both organizations were asked to respond to the following requirements:

Survey teams will include a pharmacist.

HFAP would need to restructure its survey teams to include a pharmacist.

PCAB surveyor teams consist of all pharmacists.

Will the Accreditation Agency agree to provide the board access to accreditation reports?

HFAP will report deficiencies, serious noncompliance and denial or withdrawals of accreditation to the board.

PCAB will notify the board regarding noncompliance and situations where a pharmacy's accreditation is denied or revoked.

Will the Accreditation Agency agree to conduct an annual inspection of each pharmacy?

HFAP will conduct annual inspections if required by the board but that routine inspections will impact efficiency and lead to additional costs for the pharmacies.

PCAB annual inspections would increase costs for accreditation and suggested that the board consider random inspection of ten percent of the pharmacies each year.

The board requested clarification regarding these requirements and the commitments agreed to by other accreditation agencies recognized by the board.

Mr. Lippe provided that board staff has prepared a comparison chart detailing the commitments by PCAB and HFAB and the accreditation agencies currently recognized by the board. He reviewed the following recommendations from the committee:

Recommend to the board to conditionally approve HFAP and PCAB as accreditation agencies pending confirmation that they meet the requirements of other accreditation agencies recognized by the board and the guidelines established for all accreditation agencies to follow at the October 2011 Board Meeting.

Discussion

Ms. Sodergren provided that the comparison chart was developed to ensure that HFAP and PCAB are not being subjected to additional requirements that are not also being required of the other accreditation agencies currently approved by the board.

Dr. Dang reviewed the comparison chart provided in the meeting materials. She also shared correspondence from HFAP regarding this matter which is also provided in the meeting materials.

Ms. Shellans provided comment regarding the requirements for the agencies and indicated that the board has discretion with respect to different standards for the agencies. She advised that pursuant to Section 4127.1 and 4127.2, the board is required to recognize JACHO an accreditation agency.

The board discussed the responses from each accreditation agency as well as the need for clear requirements for accreditation agencies.

Mr. Room provided that the board has statutory authority to approve or deny accreditation agencies. He stated that the board would need to pursue regulatory change to establish requirements for this approval.

It was the consensus of the board to refer this issue back to the committee for further evaluation and consideration of requirements for accreditation agencies.

The board took no action on the committee's recommendation.

Table 4b. Comparison of Approved Accreditation Organizations to PCAB and HFAP

Criteria	Accreditation Commission for Health Care Inc. (ACHC)	Community Health Accreditation Program (CHAP)	Det Norske Veritas (DNV)	The Joint Commission (TJC aka JCAHO)	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP)
Discussion of organization at licensing and board meetings	<p><u>Dec 2, 2010 Licensing Committee Meeting</u></p> <ul style="list-style-type: none"> • Tim Safley representing ACHC. • Dr. Dang indicated two pharmacies accredited by ACHC passed inspection. • Response to conducting random and unscheduled inspections: ACHC visits are unannounced. • Ms. Herold requested ACHC provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccruited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA. • Response to request for validation information: ACHC is certified by the International Organization for Standardization and agreed to provide this information to the board. • Response to how ACHC would respond if they received similar findings of pharmacies accredited by ACHC not in compliance as a result of an inspection by the BOP: ACHC would conduct an investigation to validate 	<p><u>Dec 2, 2010 Licensing Committee Meeting</u></p> <ul style="list-style-type: none"> • Terry Duncome representing CHAP. • Dr. Dang expressed concerns of pharmacies “ramp up” for the survey process after inspecting 2 pharmacies accredited by CHAP. • Response to conducting random and unscheduled inspection: CHAP does not conduct unannounced visits of facilities seeking exemption from licensure. • Response to concerns of board’s inspection of two pharmacies accredited by CHAP: Expressed results are a concern; requested information regarding the two pharmacies; discussed pharmacies with identified deficiencies must complete a plan of correction and are subject to a subsequent visit. She indicated the minimum number of visits for a facility is once every three years; but annual inspections may be necessary based on a facility’s performance. • Response to how many organizations CHAP accredits annually: CHAP accredits several hundred entities a year for all the 10 services accredited; accredits 13 pharmacies in CA. 	<p><u>June 16, 2010 Licensing Committee Meeting</u></p> <ul style="list-style-type: none"> • Patrick Horine representing DNV. • Mr. Horine provided an overview of DNV; indicated the national Integrated Accreditation for Healthcare Organization (NIAHO) standards are integrated requirements based on the CMS Conditions of Participation (CoPs) with the internationally recognized ISO 9001 Standards for the formation and implementation of the Quality Management System. The model standards are consistent with California pharmacy law. • Dr. Dang expressed concerns that the surveyors may not be adequately familiar with California pharmacy law and may not be compliant with the new compounding laws that will go into effect July 2010. <p><u>7/28/2010 Board Meeting</u></p> <ul style="list-style-type: none"> • DNV has indicated pharmacists will conduct the inspection if requested by the Board. 	<p><u>Oct 5, 2010 Licensing Committee Meeting</u></p> <ul style="list-style-type: none"> • Mark Crafton representing The Joint Commission. • Overview of process: a survey can be conducted in 4 to 6 weeks of opening on a new facility, but depends on nature of the change. • If service is being provided by a current accredited facility “original hospital” then the inspection would be completed as part of the next regular triennial survey. Also depend on the type of service being provided at the new site. • When asked if JCAHO may extend an accreditation to a new satellite pharmacy if the services provided were similar to the already accredited hospital without doing an inspection; the response was “YES.” • JCAHO indicated they now perform a periodic performance review similar to the board’s self-assessment program. The results are filed with JCAHO. • JCAHO completes a 5% random surveys annually as well as completes “for cause” survey where they believe the quality and safety is compromised. 	<p><u>Oct 18 and 19, 2011 Board Meeting;</u></p> <p>(Not discussed)</p>	<p><u>Oct 18 and 19, 2011 Board Meeting</u></p> <p>(Not discussed)</p>

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<p>whether the accreditation should be revoked; stated the pharmacy would be required to complete a plan of correction and the accreditation would be contingent on a follow-up inspection known as a “dependent survey.”</p> <ul style="list-style-type: none"> Ms. Veale asked if the board has the ability to provide investigation information to accreditation agencies. Ms. Shellan advised providing this information would make it public. Ms. Herold asked ACHC has been approved accreditation agencies in CA since 2003, why has neither agency reported a substandard report to the board. Response: ACHC responded pharmacies are given 30 days to come into compliance; pharmacies found to be deficient with a state regulation will be reported to the board immediately. Ms. Herold asked minor violations were found with the 2 pharmacies inspected by the board, how will ACHC ensure compliance in these areas. Response: A plan of correction is required for minor violations; pharmacies will be placed on a “dependant status” for more significant violations and will be subject to a focus visit. Any pharmacy requiring a second or third visit for a compliance issue will most likely be placed on revocation status. 	<ul style="list-style-type: none"> Response to if CHAP has identified critical finding in the past that have jeopardized licensure: Findings are not typical of the pharmacy program; indicated CHAP accredits 467 pharmacies in the U.S. Ms. Herold asked for statistics regarding the amount of provisional statuses issued as well as decline rates within the past 5 years. Ms. Duncome discussed a deferred status indicates a facility has deficiencies that must be corrected prior to accreditation; accreditation can be denied or withdrawn; denial rates for CHAP accreditation are increasing. Ms. Herold requested CHAP provide information to the board by 1/10/11 regarding how many sterile injectable compounding pharmacies have been accredited, reaccredited, placed on provisional status, withdrawn and denied within the last 5 years. The numbers to reflect both national and CA statistics and include nonresident pharmacies that are shipping into CA. Response to if the board’s findings will initiate a review of other CA pharmacies accredited by CHAP: CHAP will be requiring that all CA pharmacies be reviewed. Ms. Duncome provided this is the first occurrence during her nine years as president of CHAP; advised CHAP has o deficiencies upon validation visits by CMS 	<ul style="list-style-type: none"> DNV would comply with the requirement of having a pharmacist surveyor and would expect this requirement be imposed on the other agencies. All accreditation teams will include a physician or nurse as well as a “generalist” which could be a pharmacist. Approved Det Norske Veritas to serve as an accreditation agency for three years. 	<ul style="list-style-type: none"> Ms. Herold inquired if the committee felt a pharmacist should participate in the JCAHO survey. Committee discussed and was in support of this requirement. Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not, then the best candidate should complete the survey. Vote: Support. <p><u>Oct 20 and 21, 2010 Board Meeting:</u></p> <ul style="list-style-type: none"> Discussed concerns regarding no pharmacist on survey team. Response: given the large number of entities JCAHO accredits, it would be a challenge to have pharmacist in all surveys. Will try to include a pharmacist when possible. Committee recommendation was to request pharmacist participate in the surveys when possible and if not, the next best candidate should complete the survey. Response by JCAHO: Best candidate would be a registered nurse with infusion therapy experience who has been trained by a pharmacist on the JCAHO standards and has been evaluated for competency of these standards. 		

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> • Motion: Recommend to the board ACHC be reapproved as accreditation agency for three years pending receipt of the requested information. • Vote: Support <p><u>Feb 1 and 2, 2011 Public Board Meeting</u></p> <ul style="list-style-type: none"> • Dr. Dang indicated ACHC submitted the information regarding the number of pharmacies accredited in CA and the U.S. but the information did not specify which pharmacies were compounding pharmacies and specialty pharmacies. • Dr. Dang discussed concerns regarding pharmacies “ramp up” their standard for the accreditation process (survey) and pharmacies licensed in CA for sterile compounding are subjected to annual inspections. • Response to whether ACHC utilizes pharmacists as part of the survey team: ACHC provided all surveys of a pharmacy are done by a pharmacist.; the program includes four pharmacy services including 1)infusion pharmacy, 2) ambulatory infusion center, 3) infusion nursing services, and 4) specialty pharmacy. 	<ul style="list-style-type: none"> • Ms. Duncome provided pharmacies will be placed on a warning status if deficiencies are not corrected by the second visit; accreditation will be revoked if the correction is not made by the third visit; explained the initial accreditation will be denied if deficiencies identified during the initial review are not corrected by the second visit. • Motion: Recommend to the board to reapproved CHAP as accreditation agencies for three years pending receipt of the requested information. • Vote: Support <p><u>Feb 1 and 2, 2011 Public Board Meeting</u></p> <ul style="list-style-type: none"> • ACHC indicated all pharmacies are surveyed by a pharmacist. • Dr. Dang highlighted the two CHAP accredited pharmacies had several areas of noncompliance and appeared to “ramp up” their standards for the accreditation process. • Ms. Duncombe provided that CHAP has submitte copies of reports for the last CHAP surveys of the pharmacies assessed by the board. Both pharmacies were required to complete plan of corrections for deficiencies and were subject to follow up visits. Ms. Duncombe advised CHAP accredited pharmacies are always subject to follow up visits within the 3 year accreditation period. 		<ul style="list-style-type: none"> • Response to type of pharmacist surveyors: consist of 6 pharmacist consisting of both community and hospital pharmacist, all with knowledge on infusion therapy. • Response to concerns not having a commitment to have a pharmacist survey: JCAHO can prioritize that community based pharmacies have a pharmacist surveyor; however it is unlikely for the surveying hospitals. • Response to comparing survey results when a pharmacist is on the survey team and when a pharmacist is not on the team: No analysis available. Info can be provided to the Board. • Response to is it typical to have a licensed sterile injectable compounding area in the hospital surveyed: Is dependent on the size and complexity of the services of the hospital. • Response to whether surveyors are aware they will be surveying for a specific function prior to the inspection: Surveyors will not know this; the application does not require the entity disclose the depth and breadth of their pharmacy services. 		

