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

STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
LICENSING COMMITTEE MEETING
MINUTES

DATE: September 26, 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
Ryan Brooks, Public Member
Rosalyn Hackworth, Public Member
Deborah Veale, RPh

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Janice Dang, Supervising Inspector
Kristy Shellans, DCA Staff Counsel
Tessa Miller, Staff Analyst

Call to Order

Committee Chair Greg Lippe called the meeting to order at 9:35 a.m.

Chair Lippe conducted a roll call. Committee Members Lippe, Veale, Brooks, and Hackworth were present.

Board President Stanley Weisser was in attendance in the audience.

The committee discussed agenda items out of order.

2. Discussion Concerning Proposed Modifications to California Business and Professions Code Section 4209 Regarding Reporting of Intern Hours to the Board of Pharmacy

Chair Report

Chair Lippe provided that Business and Professions Code (B&PC) section 4209 specifies that an intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. He stated that this section also specifies that an intern pharmacist shall submit proof of his or her experience on a board-approved affidavit and established the criteria for submission.

Chair Lippe provided that until last year, the board accepted intern hours earned in another state, if the hours were either:

1. Verified by the state board of pharmacy in which the hours were earned or
2. Submitted board affidavits from each pharmacy where the intern has worked.

Chair Lippe provided that after recent review of this policy, it was noted that this intern hour verification was contrary to legal requirements established in B&PC section 4209(b). The result using only option #2 is a significant increase in staff resources to review the intern affidavits, not only regarding the separate hours earned by each intern, but also each pharmacist providing verification of the experience earned.

Chair Lippe provided that that staff recommends an amendment to 4209(b) to allow the board to accept verification from other state boards of pharmacy which will streamline our application process. He reviewed the proposed text provided below:

> 4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam
>
> (a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.
>
> (2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.
>
> (b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

Discussion

Committee Member Deborah Veale offered a proposal to recommend to the board to sponsor legislation to modify the section as proposed.

Public Comment

Steve Gray, representing Kaiser Permanente, expressed concern regarding subdivision (c) regarding experience obtained by an applicant licensed as a pharmacist in another state. He discussed that licensure in another state does not necessarily indicate that the applicant has experience working in a pharmacy. Dr. Gray suggested that an additional affidavit be required to certify that these individuals have experience working in a pharmacy.

Executive Officer Virginia Herold indicated that there are at least two states that do not require intern hours.

Assistant Executive Officer Anne Sodergren discussed that intern hour requirements vary by state. She advised that accreditation requirements for schools of pharmacy in all states include a specified amount of hours working in a pharmacy. Ms. Sodergren discussed that if an additional affidavit is required as suggested, applicants licensed in another state would have an additional criterion to meet that is not required for applicants in California.

Ms. Sodergren clarified that the amendment does not impact the current requirements under Section 1728 that prior to receiving authorization from the board to take the pharmacist licensure exam, applicants must submit proof of 1500 hours of pharmacy practice. She indicated that this requirement must be satisfied with a minimum of 900 hours of pharmacy practice experience obtained in a pharmacy and a maximum of 600 hours of pharmacy practice experience substantially related to the practice of pharmacy.

Discussion continued regarding the importance of training and experience earned in a pharmacy. Ms. Veale amended her proposal to expand the proposed modification to subdivision (c).

MOTION: Recommend to the board to sponsor legislation to modify Business and Professions Code section 4209 as provided below.

4209. Intern Pharmacist; Minimum Hours of Practice to Apply for Pharmacist Exam

(a) (1) An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination.

(2) This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.

(b) An intern pharmacist shall submit proof of his or her experience on board-approved affidavits, or another form specified by the board, which shall be certified under penalty of perjury by a pharmacist under whose supervision such experience was obtained or by the pharmacist-in-charge at the pharmacy while the pharmacist intern obtained the experience. Intern hours earned in another state may be certified by the licensing agency of that state to document proof of such hours.