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> • Response to whether there is a formal mechanism in the survey process to address issues and concerns: ACHC utilizes an investigative committee for both compliance and complaint issues. There is a mechanism in place for reporting to the board. • Response to whether ACHC has revoked accreditation: ACHC has revoked about 218 accreditations for all its services. The data regarding the reapplication of a revoked entity is not maintained. • Ms. Herold indicated the board should be notified of any complaints regarding the safety of drugs or the safety of the procedures being used by the accredited pharmacies. The board will work with ACHC to help facilitate this information. • ACHC requested they be notified regarding any complaints submitted to the board against an ACHC accredited pharmacy. • Response to whether ACHC is paid by the entities that it accredits: ACHC is paid by these entities. • Dr. Castellblanch discussed the board needs to be vigilant in the review of these pharmacies as they are paying for ACHC accreditation. 	<ul style="list-style-type: none"> • Dr. Castellblanch discussed the assessment results were alarming from the perspective of a non-pharmacist. • Mr. Badlani asked whether the accredited pharmacies are also licensed by the board. Ms. Herold provided that accredited pharmacies are required to follow CA pharmacy law, but are not required to have a special sterile compounding license. DA Room provided these accredited pharmacies do not have a special license in addition to their general pharmacy license. • Dr. Schell expressed concerns that these pharmacies should be visited again to ensure compliance. • Ms. Herold provided deficiencies regarding expiration dates and refrigeration would warrant a strong warning or citation. Egregious cases of noncompliance in this area would be referred to the Attorney General's office. • Dr. Castellblanch confirmed, if approved, the agencies will be re-evaluated for accreditation in 3 years. • Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised CHAP will have pharmacist on the surveying team which represents an enhancement of the current standard in this area. 		<ul style="list-style-type: none"> • Ms. Herold request board to require annual inspections for licensed sterile injectable compounding pharmacies because of the importance of having a pharmacist with adequate knowledge of sterile compounding involved in these inspections. EO offered to work with JCAHO to ensure its accredited facilities meet the board's requirements. • JCAHO indicated they monitor regulatory changes and request for notification regarding changes in California pharmacy law to ensure JCAHO surveyors are aware. • Ms. Veale recommend Licensing Committee revisit the issue of surveyors qualifications at its next meeting. • Response to whether JCAHO would be able to comply if the board required a pharmacist participate in every survey: JCAHO accredits a larger volume of organizations than others; it would make it difficult for JCAHO to comply. • Ms. Veale comment on all accrediting bodies, regardless of size, should adhere to the same requirements. 		

	(ACHC)	(CHAP)	(DNV)	(JCAHO)	(PCAB)	(HFAP)
	<ul style="list-style-type: none"> • Ms. Herold discussed the assessment of the two pharmacies accredited by ACHC were identified as minor corrections and no major areas of noncompliance. • Ms. Veale stated the committed felt comfortable that both agencies (ACHC and CHAP) had the right processes in place to ensure the standards were being met. Advised ACHC will have pharmacist on the surveying team which represents an enhancement of the current standard in this area. • Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period. • Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies. • Motion: Recommend to the board that ACHC be reapproved as accreditation agencies for three years pending receipt of the requested nformaion. • Vote: Support 	<ul style="list-style-type: none"> • Dr. Schell commented to support recommendation for approval and the board has the right to readdress this issue an any time before the 3 year period. • Ms. Herold provided the board will continue to conduct random inspections of the accredited pharmacies. • Motion: Recommend to the board that CHAP be reapproved as accreditation agencies for three years pending receipt of the requested nformaion. • Vote: Support 		<ul style="list-style-type: none"> • Dr. Schell: while it is preferred a pharmacist participate in the surveys, the board could consider whether it should require an additional survey by an agency that does not include a pharmacist for facilities accredited by JCAHO. • Motion: Request JCAHO have a pharmacist participate in surveys when possible and if not possible, then the best candidate should complete the survey. • Vote: Support 		

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
1. Periodic Inspections	Accreditation is valid for 3 years, requiring a full site inspection.	Site visit with a minimum of every 3 years. Site visit conducted after the submission of a completed self-study report. Visit is scheduled.	Triennial inspection for accreditation with annual ISO periodic inspections.	Accreditation award is continuous until the organization has its next full survey, which will be between 18 and 39 months after its previous full survey, unless accreditation is revoked for cause. The additional 3 months at the end of the survey window ensures that the surveys are not only unannounced, but unexpected. The vast majority of surveys are conducted by the three year anniversary date. However, if requested by the CA BOP, The Joint Commission will modify this time frame for pharmacies subject to these regulations to ensure resurveys are performed no more than 36 months after the previous full survey.	<p>Surveys every 3 years.</p> <ul style="list-style-type: none"> • Onsite survey lasting a minimum of one day with one surveyor; busier pharmacies may last two days with two surveyors. • Includes: personnel interviews, observation of compounding, record review, SOP reviewed, and evaluation of facility compliance to USP and PCAB standards. • A registered pharmacist generates the written report; is provided to the pharmacy; any corrective action is given a time frame to make corrections; corrective actions are required to be submitted to PCAB. • Once corrective actions are submitted, the accreditation committee makes the final decision to award accreditation. • Committee consists of 5 pharmacists: 1-USP, 1-NABP, 3-qualified experts in compounding. • If PCAB receives a complaint with probable cause or requires a call for action, PCAB will conduct a random inspection. 	Surveys every 3 years. Will require pharmacies provide HFAP with a copy of the California State Board of Pharmacy, Community Pharmacy and Hospital Outpatient Pharmacy Compounding Self Assessment.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
2. Comparison of standards	Copy of pharmacy standards submitted.	Copy of pharmacy standards submitted.	Comparison table of standards to regulations was submitted.	Refer to crosswalk comparison submitted.	<p>Standards are developed with the participation of various authorities in the field of pharmaceutical compounding.</p> <p>PCAB Board of Directors includes 7 organizations.</p> <p>American College of Apothecaries; American Pharmacist Association, International Academy of Compounding Pharmacies; National Association of Boards of Pharmacy; National Alliance of State Pharmacy Association, National Home Infusion Association; United States Pharmacopeia.</p> <p>Standards were submitted and compared to California compounding laws.</p>	<p>Standards were submitted and compared to California compounding laws.</p> <p>Submitted HFAP hospital Chapter 25 Pharmacy Services/medication use – compounding sterile preparations (Supplement for California Hospitals), Sections 25.04 and 25.05.)</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
3. Surveyor's qualifications.	<ul style="list-style-type: none"> •Maintain a current pharmacist license in one of the 50 states or territories of the U.S. •Required to have a minimum of 5 years managerial experience in homecare and/or pharmacy market. A PharmD is preferred. •Must complete the initial two day surveyor training and a minimum of two preceptorships; prior to conducting their initial survey. •Must attend an annual full day training session. •Must maintain current knowledge of industry standards, licensure regulations and changes that impact accreditation and/or licensure standards. •Are evaluated annually for their ability to perform surveys in accordance with ACHC p/p. 	<ul style="list-style-type: none"> •CHAP site visitors are required to have at least 5 years middle senior management experience in the service line in which they perform site visits. •Only a pharmacist would be assigned to survey a pharmacy. •All new staff receives a 5-day classroom orientation and 4 to 6 site visits where they are assigned an experienced pharmacy site visitor preceptor. •Job description provided. 	<ul style="list-style-type: none"> •Will make every effort to ensure a pharmacist participates as a member of the survey team when a hospital seeks to demonstrate compliance to sterile compounding requirements. •Must complete NIAHO surveyor didactic training and ISO 9001 lead auditor didactic training. •All surveyors are evaluated in terms of their interpersonal skills. •Must complete 45 hours of continuing education in their discipline within every 3 year period. •Must participate in annual surveyor training 	<ul style="list-style-type: none"> •In general, surveyors reviewing pharmacies are pharmacists or licensed registered nurses with infusion experience. •Pharmacist must have a Doctor of Pharmacy degree or equivalent. •Nurses must have graduated from an approved school of nursing and have a Master's degree in an appropriate discipline. •All surveyors must have five years of recent experience, including three year of direct clinical experience in the appropriate health care setting and two years of senior management experience. •All surveyors participate in a training and competency assessment process. •New surveyors begins with a 1-week classroom educational program tailored to their setting. •New surveyors complete a minimum of three surveys with a preceptor in the field, and must pass the Surveyor Certification Examination. New surveyors are terminated if they fail the exam after three attempts. •Surveyors must pass a re-certification exam every five years. •Continuing/ongoing surveyor education includes annual on-site training conference each January. Surveyors participate in a Quarterly educational conference call. Every other week., surveyors receive an email addressing topics of interest. 	<p>Surveyors are all registered pharmacists with extensive sterile and non-sterile compounding experience.</p> <p>Receives initial and ongoing training on conducting on-site surveys, standards interpretation, and use of survey tools.</p> <p>Training on CA compounding regulations and determining compliance with CA pharmacy laws.</p> <p>If approved by BOP, will also conduct training on CA laws where there is no PCAB standard.</p>	<p>Surveyors are registered nurses.</p> <p>Surveyors engaged in surveys of hospitals in CA will receive additional training related to surveying against the standards.</p> <p>Current plan is to conduct a surveyor training webcast for HFAP Hospital Chapter 25, Pharmacy Service /Medication Use with special focus on the additional Section 25.04 and 25.05, Supplement for California Hospitals.</p> <p>Primary instructor is Andrew Lowe, Pharm.D. Director of Pharmacy for Arrowhead Regional Medical Center.</p>