(c) An applicant for the examination who has been licensed as a pharmacist in any state for at least one year, as certified by the licensing agency of that state, may submit this certification to satisfy the required 1,500 hours of intern experience provided that the applicant has obtained a minimum of 900 hours of pharmacy practice experience in a pharmacy as a pharmacist. Certification of an applicant's licensure in another state shall be submitted in writing and signed, under oath, by a duly authorized official of the state in which the license is held.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

3. Discussion About a Proposal to Specify Continuing Education Credit for Pharmacists in Specific Content Areas

Chair Report

Chair Lippe provided that at several prior meetings of the board or its committees, there has been general discussion about developing requirements for pharmacists to earn continuing education (CE) in specific subject matter areas. He stated that to establish such a requirement would take either a legislative or regulation change.

Chair Lippe provided that 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. He stated that any topic the board determines as appropriate for mandatory CE should have generally broad-based applicability for pharmacists.

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

Chair Lippe provided that B&PC section 4231 requires a pharmacist to earn 30 hours of approved continuing education credit every two years as a condition of renewal.

Chair Lippe provided that B&PC 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

Chair Lippe provided that the committee has heard a presentation from two pharmacy directors of California counties' emergency response team and how such a topic would be applicable as an appropriate mandatory CE course. He stated that additional suggested topics also brought to the committee for consideration included the following:

- Emergency/Disaster Response
- Patient Consultation
- Maintaining Control of a Pharmacy's Drug Inventory
- Patient Consultation
- 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 specific manner (e.g. live, web-based, journal, etc.).

Discussion

Ms. Herold suggested that the board consider pursing this change by regulation rather than by statute. She also suggested that preferential credits can be awarded to encourage licensees to earn CE in specific content areas of higher importance.

Ms. Veale indicated that the California Pharmacists Association (CPhA) has indicated that they are in opposition to mandating CE in specific content areas. She asked if specific CE is required in any other state.

Ms. Herold indicated that several states require specific CE coursework. She provided that the Medical Board has also required specific CE. Ms. Herold discussed that specific content areas should be broad, such as ethics or substance abuse, in order to benefit pharmacists practicing in a variety of settings.

Ms. Veale and Committee Member Rosalyn Hackworth spoke in support of considering substance abuse as a specific content area to address the board's discipline cases in this area.

Ms. Veale suggested that licensees be able to choose one or two content areas from a specified list.

DCA Staff Counsel Kristy Shellans provided that she disagrees with the recommendation to pursue this change by regulation. She stated that mandating CE in specific content areas will require statutory change.

Ms. Shellans discussed that incentivizing specific CE is an option the board can explore.

Ms. Veale offered a proposal that the board direct staff to research implementing incentives for licensees who earn CE in specific content areas. She also suggested that the board reconsider and possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

Public Comment

Steve Gray, representing Kaiser Permanente, spoke in support of the proposal and also encouraged the board to also consider pursuing a statutory change to require CE in specific content areas.

Committee Member Ryan Brooks asked if the board can provide guidance on recommended content areas without pursing a statutory change.

Ms. Shellans provided that Section 4232 provides flexibility with respect to the subject matters of the courses and the board can provide guidance in this area. She clarified that a statutory change is needed to mandate specific content areas.

Mr. Brooks requested that board staff explore this option.

Ms. Herold discussed that the board can encourage specific content areas in *The Script.*

MOTION: Direct staff to research implementing incentives for licensees who earn CE in specific content areas including ethics, substance abuse, emergency/disaster response and patient consultation. Recommend that the board reconsider and possibly decrease the amount of CE a licensee can earn by attending meetings of the board.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

The committee discussed CE formats including live, web-based, etc. It was clarified that requiring that licensees earn CE in a specific format would require a statutory change.

Ms. Shellans expressed concern regarding restricting how licensees can obtain CE as this issue has lead to a lawsuit for another board in the department. She advised that the board should be cautious about approaching this option.

Additional Public Comment
Steve Gray provided comment regarding the increasing degradation of the quality and value of CE. He discussed that CE, whether it is live or by another means, can be abused. Dr. Gray suggested that CE include an assessment to encourage active participation. He also suggested that the board consider proctored CE and encouraged the board to continue discussions to address this issue.

1. Review of Requests for Board Action to Become a Board of Pharmacy Approved Accreditation Agency for Licensed Sterile Injectable Compounding Pharmacies

Background
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.