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(continue surveyors qualifications)				<ul style="list-style-type: none"> •All surveyors receive official newsletters with updates on new standards. •All surveyors receive an annual performance evaluation. 		
4. Acceptance by major California payors	ACHC is recognized by most major payors. In CA, Accordia of Northern CA, Aetna, BCBS, CCN managed care, California Care Plus, InsurNational California and the California Department of Health.	<ul style="list-style-type: none"> •Is accepted by major payors everywhere. Works effectively and ongoing with all payors to educate them about CHAP, and the robustness of the accreditation process. (List of specific payor sources not provided). •CMS (Medicaid and Medi-Care) 	Medi-Caid and Medi-Care (CMS) approval 9/26/2008.	Joint Commission accreditation is recognized by several California payor organizations. Example: Blue Cross of California.	<p>Accredits compounding pharmacies only.</p> <ul style="list-style-type: none"> • The only acceptance as an accrediting agency PCAB has or needs is the fact the pharmacy has a contract for prescription services with a payor. • Somewhat different than other accreditation services who accredit healthcare services in addition to pharmacy services. PCAB only accredits pharmacy services. • Pharmacist's Mutual, an insurance company for pharmacies, has recognized PCAB's standards; however, they do not sell into CA. • The American Medical Association policy 120.95 recognizes PCAB as a means to identify compounding pharmacies that adhere to quality and practice standards. 	<p>HFAP is accepted by the following healthcare payors among others: Medicare, Medicaid, Blue Cross of CA, Blue Shield of CA, Medi-Cal, Intervalley Health Plan (Senior HMO), HealthNet Health Plan (Senior HMO) and Care First Health Plan (Senior HMO).</p> <p>Also recognized by California Statute CA Welfare and Institution Code section 14043.26.</p>
5. Subjected to Unannounced inspections by BOP	ACHC welcomes feedback from the CA BOP on any ACHC accredited organization that is licensed by the Board.	<ul style="list-style-type: none"> •CHAP agreement with pharmacies include oversight visits for organizations who monitor CHAP performance. CHAP welcomes oversight and opportunity for learning, continuous improvement and accountability. 	<ul style="list-style-type: none"> •Currently DNV has accredited one hospital in California who is maintaining their LSC license with the BOP until DNV is approved. 	<p>Pharmacies subjected to the compounding regulations are accredited under The Joint Commission's Comprehensive Accreditation Manual for Home Care – Pharmacy standards.</p> <p>List of accredited pharmacies was provided.</p>	<p>Accredits pharmacies that compound non-sterile compounded drug products and sterile injectable compounded drug products.</p> <p>12 pharmacies accredited by PCAB in CA of which 5 pharmacies have LSC licenses with BOP.</p>	<p>New standards for California pharmacies were written, but have not been implemented. Current pharmacies were surveyed on HFAP basic standards.</p> <ul style="list-style-type: none"> • 25 hospital pharmacies HFAP accredited in CA.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
(Continued #5 unannounced inspections by BOP)					<ul style="list-style-type: none"> 2 of the 5 pharmacies with an LSC license were inspected. 	<ul style="list-style-type: none"> 7 of 25 hospitals do not have an LSC license in CA. <p>1 of 25 hospitals has a delinquent LSC license in CA</p>
6. Access to accreditor's reports on individual pharmacies.	<ul style="list-style-type: none"> ACHC will make available to CA BOP any provider's summary of findings as requested. The Board can access current accredited provider by visiting ACHC website. 	<ul style="list-style-type: none"> CHAP agreements allow CHAP to disclose accreditation reports to certain authority, which include the CA BOP. CHAP standards also required accredited organizations to disclose this information with a copy of the written report available on site. A process for providing reports on demand can be established. 	Will adhere to the requirements and oversight of the BOP, including DNV findings of noncompliance and corrective actions required.	Joint Commission official accreditation reports are provided to accredited organizations. These organizations are authorized and encouraged to share the accreditation report with regulatory agencies as required under state law. Should the Board of Pharmacy ask The Joint Commission to provide the accreditation report of a pharmacy subject to these regulations, The Joint Commission will contact the pharmacy and seek to obtain an authorization from the pharmacy to release the report to the Board. Once authorization is received from the pharmacy, The Joint Commission will provide the accreditation report to the Board.	<ul style="list-style-type: none"> Will need to check with legal dept if the report can be made available to the board upon request. <p>A copy is provided to the pharmacy.</p> <ul style="list-style-type: none"> A copy is not available online. <p>Will inform the Board when the PCAB accreditation committee notes noncompliance with PCAB standard or other practices documented by the surveyor places the public at harm.</p> <p>Will notify the Board of situations where PCAB denies or revokes a pharmacy's accreditation.</p>	<p>HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility.</p> <p>Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during a HFAP survey.</p> <p>HFAP will notify the board of any serious noncompliance requiring the board to follow up with an inspection. We would use the full condition level of CCR 1735 and 1751 et al as the criteria for serious noncompliance.</p> <p>We would notify the Board if HFAP denies or withdraws an accreditation from a pharmacy.</p>
7. Length of time accrediting agency has been operating as an accrediting agency.	ACHC is an independent, private, not for profit corporation established in 1986.	<ul style="list-style-type: none"> CHAP was founded in 1965 as the first organization in the U.S. to accredit community based health care organizations. CHAP is authorized by CMS to provide accreditation for home health, hospice, durable medical equipment and pharmacy. 	<ul style="list-style-type: none"> Established in 1864 in Oslo, Norway with 15 offices in the U.S. In U.S. since 1898. DNVHS offices in Houston Texas and Cincinnati, Ohio. 300 offices in over 100 countries. 	The Joint Commission has been in operations as an accrediting agency since 1951. The Joint Commission's Home Care Accreditation – Pharmacy program was established in 1988.	Incorporated in 2004 with the first pharmacy licensed in 2006.	HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since 1965.

Criteria	ACHC	CHAP	DNV	JCAHO	PCAB	HFAP
8. Ability to accredit out-of-state pharmacies.	ACHC accredits both resident and non-resident pharmacies that have businesses in any of the 50 states or territories of the U.S.	As a national organization and provider of accreditation services, CHAP is able to accredit pharmacies in all 50 states and US territories.	•Refer to #7	The Joint Commission can and does accredit pharmacies throughout the United States.	Currently 132 pharmacies are PCAB accredited throughout the United States; no pharmacies accredited in Puerto Rico.	HFAP accredits pharmacies in its hospitals across the United States.
9. Annual submission of list of accredited board of licensed facilities.	List received.	<ul style="list-style-type: none"> •CHAP has 6 currently accredited pharmacy sites in CA. •Current list submitted 6/4/2010. 	Currently, Hoag Medical Center is the only pharmacy accredited by DNV in CA. Hoag also maintains an LSC license until DNV is approved by the BOP.	List received. Also an internet search is available on The Joint Commission website to verify accreditation.	<p>Is willing to provide the board annually a list of PCAB accredited pharmacies in CA.</p> <p>To verify if a pharmacy outside of CA is PCAB accredited, the Board will be able to contact PCAB for verification.</p>	Will provide annually, no later than July 1, a list of board licensed facilities that are accredited during the past 12 months.

1. Residence Location:

		Response Percent	Response Count
Residence County:		98.3%	878
Residence ZIP:		99.6%	889
		answered question	893
		skipped question	4

2. Number of years you have worked for this employer

	Response Count
	727
answered question	727
skipped question	170

3. Check box if self employed

	Response Percent	Response Count
Self employed		100.0%
answered question		77
skipped question		820

4. Work Location

		Response Percent	Response Count
County:		98.8%	734
ZIP:		98.7%	733
		answered question	743
		skipped question	154

5. Health Occupation:

		Response Count	
		726	
		answered question	726
		skipped question	171

6. Work hours per week at this location:

		Response Percent	Response Count
40+		75.9%	567
30-29		12.0%	90
20-29		7.0%	52
10-19		2.5%	19
1-9		2.5%	19
		answered question	747
		skipped question	150

7. Work setting:

		Response Percent	Response Count
Acute care hospital		53.7%	195
Durable medical equipment/home care		2.5%	9
Long-term acute care/rehabilitation hospital/sub-acute care		3.3%	12
Skilled nursing facility		1.7%	6
Accredited education program		1.7%	6
Manufacturer/distributor		3.9%	14
Outpatient facility/physician's office/dentist's office		16.3%	59
Clinics/community health center		17.1%	62
	Other setting, please describe:		404
answered question			363
skipped question			534

8. Work activities:

		Response Percent	Response Count
% Patient Care		83.9%	605
% Research		33.0%	238
% Teaching		42.6%	307
% Administration		68.7%	495
% Other		38.4%	277
answered question			721
skipped question			176

9. Number of years you have worked for this employer:

	Response Count
	189
answered question	189
skipped question	708

10. Check box if self employed

	Response Percent	Response Count
Self employed	100.0%	31
answered question		31
skipped question		866

11. Work Location

		Response Percent	Response Count
County:		98.9%	174
ZIP:		97.2%	171
		answered question	176
		skipped question	721

12. Health Occupation:

		Response Count	
		166	
		answered question	166
		skipped question	731

13. Work hours per week at this location:

		Response Percent	Response Count
40+		50.0%	87
30-29		10.3%	18
20-29		5.2%	9
10-19		12.1%	21
1-9		22.4%	39
		answered question	174
		skipped question	723

14. Work setting:

		Response Percent	Response Count
Acute care hospital		34.8%	32
Durable medical equipment/home care		5.4%	5
Long-term acute care/rehabilitation hospital/sub-acute care		4.3%	4
Skilled nursing facility		3.3%	3
Accredited education program		2.2%	2
Manufacturer/distributor		1.1%	1
Outpatient facility/physician's office/dentist's office		30.4%	28
Clinics/community health center		18.5%	17
	Other setting, please describe:		85
answered question			92
skipped question			805

15. Work activities:

		Response Percent	Response Count
% Patient Care		90.3%	149
% Research		27.9%	46
% Teaching		40.6%	67
% Administration		52.1%	86
% Other		40.0%	66
answered question			165
skipped question			732

16. Number of years you have worked for this employer:

	Response Count
	52
answered question	52
skipped question	845

17. Check box if self employed

	Response Percent	Response Count
Self employed	100.0%	9
answered question		9
skipped question		888

18. Work Location

		Response Percent	Response Count
County:		100.0%	40
ZIP:		92.5%	37
		answered question	40
		skipped question	857

19. Health Occupation:

		Response Count
		37
		answered question
		37
		skipped question
		860

20. Work hours per week at this location:

		Response Percent	Response Count
40+		59.5%	25
30-29		9.5%	4
20-29		7.1%	3
10-19		4.8%	2
1-9		19.0%	8
		answered question	42
		skipped question	855

21. Work setting:

		Response Percent	Response Count
Acute care hospital		23.8%	5
Durable medical equipment/home care		4.8%	1
Long-term acute care/rehabilitation hospital/sub-acute care		9.5%	2
Skilled nursing facility		4.8%	1
Accredited education program		9.5%	2
Manufacturer/distributor		0.0%	0
Outpatient facility/physician's office/dentist's office		19.0%	4
Clinics/community health center		28.6%	6
	Other setting, please describe:		21
		answered question	21
		skipped question	876

22. Work activities:

		Response Percent	Response Count
% Patient Care		94.6%	35
% Research		37.8%	14
% Teaching		43.2%	16
% Administration		51.4%	19
% Other		48.6%	18
answered question			37
skipped question			860

23. List all degrees/certificates obtained

	Response Count
	662
answered question	662
skipped question	235

24. Are you presently pursuing additional credentials or certifications?

		Response Percent	Response Count
No		89.4%	601
Yes		10.6%	71
answered question			672
skipped question			225

25. If so, program name/degree type

	Response Count
	51
answered question	51
skipped question	846

26. Expected year of completion

	Response Count
	48
answered question	48
skipped question	849

27. School/Institution address

		Response Percent	Response Count
School/Institution Name:		91.0%	71
Company:		15.4%	12
Address:		28.2%	22
Address 2:		0.0%	0
City/Town:		66.7%	52
State:		76.9%	60
ZIP:		34.6%	27
Country:		48.7%	38
		answered question	78
		skipped question	819

28. Cultural/ethnic background

		Response Percent	Response Count
African American/Black/African-Born		1.9%	13
American Indian/Native American/Alaskan Native		1.6%	11
Caucasian/White European/Middle Eastern		63.0%	428
Latino/Hispanic (If Latino/Hispanic, please select one of the following)		3.1%	21
Central American		0.3%	2
Cuban		0.1%	1
Mexican		2.4%	16
Puerto Rican		0.1%	1
South American		0.0%	0
Other Hispanic		0.4%	3
Asian (If Asian, please select one of the following)		11.0%	75
Cambodian		0.1%	1
Chinese		9.6%	65
Hmong		0.0%	0
Indian		3.4%	23
Indonesian		0.0%	0
Japanese		5.0%	34
Korean		1.2%	8
Laotian		0.0%	0
Malaysia		0.1%	1

Pakistani		0.3%	2
Singaporean		0.0%	0
Thai		0.3%	2
Vietnamese		3.2%	22
Other		1.0%	7
Native Hawaiian/Pacific Islander (If Native Hawaiian/Pacific Islander, please select one of the following)		0.1%	1
Fijian		0.0%	0
Filipino		1.9%	13
Guamanian		0.0%	0
Hawaiian		0.0%	0
Samoan		0.0%	0
Tongan		0.0%	0
Other Pacific Islander		0.0%	0
Other (not listed above)		1.3%	9
Decline to state		4.7%	32
answered question			679
skipped question			218

29. Are you fluent in languages other than English? If yes:

		Response Percent	Response Count
Verbal		97.6%	207
Written		70.8%	150
answered question			212
skipped question			685

30. Select language

		Response Percent	Response Count
Afrikaans	<input type="checkbox"/>	2.8%	6
Albanian		0.0%	0
American Sign Language	<input type="checkbox"/>	0.9%	2
Amharic	<input type="checkbox"/>	0.5%	1
Apache		0.0%	0
Arabic	<input type="checkbox"/>	5.0%	11
Armenian	<input type="checkbox"/>	2.8%	6
Bantu		0.0%	0
Bengali		0.0%	0
Bisayan		0.0%	0
Bulgarian		0.0%	0
Burmese	<input type="checkbox"/>	0.5%	1
Cajun		0.0%	0
Cambodian		0.0%	0
Cantonese (Yue Chinese)	<input type="checkbox"/>	11.0%	24
Chamorro		0.0%	0
Cherokee		0.0%	0
Croatian		0.0%	0
Czech		0.0%	0
Dakota		0.0%	0
Danish		0.0%	0
Dutch	<input type="checkbox"/>	0.9%	2
Farsi	<input type="checkbox"/>	3.7%	8

Fijian		0.0%	0
Finnish		0.0%	0
Formosan (Amis)	▮	0.5%	1
French	▮	5.5%	12
French Creole		0.0%	0
German	▮	4.6%	10
Greek	▮	0.5%	1
Gujarati	▮	5.5%	12
Haitian Creole		0.0%	0
Hebrew	▮	0.9%	2
Hindi	▮	7.8%	17
Hmong		0.0%	0
Hsiang (Xiang Chinese)		0.0%	0
Hungarian	▮	0.9%	2
Ibo		0.0%	0
Ilocano/Iloko		0.0%	0
Indonesian		0.0%	0
Italian	▮	2.3%	5
Japanese	▮	1.4%	3
Kannada	▮	0.5%	1
Keres		0.0%	0
Korean	▮	2.3%	5
Kru		0.0%	0
Kurdish		0.0%	0
Lao		0.0%	0

Lettish		0.0%	0
Lithuanian		0.0%	0
Macedonian		0.0%	0
Malayalam		0.0%	0
Mandarin		7.8%	17
Mande		0.0%	0
Marathi		0.5%	1
Marshallese		0.0%	0
Mien (Lu Mien)		0.0%	0
Mon-Khmer		0.0%	0
Norwegian		0.0%	0
Navajo		0.0%	0
Nepali		0.0%	0
Panjabi (Punjabi)		2.8%	6
Pashto		0.0%	0
Patois		0.0%	0
Persian		1.8%	4
Polish		0.9%	2
Purtuguese		0.9%	2
Rumanian		0.5%	1
Russian		2.8%	6
Samoan		0.0%	0
Sebuano		0.0%	0
Serbian		0.0%	0
Serbo-Croatian		0.0%	0
Sinhalese		0.0%	0

Slovak		0.0%	0
Spanish		25.2%	55
Swahili		0.0%	0
Swedish		0.0%	0
Syriac		0.0%	0
Tagalog		2.8%	6
Tamil		0.5%	1
Telugu		0.5%	1
Thai		0.9%	2
Tonga		0.0%	0
Turkish		0.5%	1
Ukrainian		0.5%	1
Urdu		1.8%	4
Vietnamese		9.6%	21
Yiddish		0.0%	0
Yoruba		0.0%	0
Other (not listed)		2.3%	5
Decline to state		6.0%	13
answered question			218
skipped question			679

31. I plan to retire:

		Response Percent	Response Count
Within the next 2 years		4.7%	32
Within the next 5 years		13.4%	92
Within the next 10 years		17.9%	123
Not planning to retire within the next 10 years		55.0%	377
Already retired		2.8%	19
Retired, work part time		3.8%	26
Plan to work part time		2.5%	17
answered question			686
skipped question			211

Assembly Bill No. 2699

CHAPTER 270

An act to amend Section 900 of, and to add and repeal Section 901 of, the Business and Professions Code, relating to healing arts.

[Approved by Governor September 23, 2010. Filed with Secretary of State September 24, 2010.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2699, Bass. Healing arts: licensure exemption.

Existing law provides for the licensure and regulation of various healing arts practitioners by boards within the Department of Consumer Affairs. Existing law provides an exemption from these requirements for a health care practitioner licensed in another state who offers or provides health care for which he or she is licensed during a state of emergency, as defined, and upon request of the Director of the Emergency Medical Services Authority, as specified.

This bill would also provide, until January 1, 2014, an exemption from the licensure and regulation requirements for a health care practitioner, as defined, licensed or certified in good standing in another state or states, who offers or provides health care services for which he or she is licensed or certified through a sponsored event, as defined, (1) to uninsured or underinsured persons, (2) on a short-term voluntary basis, (3) in association with a sponsoring entity that registers with the applicable healing arts board, as defined, and provides specified information to the county health department of the county in which the health care services will be provided, and (4) without charge to the recipient or a 3rd party on behalf of the recipient, as specified. The bill would also require an exempt health care practitioner to obtain prior authorization to provide these services from the applicable licensing board, as defined, and to satisfy other specified requirements, including payment of a fee as determined by the applicable licensing board. The bill would require the applicable licensing board to notify the sponsoring entity, as defined, of the sponsored event whether the board approves or denies a request for authorization to provide these services within 20 days of receipt of the request. The bill would also prohibit a contract of liability insurance issued, amended, or renewed on or after January 1, 2011, from excluding coverage of these practitioners or a sponsoring entity for providing care under these provisions.

Because this bill would expand the definition of certain crimes, the bill would create a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 900 of the Business and Professions Code is amended to read:

900. (a) Nothing in this division applies to a health care practitioner licensed in another state or territory of the United States who offers or provides health care for which he or she is licensed, if the health care is provided only during a state of emergency as defined in subdivision (b) of Section 8558 of the Government Code, which emergency overwhelms the response capabilities of California health care practitioners and only upon the request of the Director of the Emergency Medical Services Authority.

(b) The director shall be the medical control and shall designate the licensure and specialty health care practitioners required for the specific emergency and shall designate the areas to which they may be deployed.

(c) Health care practitioners shall provide, upon request, a valid copy of a professional license and a photograph identification issued by the state in which the practitioner holds licensure before being deployed by the director.

(d) Health care practitioners deployed pursuant to this chapter shall provide the appropriate California licensing authority with verification of licensure upon request.

(e) Health care practitioners providing health care pursuant to this chapter shall have immunity from liability for services rendered as specified in Section 8659 of the Government Code.

(f) For the purposes of this section, “health care practitioner” means any person who engages in acts which are the subject of licensure or regulation under this division or under any initiative act referred to in this division.

(g) For purposes of this section, “director” means the Director of the Emergency Medical Services Authority who shall have the powers specified in Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

SEC. 2. Section 901 is added to the Business and Professions Code, to read:

901. (a) For purposes of this section, the following provisions apply:

(1) “Board” means the applicable healing arts board, under this division or an initiative act referred to in this division, responsible for the licensure or regulation in this state of the respective health care practitioners.

(2) “Health care practitioner” means any person who engages in acts that are subject to licensure or regulation under this division or under any initiative act referred to in this division.

(3) “Sponsored event” means an event, not to exceed 10 calendar days, administered by either a sponsoring entity or a local government, or both, through which health care is provided to the public without compensation to the health care practitioner.

(4) “Sponsoring entity” means a nonprofit organization organized pursuant to Section 501(c)(3) of the Internal Revenue Code or a community-based organization.

(5) “Uninsured or underinsured person” means a person who does not have health care coverage, including private coverage or coverage through a program funded in whole or in part by a governmental entity, or a person who has health care coverage, but the coverage is not adequate to obtain those health care services offered by the health care practitioner under this section.

(b) A health care practitioner licensed or certified in good standing in another state, district, or territory of the United States who offers or provides health care services for which he or she is licensed or certified is exempt from the requirement for licensure if all of the following requirements are met:

(1) Prior to providing those services, he or she:

(A) Obtains authorization from the board to participate in the sponsored event after submitting to the board a copy of his or her valid license or certificate from each state in which he or she holds licensure or certification and a photographic identification issued by one of the states in which he or she holds licensure or certification. The board shall notify the sponsoring entity, within 20 calendar days of receiving a request for authorization, whether that request is approved or denied, provided that, if the board receives a request for authorization less than 20 days prior to the date of the sponsored event, the board shall make reasonable efforts to notify the sponsoring entity whether that request is approved or denied prior to the date of that sponsored event.