The board has over 240 such licensed facilities in California, and approximately 90 nonresident pharmacies with such permits.

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.

There are three accreditation agencies approved by the board: 1. Accreditation Commission for Health Care, Inc (ACHC), 2. Community Health Accreditation Program (CHAP), and Det Norske Veritas (DNV).

The board also has specific regulation requirements to be followed by all pharmacies that perform sterile injectable compounding duties whether licensed by the board or accredited by one of three accreditation agencies. At the beginning of 2010, the board modified its regulations for pharmacies that compound medication. Included in these requirements are modified requirements for pharmacies that compound sterile injectable medication.

In 2003, the Licensing Committee developed criteria for approval of accreditation agencies for sterile injectable compounding pharmacies under Business and Professions Code section 4127.1, and generally that these criteria should assess the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors:

1. Periodic inspection -The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years. (Note during 2011 discussions with the accrediting agencies, the board urged annual inspections during the review process.)
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.

During prior reviews of the accrediting agencies, board staff were directed to (1) review and assess all accreditation agencies seeking board approval as accrediting agencies for sterile injectable compounding pharmacies, (2) bring staff’s report to a future

Licensing Committee Meeting, and (3) bring the committee's recommendations to the board for action at a future meeting.

Discussion

Supervising Inspector Janice Dang reviewed requests from two additional organizations seeking to become board-approved accrediting agencies for sterile injectable compounding pharmacies. She introduced Michael Zarski and Andrew Lowe, representing the American Osteopathic Association Healthcare Facilities Accreditation Program (HFAP), and Joe Cabaleiro, representing Pharmacy Compounding Accreditation Board (PCAB).

Mr. Zarski and Mr. Cabaleiro each provided an overview of their request and of their resepective organizations.

Dr. Dang provided an overview of her findings from an application review for both organizations. A copy of this review is attached, following this meeting summary.

Dr. Dang reviewed results of random inspections of two pharmacies accredited by each organization. She discussed that three of the four inspections were good with only minor corrections ordered. Dr. Dang reviewed her concerns with the inspection of the second pharmacy accredited by HFAP. She explained that this pharmacy had not addressed any discussion points pointed out during a previous inspection by the board about three months prior to her inspection. She stated that these issues were also not addressed by the HFAP survey team during their survey a week prior to Dr. Dang's inspection of the pharmacy.

Ms. Veale requested that HFAP research Dr. Dang's findings of the second HFAP accredited pharmacy and submit a written analysis to the board.

The committee discussed these findings and considered the organizations currently recognized by the board and the requirements set forth prior to their recognition as an accreditation agency. Both organizations were asked to respond to the following requirements:

- Survey teams will include a pharmacist.

  Mr. Zarski discussed that he believes that an organization already recognized by the board does not have a pharmacist on the survey team. He asked that the standards for all organizations be fair and consistent. Mr. Zarski indicated that it would take some time to restructure its survey teams to include a pharmacist.

  Mr. Cabaleiro provided that PCAB surveyor teams consist of all pharmacists.

  The committee discussed whether other organizations have committed to having a pharmacist on the survey team. Ms. Herold indicated that she will confirm and report back to the committee.

- Agency agrees to provide the board access to accreditation reports.

  Mr. Zarski discussed that HFAP will report deficiencies, serious noncompliance and denial or withdrawls of accreditation to the board.

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

  Ms. Herold provided comment on the importance of communication between the board and accreditation agencies, specifically regarding issues impacting patient safety.

  Ms. Shellans discussed that access to accreditation reports is critical to ensure patient safety and to verify that the accreditation agency is operating appropriately. She advised that the board needs to have access to these reports.

  The committee requested clarification regarding whether the other organizations currently recognized by the board have committed to sharing access to these reports.

- Agency agrees to conduct an annual inspection of each pharmacy.

  Mr. Zarski discussed that routine inspections will impact efficiency and lead to additional costs for the pharmacies. He stated that HFAP will conduct annual inspections if required by the board.

  Mr. Cabaleiro also discussed that annual inspections would increase costs for accreditation. He suggested that the board consider random inspection of ten percent of the pharmacies each year. He questioned whether other organizations have agreed to this annual inspection requirement.

  Ms. Herold discussed that the board requires annual inspections of accredited pharmacies to ensure a comparable standard of licensure by the board.

The committee discussed that clarification is needed regarding the requirements agreed to by other accreditation agencies recognized by the board. Staff agreed to research and report back to the committee.

Mr. Brooks suggested that the board establish clear guidelines for all accreditation agencies to follow.

Ms. Veale suggested that board staff develop a comparison of the current accreditation agencies and HFAP and PCAB to review and compare all criteria assessed during the application review and the requirements agreed to prior to recognition. She requested that the comparison be reviewed by the board at the October 2011 Board Meeting.

Ms. Hackworth provided comment in support of this comparison and stated that all organizations should be held to the same standard.

Chair Lippe advised that the board may approve accreditation of HFAP and PCAB after confirmation that they meet the same standards as required by the other accreditation agencies.

Mr. Brooks thanked Mr. Zarski and Mr. Cabaleiro for appearing before the committee. He indicated that the board will send a letter to notify them of the board's decision once the review is completed and the board approves each as a recognized accreditation agency.

Ms. Shellans recommended that the board establish guidelines for accreditation agencies prior to granting approval.

Mr. Cabaleiro provided comment regarding the variance in programs and procedures of the various accreditation agencies. He requested that the board takes this variance into consideration when conducting its comparison.

No public comment was provided.

MOTION: Direct board staff to develop a comparison of the current accreditation agencies and HFAP and PCAB to review and compare all criteria assessed during the application review and the requirements agreed to prior to recognition to be reviewed by the board at the October 2011 Board Meeting.

M/S: Veale/Hackworth

Support: 4 Oppose: 0 Abstain: 0

MOTION: 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.

M/S: Brooks/Veale

Support: 4 Oppose: 0 Abstain: 0

4. Discussion Concerning DCA's Focus on Continuing Competency

Discussion
Chair Lippe provided that the Department of Consumer Affairs has asked all boards to evaluate how they can ensure the continued competency of their practitioners.

Ms. Shellans advised that the board will be evaluated in this area during the upcoming sunset review process.

Ms. Herold provided that the National Association of Boards of Pharmacy (NABP) is developing an assessment for the board to use to evaluate competency. She advised that this assessment will be available in 2012 and will satisfy the department's requirement for continuing competency.

It was the consensus of the committee to defer this item to be discussed at the upcoming Board Meeting in October 2011.

No public comment was provided.

5. Office of Statewide Health Planning and Development's Manpower Assessment and Survey of Licensees

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.

Chair Report
Chair Lippe provided that the Licensing Committee of the board has discussed possible implementation strategies to assist OSHPD with their collection efforts. He stated that 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.

Chair Lippe provided that the committee was advised in March 2011 that the department was working with OSHPD on the development of a survey and that the board could provide a link via our website. He advised that board staff was advised that the department is no longer moving towards such implementation. Chair Lippe explained as a result, this item will be brought back to the Licensing Committee and the full board to discuss alternate implementation strategies.

Chair Lippe stated that as mandating submission of this information would require either a regulation and/or statutory change, board staff recommends that the board consider

development of a survey that could be accessed from the board's Web site. He discussed that an on-line resource such as Survey Monkey, could serve as an easy collection method that would have minimal impact on board staff.

Chair Lippe reviewed the following data to be collected:
(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.

Discussion
Mr. Brooks suggested that survey participation be incentivized to increase participation.

Ms. Sodergren discussed that this issue will also be addressed during the Board's sunset review. She asked the committee to consider first deploying the survey to begin collecting that data and then to later create an incentive for participation.

Ms. Shellans discussed that in this case, California law prohibits collection of personal data if it can be linked back to the individual who provided the data. She recommended that the survey not record the participant's license number or any other personal data.

Mr. Brooks recommended that a disclosure regarding voluntary participation be added to the survey.

Ms. Shellans offered to identify possible disclosure language for the survey.

Ms. Sodergren stated that she will work with board counsel on the survey to be reviewed by the board at the October 2011 Board Meeting.