(B) Satisfies the following requirements:

(i) The health care practitioner has not committed any act or been convicted of a crime constituting grounds for denial of licensure or registration under Section 480 and is in good standing in each state in which he or she holds licensure or certification.

(ii) The health care practitioner has the appropriate education and experience to participate in a sponsored event, as determined by the board.

(iii) The health care practitioner shall agree to comply with all applicable practice requirements set forth in this division and the regulations adopted pursuant to this division.

(C) Submits to the board, on a form prescribed by the board, a request for authorization to practice without a license, and pays a fee, in an amount determined by the board by regulation, which shall be available, upon appropriation, to cover the cost of developing the authorization process and processing the request.

(2) The services are provided under all of the following circumstances:

(A) To uninsured or underinsured persons.

(B) On a short-term voluntary basis, not to exceed a 10-calendar-day period per sponsored event.

(C) In association with a sponsoring entity that complies with subdivision (c).

(D) Without charge to the recipient or to a third party on behalf of the recipient.

(c) The board may deny a health care practitioner authorization to practice without a license if the health care practitioner fails to comply with the requirements of this section or for any act that would be grounds for denial of an application for licensure.

(d) A sponsoring entity seeking to provide, or arrange for the provision of, health care services under this section shall do both of the following:

(1) Register with each applicable board under this division for which an out-of-state health care practitioner is participating in the sponsored event by completing a registration form that shall include all of the following:

(A) The name of the sponsoring entity.

(B) The name of the principal individual or individuals who are the officers or organizational officials responsible for the operation of the sponsoring entity.

(C) The address, including street, city, ZIP Code, and county, of the sponsoring entity's principal office and each individual listed pursuant to subparagraph (B).

(D) The telephone number for the principal office of the sponsoring entity and each individual listed pursuant to subparagraph (B).

(E) Any additional information required by the board.

(2) Provide the information listed in paragraph (1) to the county health department of the county in which the health care services will be provided, along with any additional information that may be required by that department.

(e) The sponsoring entity shall notify the board and the county health department described in paragraph (2) of subdivision (d) in writing of any change to the information required under subdivision (d) within 30 calendar days of the change.

(f) Within 15 calendar days of the provision of health care services pursuant to this section, the sponsoring entity shall file a report with the board and the county health department of the county in which the health care services were provided. This report shall contain the date, place, type, and general description of the care provided, along with a listing of the health care practitioners who participated in providing that care.

(g) The sponsoring entity shall maintain a list of health care practitioners associated with the provision of health care services under this section. The sponsoring entity shall maintain a copy of each health care practitioner's current license or certification and shall require each health care practitioner to attest in writing that his or her license or certificate is not suspended or revoked pursuant to disciplinary proceedings in any jurisdiction. The sponsoring entity shall maintain these records for a period of at least five years following the provision of health care services under this section and shall, upon request, furnish those records to the board or any county health department.

(h) A contract of liability insurance issued, amended, or renewed in this state on or after January 1, 2011, shall not exclude coverage of a health care

practitioner or a sponsoring entity that provides, or arranges for the provision of, health care services under this section, provided that the practitioner or entity complies with this section.

(i) Subdivision (b) shall not be construed to authorize a health care practitioner to render care outside the scope of practice authorized by his or her license or certificate or this division.

(j) (1) The board may terminate authorization for a health care practitioner to provide health care services pursuant to this section for failure to comply with this section, any applicable practice requirement set forth in this division, any regulations adopted pursuant to this division, or for any act that would be grounds for discipline if done by a licensee of that board.

(2) The board shall provide both the sponsoring entity and the health care practitioner with a written notice of termination including the basis for that termination. The health care practitioner may, within 30 days after the date of the receipt of notice of termination, file a written appeal to the board. The appeal shall include any documentation the health care practitioner wishes to present to the board.

(3) A health care practitioner whose authorization to provide health care services pursuant to this section has been terminated shall not provide health care services pursuant to this section unless and until a subsequent request for authorization has been approved by the board. A health care practitioner who provides health care services in violation of this paragraph shall be deemed to be practicing health care in violation of the applicable provisions of this division, and be subject to any applicable administrative, civil, or criminal fines, penalties, and other sanctions provided in this division.

(k) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(l) This section shall remain in effect only until January 1, 2014, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2014, deletes or extends that date.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Board of Pharmacy Licensing Statistics - Fiscal Year 2011/12

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	153	144	105	119	191	80							792
Pharmacist (initial licensing applications)	149	449	90	381	161	102							1332
Intern pharmacist	36	474	389	296	63	59							1317
Pharmacy technician	929	1127	1054	383	541	476							4510
Pharmacy	23	35	27	14	22	42							163
Pharmacy Exempt	0	0	0	0	0	0							0
Pharmacy - Temp	11	14	6	0	6	19							56
Sterile Compounding	0	9	2	4	7	11							33
Sterile Compounding - Exempt	0	0	0	0	0	0							0
Sterile Compounding - Temp	0	4	0	0	0	5							9
Nonresident Sterile Compounding	1	1	2	0	0	0							4
Clinics	3	3	9	3	8	0							26
Clinics Exempt	0	0	0	0	0	0							0
Hospitals	1	1	0	0	1	0							3
Hospitals Exempt	0	0	0	0	0	0							0
Hospitals - Temp	0	0	0	0	0	0							0
Drug Room	0	0	0	0	0	0							0
Drug Room Exempt	0	0	0	0	0	0							0
Nonresident Pharmacy	4	5	5	2	10	55							81
Nonresident Pharmacy - Temp	1	0	3	0	0	45							49
Licensed Correctional Facility	0	0	0	0	0	0							0
Hypodermic Needle and Syringes	0	2	0	3	6	0							11
Hypodermic Needle and Syringes Exempt	0	0	0	0	0	0							0
Nonresident Wholesalers	7	11	7	5	15	14							59
Nonresident Wholesalers - Temp	1	0	0	0	0	8							9
Wholesalers	5	8	10	6	9	19							57
Wholesalers Exempt	0	0	0	0	0	0							0
Wholesalers - Temp	1	1	0	0	1	0							3
Veterinary Food-Animal Drug Retailer	0	0	1	0	0	0							1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0							0
Designated Representatives	53	53	67	12	39	40							264
Designated Representatives Vet	0	1	1	0	0	0							2
Total	1378	2342	1778	1228	1080	975	0	0	0	0	0	0	8781



California State Board of Pharmacy

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

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 labels are configurable to comply with California's labeling requirements.

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.

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 stronger standards for all accreditation agencies (e.g., pharmacist surveyors, annual inspections, sharing reports). She stated that this process would take a minimum of one year before regulations could be in effect.

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.

Supervising Inspector Janice Dang introduced Michael Zarski and Andrew Lowe, representing HFAP, and Joe Cabaleiro, representing PCAB. She discussed that 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 regarding the following concerns and discrepancies for agencies currently recognized by the board:

- Survey teams will include a pharmacist.
- Agency agrees to provide the board access to accreditation reports.
- Agency agrees 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 to the board to 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 previous proposed regulation language considered by the board and comments made during discussions on the approval of accreditation agencies.

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 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. Herold provided that the approval should immediately cease.

Ms. Veale also 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 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 ratify 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.

LICENSING COMMITTEE

Goal 2: Ensure the qualifications of licensees.

Outcome: Qualified licensees

Objective 2.1	Issue licenses within three working days of a completed application by June 30, 2011.								
Measure:	Percentage of licenses issued within three work days.								
Tasks:	1. Review 100 percent of all applications within 7 work days of receipt.								
		# of Apps. Received:				Average Days to Process:			
		Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
	Pharmacist (exam applications)	402	390			34	17		
	Pharmacist (initial licensing)	668	644			9	6		
	Pharmacy Intern	899	418			12	14		
	Pharmacy Technician	3,110	1,400			67	80		
	Pharmacies	85	78			20	18		
	Non-Resident Pharmacy	14	67			25	29		
	Wholesaler	23	34			29	27		
	Veterinary Drug Retailers	1	0			1	0		
	Designated Representative	175	91			33	25		
	Out-of-state distributors	25	34			32	29		
	Clinics	15	11			19	22		
	Hypodermic Needle & Syringe Distributors	2	9			20	18		
	Sterile Compounding	15	22			18	19		
	Change of Permit	171	171			30	33		
Pharmacist in Charge	362	431			30	45			
Designated Representative in Charge	32	44			30	30			
Discontinuance of Business	39	40			30	60			

2. Process 100 percent of all deficiency documents within five work days of receipt.

	Average Days to process deficiency:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	3	15		
Pharmacist (initial licensing)	3	3		
Pharmacy Intern	2	2		
Pharmacy Technician	24	10		
Pharmacies	5	6		
Non-Resident Pharmacy	6	6		
Wholesaler	6	4		
Veterinary Drug Retailers	6	0		
Designated Representative	6	4		
Out-of-state distributors	6	4		
Clinics	5	6		
Hypodermic Needle & Syringe	6	4		

3. Make a licensing decision within three work days after all deficiencies are corrected.

	Average Days to Determine to Deny/Issue License:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist (exam applications)	2	2		
Pharmacist (initial licensing)	2	2		
Pharmacy Intern	5	5		
Pharmacy Technician	2	2		
Pharmacies	5	5		
Non-Resident Pharmacy	5	5		
Wholesaler	5	3		
Veterinary Drug Retailers	5	0		
Designated Representative	5	3		
Out-of-state distributors	5	3		
Clinics	5	5		
Hypodermic Needle & Syringe	5	3		

4. Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.