No public comment was provided.

6. Competency Committee Report

Chair Report

California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chair Lippe provided that the board instituted a quality assurance review of the CPJE effective August 8, 2011. He stated that this process is done periodically to ensure the reliability of the examination. Chair Lippe indicated that as of the date of this report, the quality assurance review is still under review. He stated that the board anticipates releasing results by the beginning of October 2011.

Examination Development

Chair Lippe provided that both Competency Committee workgroups met in August 2011 at the annual meeting to discuss examination development. He stated that each Competency Committee workgroup will also meet once in the fall of 2011 for examination development.

There was no committee discussion or public comment.

7. Licensing Statistics

Chair Lippe referenced the licensing statistics that were provided to the committee. A copy of the statistics are attached, following this meeting summary.

There was no committee discussion or public comment.

8. Public Comment for Items Not on the Agenda

Steve Gray, representing Kaiser Permanente, provided comment regarding fraud and licensing of pharmacies. He suggested that this issue be discussed at a future meeting.

The meeting was adjourned at 12:22 p.m.

Table 1. Application Review for Pharmacy Compounding Accreditation Board (PCAB) and American Osteopathic Association – Healthcare Facilities Accreditation Program (HFAP)

Criteria	Pharmacy Compounding Accreditation Board (PCAB)	American Osteopathic Association, Healthcare Facilities Accreditation Program (HFAP)
1. Periodic Inspections	Surveys every 3 years. • 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.
2. Comparison of standards	Standards are developed with the participation of various authorities in the field of pharmaceutical compounding. • PCAB Board of Directors includes 7 organizations. • 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. Standards were submitted and compared to California compounding laws.	Standards were submitted and compared to California compounding laws. • Submitted HFAP hospital Chapter 25 Pharmacy Services/medication use – compounding sterile preparations (Supplement for California Hospitals), Sections 25.04 and 25.05.)

3. Surveyor's qualifications.	Surveyors are all registered pharmacists with extensive sterile and non-sterile compounding experience. • Receives initial and ongoing training on conducting on-site surveys, standards interpretation, and use of survey tools. • Training on CA compounding regulations and determining compliance with CA pharmacy laws. • If approved by BOP, will also conduct training on CA laws where there is no PCAB standard.	Surveyors are registered nurses. • Surveyors engaged in surveys of hospitals in CA will receive additional training related to surveying against the standards. • 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. • Primary instructor is Andrew Lowe, Pharm.D. Director of Pharmacy for Arrowhead Regional Medical Center.
4. Acceptance by major California payors	Accredits compounding pharmacies only. • 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.	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). Also recognized by California Statute CA Welfare and Institution Code section 14043.26.
5. Subjected to Unannounced inspections by BOP	Accredits pharmacies that compound non-sterile compounded drug products and sterile injectable compounded drug products. • 12 pharmacies accredited by PCAB in CA of which 5 pharmacies have LSC licenses with BOP. • 2 of the 5 pharmacies with an LSC license were inspected.	New standards for California pharmacies were written, but have not been implemented. Current pharmacies were surveyed on HFAP basic standards. • 25 hospital pharmacies HFAP accredited in CA. • 7 of 25 hospitals do not have an LSC license in CA. • 1 of 25 hospitals has a delinquent LSC license in CA.

6. Access to accreditation reports on individual pharmacies.	• Will need to check with legal dept if the report can be made available to the board upon request. A copy is provided to the pharmacy. • A copy is not available online. 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. Will notify the Board of situations where PCAB denies or revokes a pharmacy's accreditation.	HFAP requires responses to all deficiencies cited indicating the corrective action taken by the facility. Following CMS national protocols, HFAP conducts resurveys of facilities that have deficiencies cited at a full Medicare Conditions of Participation during a HFAP survey. 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. We would notify the Board if HFAP denies or withdraws an accreditation from a pharmacy.
7. Length of time accrediting agency has been operating as an accrediting agency.	Incorporated in 2004 with the first pharmacy licensed in 2004.	HFAP has been accrediting hospitals and other health types of healthcare facilities since 1945 and under Medicare since 1965.
8. Ability to accredit out-of-state pharmacies.	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.	• Is willing to provide the board annually a list of PCAB accredited pharmacies in CA. • To verify if a pharmacy outside of CA is PCAB accredited, the Board will be able to contact PCAB for verification.	Will provide annually, no later than July 1, a list of board licensed facilities that are accredited during the past 12 months.