	Licenses Issued:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	675	631		
Pharmacy Intern	565	693		
Pharmacy Technician	2,484	2,941		
Pharmacies	70	44		
Non-Resident Pharmacy	9	16		
Wholesaler	20	27		
Veterinary Drug Retailers	0	0		
Designated Representative	148	113		
Out-of-state distributors	25	16		
Clinics	11	9		
Hypodermic Needle & Syringe	7	0		
Sterile Compounding	14	11		

5. Withdrawn licenses to applicants not meeting board requirements.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacy Technician	121	284		
Pharmacies	0	2		
Non-Resident Pharmacy	5	1		
Clinics	0	0		
Sterile Compounding	0	0		
Designated Representative	6	4		
Hypodermic Needle & Syringe	0	0		
Out-of-state distributors	0	0		
Wholesaler	0	1		
Veterinary Drug Retailers	0	0		
Registered Pharmacist	0	28		
Intern Pharmacist	0	0		

6. Deny applications to those who do not meet California standards.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist	2	4		
Intern Pharmacist	0	0		
Pharmacy Technician	14	18		
Pharmacies	0	3		
Non-Resident Pharmacy	1	1		
Clinics	0	0		
Sterile Compounding	0	0		
Designated Representative	1	0		
Hypodermic Needle & Syringe	0	0		
Out-of-state distributors	0	0		
Wholesaler	0	1		

7. Responding to e-mail status requests and inquiries to designated e-mail addresses.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	2,501	1,316		
Pharmacy Technicians	3,653	2,814		
Site licenses (pharmacy, clinics)	1,002	1,130		
Site licenses (wholesalers, nonresident pharmacies)	1,159	861		
Pharmacist in Charge	257	178		
Renewals	372	567		

8. Responding to telephone status request and inquiries.

	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Pharmacist/Pharmacist Intern	*	*		
Pharmacy Technicians	*	*		
Site licenses (pharmacy, clinics)	468	472		
Site licenses (wholesalers, nonresident pharmacies)	122	120		
Pharmacist in Charge	93	70		
Renewals	2,380	1,538		

* Voicemail status requests have been suspended to allow staff time to focus on processing applications and issuing licenses

Objective 2.2	Cashier 100 percent of all revenue received within two working days of receipt by June 30, 2011.																																																																														
Measure:	Percentage of revenue cashiered application within 2 working days.																																																																														
Tasks:	<table border="1" data-bbox="370 289 1515 798"> <thead> <tr> <th rowspan="2"></th> <th colspan="4">Revenue Received:</th> <th colspan="4">Average Days to Process:</th> </tr> <tr> <th>*Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4*</th> <th>Qtr 1</th> <th>Qtr 2</th> <th>Qtr 3</th> <th>Qtr 4</th> </tr> </thead> <tbody> <tr> <td>Applications</td> <td>457,041</td> <td>340,611</td> <td></td> <td></td> <td>4</td> <td>3</td> <td></td> <td></td> </tr> <tr> <td>Renewals</td> <td>1,607,099</td> <td>1,371,797</td> <td></td> <td></td> <td>4</td> <td>7</td> <td></td> <td></td> </tr> <tr> <td>Cite and Fine</td> <td>223,625</td> <td>92,920</td> <td></td> <td></td> <td>5</td> <td>7</td> <td></td> <td></td> </tr> <tr> <td>Probation/ Cost Recovery</td> <td>69,591</td> <td>38,014</td> <td></td> <td></td> <td>5</td> <td>9</td> <td></td> <td></td> </tr> <tr> <td>Request for Information/ License Verification</td> <td>3,375</td> <td>3,360</td> <td></td> <td></td> <td>7</td> <td>9</td> <td></td> <td></td> </tr> <tr> <td>Fingerprint Fee</td> <td>26,775</td> <td>24,479</td> <td></td> <td></td> <td>5</td> <td>8</td> <td></td> <td></td> </tr> </tbody> </table>									Revenue Received:				Average Days to Process:				*Qtr 1	Qtr 2	Qtr 3	Qtr 4*	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Applications	457,041	340,611			4	3			Renewals	1,607,099	1,371,797			4	7			Cite and Fine	223,625	92,920			5	7			Probation/ Cost Recovery	69,591	38,014			5	9			Request for Information/ License Verification	3,375	3,360			7	9			Fingerprint Fee	26,775	24,479			5	8		
	Revenue Received:				Average Days to Process:																																																																										
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4																																																																							
Applications	457,041	340,611			4	3																																																																									
Renewals	1,607,099	1,371,797			4	7																																																																									
Cite and Fine	223,625	92,920			5	7																																																																									
Probation/ Cost Recovery	69,591	38,014			5	9																																																																									
Request for Information/ License Verification	3,375	3,360			7	9																																																																									
Fingerprint Fee	26,775	24,479			5	8																																																																									
* 1st quarter reflects July and August 2011 data available at the time of report development.																																																																															

Update 100 percent of all information changes to licensing records within five working days by June 30, 2011.

Percentage of licensing records changes within five working days.

	Requests Received:				Average Days to Process:			
	Qtr 1	Qtr 2	Qtr 3	Qtr 4	Qtr 1	Qtr 2	Qtr 3	Qtr 4
Address/Name Changes	3,378	2,903			1	1		
Off-site Storage Applications (approved)	24	32			20	59		
Transfer of Intern Hours to Other States	45	31			6	17		

Objective 2.4	Implement at least 25 changes to improve licensing decisions by June 30, 2011.
Measure:	Number of implemented changes.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="370 218 1487 506"> <p>1. Determine why 26 states do not allow the use of a CA license as the basis for transfer of pharmacist license to that state. <i>Jan. 2007:</i> Survey of some states indicate misunderstanding of why California cannot accept NAPLEX scores earned before January 1, 2004. Educational efforts, on a state by state basis, initiated. <i>March 2007:</i> Pennsylvania agrees to accept California NAPLEX scores. <i>May 2007:</i> At National Association of Boards of Pharmacy meeting several states agree to reconsider their position against accepting California scores.</p> <li data-bbox="370 516 1487 695"> <p>2. Evaluate the drug distribution system of clinics and their appropriate licensure. <i>1st Qtr 09/10:</i> Continued to advise clinics and their advocates about the barrier the Capen decision places on surgicenters/clinics from obtaining a board clinic permit. A legislative solution is needed. <i>3rd Qtr 09/10:</i> Board hears presentation by Fort Sutter Surgery Center discussing the issue.</p> <li data-bbox="370 705 1487 1062"> <p>3. Work with the Department of Corrections on the licensure of pharmacies in prisons. <i>June 2007:</i> Meet with the Department of Corrections Receiver to discuss possible regulatory structures for drug dispensing and distribution within correctional facilities. <i>Oct. 2008:</i> Board staff meet with Department of Corrections staff to develop regulatory structure for prisons. <i>Dec. 2008:</i> Met with receiver for correctional facilities to discuss regulatory structure. <i>1st Qtr 10/11:</i> Governor includes provisions for pharmacy services in prisons. <i>3rd Qtr 10/11:</i> Legislation introduced to include some changes. (AB 389, Lowenthal) <i>4th Qtr 10/11:</i> AB 389 amended and no longer addressing licensure issue.</p> <li data-bbox="370 1073 1487 1734"> <p>4. Work with local and state officials on emergency preparedness and planning for pandemics and disasters. Planning to include the storage and distribution of drugs to assure patient access and safety. <i>2nd Qtr 09/10:</i> Board votes that in declared emergencies where a board meeting cannot quickly be scheduled, a subcommittee of three members can make decisions for patient safety under provisions of Business and Professions Code section 4062 and the board's emergency response policy. <i>4th Qtr 09/10:</i> Licensing continued reviewing requests from CDPH seeking clarification on board disaster response policy. <i>2nd Qtr 10/11:</i> Discussion of the California Hospital Association's repopulation after hospital evacuation guidelines and checklist at Licensing Committee Meeting. <i>3rd Qtr 10/11:</i> Board discussed its role in repopulation of hospitals in working with the CDPH to inspect the pharmacy to validate that there are appropriate safeguards to ensure the safety of the drugs. Licensing Committee hosts a presentation on emergency preparedness during quarterly meeting. Committee discusses need for possible mandatory CE in this area.</p> <li data-bbox="370 1745 1487 1835"> <p>5. Evaluate the need to issue a provisional license to pharmacy technician trainees. <i>Dec. 2010:</i> Update on the board's psychometric evaluation for the ExCPT and PTCB at the Licensing Committee.</p>

6. Evaluate use of a second pharmacy technician certification examination (ExCPT) as a possible qualifying route for registration of technicians.

Sep. 2006: *Committee hears presentation on ExCPT exam approved for certification of technicians by five states. Committee directs staff to evaluate exam for possible use in California.*

Dec. 2006: *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*

March 2007: *DCA recruiting for Chief of Examination Resources Office; review postponed. Additional methods to accomplish review considered.*

May 2007: *Board seeks private contractor to evaluate both ExCPT and PTCB exams for job validity.*

Sep. 2007: *Board required to check with other state agencies to ensure that state-employed PhD psychometricians are not able to perform this review before the board can contract for services. Committee recommends delay until CSHP and CPhA complete their review of pharmacy technician training and knowledge.*

Oct. 2007: *Board postpones work on this topic until CSHP and CPhA complete their review.*

March 2009: *Board executive staff meet with the executive director of the ExCPT exam.*

April 2009: *Board directs staff to secure a psychometric review of both the PTCB and ExCPT exams, in wake of AB 418 being stalled in the legislature.*

2nd Qtr 09/10: *Board initiates discussions with DCA regarding use of their Ph.D to evaluate the validation studies.*

2nd Qtr 10/11: *DCA psychometric expert initiates review of PTCB and ExCPT exams.*

3rd Qtr 10/11: *Board staff reports interagency agreement has been signed with OPES. The DCA psychometric expert has begun its review of the PTCB and ExCPT examinations.*

7. Review requirements for qualifications of pharmacy technicians with stakeholders

4th Qtr 07/08: *Future work on the training of technicians will occur as joint activities of the pharmacist associations.*

Legislation to require an exam and continuing education for pharmacy technicians is dropped (AB 1947)

Board participates in CSHP sponsored stake holder meeting.

2nd Qtr 08/09: *Executive officer participates in a meeting with CPhA and CSHP to provide technical advice on proposed legislation to be introduced next year. Attend CSHP sponsored stakeholder meeting.*

3rd Qtr 08/09: *Senate Bill 418 introduced to add new requirements for technicians. SB 418 is later dropped for the year.*

8. **Implement the Department of Consumer Affairs Applicant Tracking System to facilitate implementation of I-Licensing system, allowing online renewal of licenses by 2008.**
Note: I-Licensing system has been cancelled and the BreEZe system will take its place.
July 2006: Executive officer becomes executive sponsor of program.
Nov. 2006: Board completes system identification of parameters for each licensing program.
Dec. 2006 - Jan. 2007: Preparatory work and pilots completed; board staff initiates transfer to ATS system as sole platform for applicant tracking for all licensing programs.
3rd Qtr 08/09: Request for Proposal for I-Licensing system modified to contain revised parameters. Staff changes in the Office of Information Services cause additional delay in moving the project forward. ATS project implemented.
2nd Qtr 09/10: Board advised of new initiative to facilitate online applicant submission and renewal.
4th Qtr 09/10: Board analyst temporarily assigned to assist on BreEZe project.
1st Qtr 10/11: Assistant Executive Officer chairs forms design workgroup to consolidate forms for all boards (reducing programming costs). Executive staff continue on BreEZe execution steering committee.
2nd Qtr 10/11: Board analyst continues to work with the department on the BreEZe project.
3rd Qtr 10/11: Executive staff and analyst continue to work with DCA on implementation issue.
4th Qtr 10/11: Board has assigned two analysts to work with DCA two days a week on the implementation of BreEZe. Executive Officer nominated to key position on change board. Assistant Executive Officer assumes role as project manager over forms consolidation. Two Board staff loaned to the project on a part-time basis.
1st Qtr 11/12: Board staff met with BreEZe staff to conduct final review of board requirements and work flow.
2nd Qtr 11/12: The board's subject matter experts continue to participate in working with the DCA in implementing BreEZe.
9. **Participate with California's Schools of Pharmacy in reviewing basic level experiences required of intern pharmacists, in accordance with new ACPE standards.**
3rd Qtr 06/07: Board attends 3 day-long working sessions convened by California's schools of pharmacy to develop list of skills students should possess by end of basic intern level experience (about 300 hours).
Oct. 2007: Board considers basic internship competencies developed under the program and develops letter of support.
Oct. 2008: California Pharmacy Council meets to discuss Intern requirements.
Dec. 2009: Licensing Committee again discusses the requirements given that other states are no longer transferring intern hours.