10. Summary of random inspections conducted by the BOP.	PCAB Pharmacy #1: • Last LSC inspection 4/14/2011 with one correction to complete the compounding self assessment. • Accreditation period: 10/21/2010 to 10/20/2013. • Compounds sterile to sterile and non-sterile to sterile injectable drugs. Minimal compounding of non-sterile drug products (creams, ointments, capsules, etc.) • Reviewed and were in compliance: policies and procedures, compounding records, training records, equipment maintenance records, quality assurance program, end product testing, cleaning records, competency testing records, master formulas, physical environment, labeling, and acquisition and disposition records. • Does in-house sterility testing and contracts with a lab for quality assurance testing. • Discussion points: 1) recommend to add verifying licenses with the board's website of any wholesaler prior to purchasing to assure the pharmacy is conducting business with a reliable supplier; 2) electronic DEA 222 forms to document quantity and date received. • No corrections issued.	HFAP Pharmacy #1: • Last LSC inspection 10/13/2010 with one correction to complete the compounding self assessment. • Accreditation period: 2009 to 2012 • Hospital pharmacy, inpatient orders only. Capacity: 150 beds. Compounds sterile to sterile only. • Reviewed and were in compliance: policies and procedures, compounding records, training records, equipment maintenance records, quality assurance program, competency testing records, master formulas, physical environment, labeling and acquisition and disposition records. • Discussion point: 1. In process of revising quality assurance program to test for integrity, quality, strength and potency. • Two corrections were issued: 1. Interviewed PIC and housekeeping. Ceiling, walls and floors were cleaned weekly but was documented with housekeeping's initial with the daily cleaning. 2. Unable to locate the Power of Attorney to allow the second pharmacist to execute the DEA 222 order form for Schedule II drugs.
	PCAB Pharmacy #2: • Last LSC inspection 2/9/2011with no corrections issued. • Accreditation period: 2/19/2010 to 2/18/2013. • Compounds sterile to sterile injectables, non-sterile to sterile injectables and non-sterile compounded drug products (creams, ointments, tablets, capsules, etc.). • Reviewed and were in compliance: policies and procedures, compounding records, training records, equipment maintenance records, quality assurance program, end product testing, cleaning records, competency testing records, master formulas, physical environment, and labeling. • Does in-house sterility testing and contracts with a lab for quality assurance testing. • One correction issued: BPC 4081 for invoices not available during inspection. On invoices were kept offsite. No invoices were available for inspection.	HFAP Pharmacy #2; • Last LSC inspected 6/28/2011 with no corrections issued. Discussion points: 1. Written competency was not completed for the renewal period. 2. Remove corrugated boxes near the iso-barrier; limit boxes in area; obtain bins and shelves that are washable. 3. Requirement for master formula prior to compounding. 4. Requirement for compounding worksheets. 5. Requirement for qualitative and quantitative analysis. • Accreditation period: 2008 to 2011. Was surveyed by HFAP the week prior to the board's inspection. Report from HFAP was pending. Discussed HFAP preliminary report/exit interview with the Director of Quality Assurance who stated there was no deficiency with pharmacy services. Pharmacy was surveyed by a registered nurse. • Long term acute care hospital, inpatient only. Capacity 49 beds. Compounds sterile to sterile injectable drugs. • Reviewed and were in compliance: Equipment maintenance records, sterility testing records, competency testing records, physical environment and labeling.