- 10. Implement new test administration requirements for the CPJE.**
- March 2007:* Board advised about new exam vendor for CPJE effective June 1, 2007. Board notifies all CPJE eligible candidates of pending change, advises California schools of pharmacy graduating students and applicants in general.
- June 2007:* Shift to new exam vendor, PSI, takes place. New Candidates Guide is printed and distributed. Some transition issues to new vendor exist and are being worked on.
- 4th Qtr 09/10:* Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
- 2nd Qtr 07/08:* Transition efforts to PSI continue.
- 3rd Qtr 07/08:* New security procedures put in place and corresponding revisions to the Candidates' Guide are published and released.
- 1st Qtr 09/10:* Competency Committee develops occupational analysis survey.
- 2nd Qtr 09/10:* Competency Committee develops new content online for CPJE.
- 3rd Qtr 09/10:* Board approves new job content outline submitted by the Competency Committee as a result of the job analysis with an effective date of 4/1/2011.
- 2nd Qtr 10/11:* Documents advising applicants of new exam structure developed and released.
- 3rd Qtr 10/11:* Board staff updated CPJE Candidate Information Bulletin and Web site for new Content Outline effective April 1, 2011.
- 4th Qtr 10/11:* New CPJE Content Outline implemented.
- 11. Participate in ACPE reviews of California Schools of Pharmacy.**
- Oct. 2007:* Board participates in review of California Northstate College of Pharmacy.
- Jan. 2008:* Board participates in review of UCSF.
- March 2008:* Board participates in review of Touro.
- 3rd Qtr 08/09:* Board participates in three ACPE reviews of the schools of pharmacy at USC, Touro and California Northstate.
- 3rd Qtr 09/10:* Board participates in ACPE review of the school of pharmacy at UOP.
- 12. Initiate review of Veterinary Food Animal Drug Retailer Designated Representative training.**
- Sept. 2007:* Licensing Committee initiates review of training requirements for Designated Representatives and notes problems with unavailability 40-hour course specified in board regulations.
- Oct. 2007:* Board evaluates options for training of designated representatives.
- Sept. 2008:* Licensing Committee hears testimony regarding program.
- June 2009:* Evaluation of designated representative training scheduled for September.

- 13. Convene Committee to evaluate drug distribution within hospitals.**
2nd Qtr 08/09: Executive Officer presents information at CSHP Seminar on failure of the recall system to remove Heparin from nearly 20% of California hospitals months after recall.
3rd Qtr 08/09: Board establishes subcommittee to initiate review.
March 2009: First meeting convened.
June 2009: Second meeting convened in San Francisco.
Sept. 2009: Third meeting convened in Sacramento.
Dec. 2009: Work of Hospital Subcommittee nearly completed. Board to review parameters for recalls at January 2010 meeting.
2nd Qtr 09/10: Document finalized.
- 14. Improve reporting of and accounting for intern hours.**
4th Qtr 08/09: Licensing Committee discusses how intern hours are reported to the board and specifics of where intern hours can be earned.
2nd Qtr 10/11: The new Intern Hours Affidavit form was approved by legal counsel.
3rd Qtr 10/11: New Intern Hours Affidavit form made available on the board's Web site.
4th Qtr 10/11: Intern hours affidavit form modified to more specifically detail compliance with statutory requirements.
- 15. Participate in initiatives to increase the number of pharmacists in California to meet demand.**
4th Qtr 08/09: Board executive staff attend forums aimed at ensuring continual growth in the number of pharmacists and pharmacy technicians in California.
- 16. Assess the operations of specialty pharmacy services.**
4th Qtr 08/09: Board initiates review of refill pharmacies.
2nd Qtr 10/11: Board considers request from PETNET Solutions for a waiver of security requirements for pharmacies to permit after hours maintenance of equipment without a pharmacist present. The board lacks the authority to waive California pharmacy law in the manner requested.
4th Qtr 10/11: Board staff work with Radio Pharmaceutical Company to address specific licensing requirement challenges.
- 17. Encourage use of technology where it benefits the public.**
June 2009: Presentation to Licensing Committee of new robotic technology to compound drugs in hospitals.
Oct. 2009: Automation equipment demonstrated to Board that would facilitate unit dose packaging in hospitals and allow for barcoding.
Jan. 2010: Demonstration to Board of patient medication instructions in various languages accessible by emerging software available to pharmacies.
4th Qtr 10/11: Board takes a support if amended positive on AB 377 (Solorio) which would include the use of barcode technology in a hospital that was a centralized hospital pharmacy for repackaging and compounding.
- 18. Secure the implementation of e-prescribing in California by the earliest possible date.**
4th Qtr 08/09: Licensing Committee sees presentation on e-prescribing pilot programs sponsored by the California HealthCare Foundation and CalPERS.
2nd Qtr 10/11: Board hears presentation by CalERx on the status of e-prescribing in California.
Executive Officer provides presentations on e-prescribing at annual CalERx meeting.
Board establishes an ad hoc task force to develop a guidance document on the e-prescribing of controlled substances.
3rd Qtr 10/11: Guidance document prepared and reviewed by board.
4th Qtr 10/11: Medical Board to review the section for prescribers.

- 19. Ensure the public receives necessary pharmaceuticals in emergency response activities to the H1N1 pandemic.**
4th Qtr 08/09: Board assists the California Department of Public Health in responding to distribution of Tamiflu and Relenza. Pharmacy law requirements regarding labeling and dispensing not waived as standard and necessary pharmacists care could still be provided.
2nd Qtr 09/10: Board continues to work with Department of Public Health on H1N1 distribution issues.
- 20. Automate fingerprint background results with the Department of Justice.**
2nd Qtr 09/10: Began working with the DCA to implement automation of background results for applicants to be automatically imported into the board's Applicant Tracking System (ATS).
3rd Qtr 09/10: Continued working with the DCA on developing programming specifics in order to go live on February 17, 2010. Board staff develops the procedures.
4th Qtr 09/10: Final revision to the procedures, trained staff, and assigned job task to staff. Board staff continues to manage automated process and resolve issues.
4th Qtr 10/11: Key staff position filled to manage automated responses and resolve issues.
- 21. Evaluate pharmacy technician, pharmacist, and intern pharmacist application process to identify areas for improvement and to modify the application requirements to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB).**
3rd Qtr 09/10: Staff reached out to pharmacy technician programs to advise them of statutory changes to the application fee. Staff revised pharmacy technician application after reviewing most common deficiencies for legal review.
4th Qtr 09/10: Staff reached out to pharmacy technician programs educating them on the most common application deficiencies.
1st Qtr 10/11: Staff finalized the draft pharmacy technician, pharmacist, and intern pharmacist application. Legal approved the draft pharmacy technician and intern pharmacist application.
2nd Qtr 10/11: Legal approved the pharmacist application. Proposal to initial a regulation change to update the pharmacy technician application at the Licensing Committee meeting. Licensing Committee made recommendations for board to pursue the changes to the pharmacy technician application. Licensing Committee made recommendations for board to pursue the changes to require "Self-Query" reports from the National Practitioners Data Bank – Healthcare Integrity and Protections Data Bank (NPDB-HIPDB) for the pharmacy technician, pharmacist, and intern pharmacist application for licensure. At the recommendation of the Licensing Committee, the board authorized the Executive Officer to take all steps necessary to initiate a rulemaking update to the pharmacy technician application form and NPDB/HIPDB self-query report.

3rd Qtr 10/11: Regulation change noticed to require self-query report with technician application.
The board approved to initiate a rulemaking file to add 1727.2 and to amend 1728 related to requiring an intern pharmacist and pharmacist applicant to submit a Self-Query from the NPDB-HIPDB.
The board approved to modify the Pharmacy Technician Application and direct staff to take all steps necessary to complete the rulemaking process.
The pharmacist examination and licensure application and intern pharmacist application was updated and made available on the board's Web site in a fillable format, which includes the new Intern Hours Affidavit form.

4th Qtr 10/11: The rulemaking package was submitted to DCA on June 29, 2011 for California Code of Regulations section 1793.5 pharmacy technician application.

1st Qtr 11/12: The rulemaking package was approved by OAL with an effective date of October 1, 2011.

The new pharmacy technician application was made available on the board's Web site.

Pharmacy technician programs were notified of the new application and requirements.

22. Implement Fingerprint Requirement for Pharmacist Renewal.

4th Qtr 09/10: Regulation approved by Office of Administrative Law (effective date of regulation is December 7, 2010).

Department drafted programming changes to accommodate requirement.
Board staff tested changes in a testing environment.

2nd Qtr 10/11: Obtained FBI approval through DOJ for job title on Live Scan for licensed pharmacists.

Board staff working with the department to implement importing automated fingerprint response into ATS.

Implementation delayed due to hiring freeze and approval by FBI of new category for reprinted pharmacists.

3rd Qtr 10/11: Staff added to the board's Web site the pharmacist renewal fingerprinting requirements for those licensed prior to 2001. Included on the Web site is the Live Scan form and instructions required for renewal. Staff developed the letter notifying pharmacist licensees that have been identified as to comply with this renewal requirement and forwarded to Legal for review and approval. Board staff continues to work with the DCA on programming requirements to facilitate implementation.

4th Qtr 10/11: Staff worked with DOJ and DCA to establish procedures for implementation in July 2011.

Letter finalized. Article included in *The Script* advising registered pharmacists of the requirement.

1st Qtr 11/12: Procedures implemented to import fingerprint responses directly from DOJ into the board's database.

Board notified pharmacists impacted by implementation of CCR 1702.

23. Evaluate licensing requirements for businesses seeking licensure that are under common ownership.

4th Qtr 09/10: Board staff developed standards for common ownership requirements.

24. Evaluate Continuing Education Requirement for Pharmacists

2nd Qtr 10/11: Board discussed a proposal to specify continuing education credit for pharmacists in specific content areas and forwarded to Licensing Committee.