		• Discussion points: 1. Staffed with one pharmacist and one tech only. Only pharmacist compounds. Pharmacist was self testing himself for competency. Recommend having another pharmacist to verify his compounding technique and written testing. 2. Daily cleaning being documented but not weekly cleaning for walls, ceiling and floors. 3. PIC in process of organizing a closet space into the sterile compounding area where the iso-barrier hood is located. Was in the process of removing corrugated boxes and placing IV solutions into plastic bins. • Three corrections were issued: 1. PIC was in the process of creating master formulas and was waiting for the next PT Committee meeting for approval. Will be utilizing master formula until approval. 2. Compounding records was not utilized. During inspection, PIC created a compounding record to record the required elements of CCR 1735.3 and was instructed to implement immediately. 3. Quality assurance testing only included quarterly sterility testing and was not designed to monitor and ensure integrity, potency, quality and strength.

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	168	102	132	152	118	101	84	94	114	217	627	539	2448
Pharmacist (initial licensing applications)	335	343	169	184	87	68	25	136	66	94	15	10	1532
Intern pharmacist	61	472	381	341	41	52	94	68	125	118	103	85	1941
Pharmacy technician	1074	955	870	930	776	886	831	760	1110	896	914	1088	11090
Pharmacy	22	28	28	22	27	23	20	20	32	19	24	33	298
Pharmacy - Temp	10	5	10	25	15	9	8	2	7	5	9	7	112
Sterile Compounding	3	2	2	3	8	3	2	2	3	3	5	3	39
Sterile Compounding NSC	2	2	2	5	0	3	2	3	0	2	1	2	24
Sterile Compounding - Temp	0	0	0	0	5	2	0	0	0	0	0	0	7
Clinics	4	2	8	8	0	3	8	7	6	4	1	3	54
Hospitals	6	0	0	17	10	1	2	0	3	0	3	0	42
Hospitals DRM													
Hospitals - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Nonresident Pharmacy	6	8	6	8	4	9	6	3	3	4	6	10	73
Nonresident Pharmacy - Temp	0	0	0	2	0	1	2	0	1	0	0	0	6
Licensed Correctional Facility	0	0	0	0	0	0	1	0	0	0	1	0	2
Hypodermic Needle and Syringes	2	2	3	1	1	1	1	2	0	0	1	5	19
Nonresident Wholesalers	10	10	9	7	10	13	6	10	8	12	8	13	116
Nonresident Wholesalers - Temp	0	0	2	3	0	1	1	0	1	0	0	0	8
Wholesalers	7	9	6	3	9	3	4	4	6	13	8	11	83
Wholesalers - Temp	0	1	0	0	0	0	0	0	1	1	1	1	5
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	1	1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives	43	42	39	49	25	32	43	29	48	45	77	33	505
Designated Representatives EXV	0	0	0	0	0	0	0	3	0	0	1	0	4
Total	1753	1983	1667	1760	1136	1211	1140	1143	1534	1433	1805	1844	18409

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

Issued	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Pharmacist	225	471	77	267	85	90	13	124	68	107	14	15	1556
Intern pharmacist	74	309	543	333	64	53	80	49	72	94	109	130	1910
Pharmacy technician	793	929	792	785	774	1042	383	857	740	621	514	106	8336
Pharmacy	24	18	23	17	28	26	25	26	14	28	12	24	265
Pharmacy - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Sterile Compounding	3	1	1	1	1	9	0	2	2	2	0	3	25
Sterile Compounding NSC	1	0	0	2	2	1	3	0	1	0	0	0	10
Sterile Compounding - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Clinics	9	6	3	1	3	5	7	4	16	9	5	3	71
Hospitals	2	1	0	3	6	9	10	3	0	1	0	1	36
Hospitals DRM	0	1	0	0	1	1	0	0	0	0	0	0	3
Hospitals - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Nonresident Pharmacy	4	0	10	6	4	5	4	8	7	4	6	5	63
Nonresident Pharmacy - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Licensed Correctional Facility	0	0	0	0	0	0	1	0	0	0	0	0	1
Hypodermic Needle and Syringes	1	0	2	2	1	1	0	2	0	1	1	1	12
Nonresident Wholesalers	4	3	4	7	12	6	3	12	9	2	3	15	80
Nonresident Wholesalers - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Wholesalers	4	6	6	3	5	4	0	8	8	2	3	10	59
Wholesalers - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	1	1
Veterinary Food-Animal Drug Retailer - Temp	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives	25	29	41	43	35	17	48	29	27	28	25	53	400
Designated Representative EXV	0	0	0	1	0	0	0	0	0	1	0	0	2
Total	1169	1774	1502	1471	1021	1269	577	1124	964	900	692	367	12830

Pending	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist Examination	725	566	622	605	498	487	384	356	358	384	928	901	901
Pharmacist Examination Eligible	1043	1043	979	799	825	760	744	629	677	706	755	1286	1286
Intern pharmacist	270	441	274	276	243	241	134	151	200	216	207	155	155
Pharmacy technician	2505	2550	2697	2693	2751	2465	2698	2585	2841	3073	3334	4366	4366
Pharmacy	75	81	85	90	86	80	65	58	68	65	75	84	84
Sterile Compounding	24	26	26	29	34	28	21	22	22	25	29	26	26
Clinics	29	26	23	28	26	24	26	28	19	15	12	14	14
Hospitals	8	8	6	13	23	13	4	4	4	3	5	6	6
Nonresident Pharmacy	43	51	40	44	44	46	47	42	38	36	36	43	43
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0	0	1	1	1
Hypodermic Needle and Syringes	12	15	12	11	11	11	9	8	8	6	6	10	10
Nonresident Wholesalers	78	86	74	72	69	76	68	66	67	79	84	82	82
Wholesalers	48	49	47	48	52	52	51	48	45	56	50	53	53
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0	0	0	0	0
Designated Representatives	188	197	180	175	163	181	153	158	181	192	232	217	217
Total	5048	5139	5065	4883	4825	4464	4404	4155	4528	4856	5754	7244	7244

Board of Pharmacy Licensing Statistics - Fiscal Year 2010/11

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN*	FYTD
Change of Pharmacist-in-Charge***													
Received	104	128	102	154	108	106	84	82	115	125	120	125	1353
Processed	118	132	99	136	123	90	60	76	160	65	148	110	1317
Pending	389	385	388	381	366	463	487	493	448	508	480	495	495
Change of Exemptee-in-Charge***													
Received	8	9	6	12	8	12	13	6	8	6	18	16	122
Processed	4	0	7	0	0	0	0	9	7	4	9	1	41
Pending	108	117	116	128	136	148	161	158	159	161	170	185	185
Change of Permits													
Received	48	69	54	43	59	53	67	46	59	66	47	55	666
Processed	4	44	15	39	38	159	74	44	102	26	67	26	638
Pending	222	247	286	303	324	218	211	213	170	210	190	219	219
Discontinuance of Business***													
Received	20	21	10	24	17	78	n/a	1	26	17	20	13	247
Processed	0	0	28	1	0	78	0	2	0	16	1	58	184
Pending	135	156	138	162	179	179	179	178	204	205	224	179	179

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY*	JUN*	FYTD
Renewals Received													
Pharmacist	1574	1340	3322	2317	1054	1696	1455	980	1530	1209	475	131	17083
Pharmacy technician	2958	2262	4676	2504	1875	2595	2219	1727	2401	1993	1159	500	26869
Pharmacy	407	298	507	879	226	692	329	456	1441	568	480	9	6292
Sterile Compounding	26	17	76	39	23	30	13	18	19	22	7	1	291
Sterile Compounding NSC													71
Clinics	106	68	145	91	47	80	92	84	74	82	30	5	904
Nonresident Pharmacy	31	20	70	18	18	27	21	23	26	24	8	3	289
Licensed Correctional Facility	0	0	0	0	49	0	0	0	0	0	0	0	49
Hypodermic Needle and Syringes	17	10	50	28	23	33	18	17	13	18	9	6	242
Nonresident Wholesalers	56	43	86	35	43	33	39	28	45	54	15	6	483
Wholesalers	73	27	87	26	37	42	31	24	52	35	13	3	450
Veterinary Food-Animal Drug Retailer	2	1	5	2	3	4	2	1	0	0	1	0	21
Designated Representative EXV													59
Designated Representative	258	185	416	179	170	255	184	226	258	237	70	20	2458
Total	5508	4271	9440	6118	3568	5487	4403	3584	5859	4242	2267	684	55561