Licensing Committee discussed multiple specific areas for optional continuing education. The committee decided to amend the regulation 16CCR 1732.2. to allow for continuing education hours for various specified activities.

Regulation 16CCR 1732.2. was noticed for public comment on Nov. 22, 2010.

3rd Qtr 10/11: Board approved based on Licensing Committee recommendation to pursue specific content areas for continuing education and authorized staff to investigate implementation.

Subcommittee of the Licensing Committee discussed possible course content and methods of requiring continuing education.

2nd Qtr 11/12: The licensing committee made a motion to 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.

The licensing committee made a motion to 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; and Drug Abuse.

25. Improve pharmacy technician application forms to reduce deficiencies and require HIPDB.

1st Qtr 10/11: Identify changes and initiate rulemaking process to adopt changes to application forms.

2nd Qtr 10/11: Additional enhancements identified, and returned to board for approval.

3rd Qtr 10/11: Regulation change initiated to require new application form.

Board adopts changes to implement via promulgation of regulations.

4th Qtr 10/11: The rulemaking package was submitted to DCA on June 29, 2011 for California Code of Regulations section 1793.5 pharmacy technician application.

1st Qtr 11/12: The rulemaking package was approved by OAL with an effective date of October 1, 2011.

The new pharmacy technician application was made available on the board's Web site.

Pharmacy technician programs were notified of the new application and requirements.

26. Require a self query HIPDB report as a condition for applying for a pharmacists intern and pharmacist license and as part of the application process to take the CPJE.

1st Qtr 10/11: Board approves concept and staff readies regulation changes to implement.

2nd Qtr 10/11: Board approves language to initiate rulemaking process.

4th Qtr 10/11: Rulemaking process initiated.

27. Implement AB1424 Tax Payor Notification

2nd Qtr 11/12: Board staff updated all initial and renewal applications as required by AB1424 to include the language approved by legal counsel by the January 1, 2012 effective date.

Board staff worked with the DCA to ensure each renewal application mailed by EDD includes the required insert as required by AB1424 to include the language approved by legal counsel by the January 1, 2012 effective date.

3rd Qtr 11/12: Board staff to work with the DCA to ensure AB1424 is implemented by July 1, 2012.

28. Implement Office of Statewide Health Planning and Development's (OSHPD) Manpower Assessment and Survey of Licensees

2nd Qtr 11/12: Board staff finalized and posted an on-line survey to assist OSHPD in their charge to serve as the repository for comprehensive data and standardize data collection tools and methods.

Board staff developed a notice advising pharmacist and pharmacy technician licensees of the OSHPD survey and encouraging participation. The notice was included in the renewal packet mailed to pharmacist and pharmacy technicians.

Title 16. Board of Pharmacy Proposed Language

To Amend 1793.5. in Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~04/11/2012~~)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.

(2) A description of the applicant's qualifications and supporting documentation for those qualifications.

(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).

(4) A sealed, original Self-Query from the National Practitioner Data Bank - Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207 and 4400, Business and Professions Code. Reference: Sections 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4402 and 4400, Business and Professions Code; and Section 11105, Penal Code.

**California State Board of Pharmacy**

1625 N. Market Blvd, N219, Sacramento, CA 95834

Phone: (916) 574-7900

Fax: (916) 574-8618

www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY

DEPARTMENT OF CONSUMER AFFAIRS

GOVERNOR EDMUND G. BROWN JR.

PHARMACY TECHNICIAN APPLICATION

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in an incomplete application and a deficiency letter being mailed to you. Please read all the instructions prior to completing this application. **Page 1, 2, and 3 of the application must be completed and signed by the applicant.** All questions on this application must be answered. If not applicable indicate N/A. Attach additional sheets on paper if necessary.

Applicant Information – Please Type or Print

Full Legal Name-Last Name	First Name	Middle Name	
Previous Names (AKA, Maiden Name, Alias, etc)			
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc)			
City	State	Zip Code	
Residence Address (if different from above)			
City	State	Zip Code	
Home#	Cell #	Work#	Email Address
Date of Birth (Month/Day/Year)	**Social Security No	Driver's License #	State

Mandatory Education (check one box)

Please indicate how you satisfy the mandatory education requirement in Business and Professions Code Section 4202(a).

High school graduate or foreign equivalent.

Attach a certified copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

Completed a General Education Development (GED)

Attach an official transcript or your GED test results.

TAPE A COLOR PASSPORT STYLE PHOTOGRAPH (2"X2") TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION
NO POLAROID OR SCANNED IMAGES
PHOTO MUST BE ON PHOTO QUALITY PAPER

Pharmacy Technician Qualifying Method (check one box)

Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to Section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

Attached is a certified copy of PTCB certificate – Date certified: _____

Attached is a certified copy of your military training DD214

Self-Query Report by the National Practitioner Data Bank Healthcare Integrity and Protection Data Bank (NPDB-HIPDB)

Attached is the sealed envelope containing my Self-Query Report from the NPDB-HIPDB. (This must be submitted with your application.)

FOR BOARD USE ONLY

Photo <input type="checkbox"/>	FP Cards/Live Scan <input type="checkbox"/>	License no. _____	App fee no. _____
Enf 1 st Check <input type="checkbox"/>	FP Cards Sent _____	Date issued _____	Amount _____
Enf 2 nd Check <input type="checkbox"/>	FP Fees <input type="checkbox"/>	Date expires _____	Date cashiered _____
Qualify Code _____	DOJ Clear Date: _____		
HIPDB <input type="checkbox"/>	FBI Clear Date: _____		

You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.

<p>1. Do you have a medical condition which in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks? If "yes," attach a statement of explanation. If "no," proceed to #2. Are the limitations caused by your medical condition reduced or improved because you receive ongoing treatment or participate in a monitoring program? If "yes," attach a statement of explanation.</p> <p>If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing medical condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>2. Do you currently engage, or have you been engaged in the past two years, in the illegal use of controlled substances?</p> <p>If "yes," are you currently participating in a supervised rehabilitation program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>Attach a statement of explanation.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>3. Has disciplinary action ever been taken against your pharmacist license, intern permit or technician license in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>4. Have you ever had an application for a pharmacist license, intern permit or technician license denied in this state or any other state? If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>5. Have you ever had a pharmacy permit, or any professional or vocational license or registration, denied or disciplined by a government authority in this state or any other state? If "yes," provide the name of company, type of permit, type of action, year of action and state.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>6. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state? If yes, provide company name, type of permit, permit number and state where licensed.</p>	Yes <input type="checkbox"/> No <input type="checkbox"/>																																
<p>7. Have you ever been convicted of any crime in any state, the USA and its territories, military court or foreign country?</p> <p>Check the box next to "Yes" if you have ever been convicted or plead guilty to any crime. "Conviction" includes a plea of no contest and any conviction that has been set aside or deferred pursuant to Sections 1000 or 1203.4 of the Penal Code, including infractions, misdemeanor, and felonies. You do not need to report a conviction for an infraction with a fine of less than \$300 unless the infraction involved alcohol or controlled substances. You must, however, disclose any convictions in which you entered a plea on no contest and any convictions that were subsequently set aside pursuant or deferred pursuant to sections 1000 or 1203.4 of the Penal Code.</p> <p>Check the box next to "NO" if you have not been convicted of a crime.</p> <p>You may wish to provide the following information in order to assist in the processing of your application: descriptive explanation of the circumstances surrounding the conviction (i.e. dates and location of incident and all circumstances surrounding the incident.) If documents were purged by the arresting agency and/or court, a letter of explanation from these agencies is required.</p> <p>Failure to disclose a disciplinary action or conviction may result in the license being denied or revoked for falsifying the application. Attach additional sheets if necessary.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr style="background-color: #cccccc;"> <th style="width: 15%;">Arrest Date</th> <th style="width: 15%;">Conviction Date</th> <th style="width: 35%;">Violation(s)</th> <th style="width: 35%;">Court of Jurisdiction (Full Name and Address)</th> </tr> </thead> <tbody> <tr><td> </td><td> </td><td> </td><td> </td></tr> </tbody> </table>	Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)																													Yes <input type="checkbox"/> No <input type="checkbox"/>
Arrest Date	Conviction Date	Violation(s)	Court of Jurisdiction (Full Name and Address)																														

APPLICANT AFFIDAVIT

You must provide a written explanation for all affirmative answers. Failure to do so will result in this application being deemed incomplete. Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being rejected as incomplete.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form as authorized by Business and Professions Code Sections 4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6. The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

Mandatory Submission. Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by Civil Code Section 1798.40.

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

*Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 et seq.) and the Public Records Act (Government Code Section 6250 et seq.) and will be placed on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address, you must also provide your residence address to the board, in which case your residence will not be available to the public.

**Disclosure of your U.S. social security account number is mandatory. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security account number. Your social security account number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security account number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a \$100 penalty against you.

NOTICE: Effective July 1, 2012, the State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if the state tax obligation is not paid.

MANDATORY REPORTER

Under California law, each person licensed by the Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect purposes.

California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of Section 11166 and Section 15630 is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars (\$1,000), or by both that imprisonment and fine. For further details about these requirements, consult Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and subsequent sections.

APPLICANT AFFIDAVIT

(must be signed and dated by the applicant)

I, _____, hereby attest to the fact that I am the applicant whose signature appears
(Print full Legal Name)

below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this application, including all supplementary statements. I also certify that I have read the instructions attached to this application.

Signature of Applicant

Date



California State Board of Pharmacy
 1625 N. Market Blvd, N219, Sacramento, CA 95834
 Phone: (916) 574-7900
 Fax: (916) 574-8618
 www.pharmacy.ca.gov

STATE AND CONSUMER SERVICES AGENCY
 DEPARTMENT OF CONSUMER AFFAIRS
 GOVERNOR EDMUND G. BROWN JR.

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying). All dates must include the month, day, and year in order for the form to be accepted.

This is to certify that _____ has
Print Name of Applicant

Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists as specified in Title 16 California Code of Regulations Section 1793.6(a) on _____/_____/_____ (completion date must be included)

Completed 240 hours of instruction as specified in Title 16 California Code of Regulations Section 1793.6(c) on _____/_____/_____ (completion date must be included)

Completed an Associate Degree in Pharmacy Technology and was conferred on her/him on _____/_____/_____ (graduation date must be included)

Graduated from a school of pharmacy accredited by the American Council on Pharmaceutical Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on her/him on _____/_____/_____ (graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:

Signed: _____ Title: _____ Date: _____/_____/_____

<p>Affix school seal here.</p> <p>OR</p> <p>Attach a business card of the pharmacist who provided the training pursuant to Section 1793.6(c) of the California Code of Regulation here.</p>	<p>University, College, or School of Pharmacy Name: _____</p> <p>Address: _____</p> <p>_____</p> <p>Print Name of Director, Registrar, or Pharmacist: _____</p> <p>Phone Number: _____</p> <p>Email: _____</p>
--	--