California State Board of Pharmacy
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STATE BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
PUBLIC BOARD MEETING
MINUTES

DATE: May 2-3, 2018

LOCATION: Sheraton Mission Valley San Diego – Connections Ballroom
1433 Camino Del Rio S.
San Diego, Ca 92108

BOARD MEMBERS PRESENT:
Amy Gutierrez, PharmD, President
Victor Law, RPh, Vice President
Allen Schaad, RPh, Treasurer
Greg Lippe, Public Member
Valerie Muñoz, Public Member
Deborah Veale, RPh
Ricardo Sanchez, Public Member
Albert Wong, RPh
Lavanza Butler, RPh
Stanley Weisser, RPh

BOARD MEMBERS NOT PRESENT:
Amjad Khan, Public Member
Ryan Brooks, Public Member

STAFF PRESENT:
Virginia Herold, Executive Officer
Anne Sodergren, Assistant Executive Officer
Laura Freedman, DCA Counsel
Kelsey Pruden, DCA Counsel
Desiree Kellogg, Deputy Attorney General
Laura Hendricks, Staff Analyst

I. Call to Order, Establishment of Quorum and General Announcements

President Gutierrez called the meeting to order at 11:04 a.m. Board members present: Gregory Lippe, Albert Wong, Deborah Veale, Allen Schaad, Lavanza Butler, Victor Law, Amy Gutierrez, Valerie Munoz, Ricardo Sanchez and Stanly Weisser.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

There were no comments from the board or from the public.

III. February 6-7, 2018 Board Meeting Minutes

There were no comments from the public or from the board.

Motion: Approve the February 2018 board meeting minutes.

M/S: Weisser/Law

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

IV. March 27, 2018 Board Meeting Minutes

Motion: Approve the March 2018 board meeting minutes.

M/S: Weisser/Law

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale			x	
Weisser	x			
Wong	x			

V. Recognition and Celebration of Pharmacists Licensed in California for 50 Years

There were no 50-year pharmacists in attendance.

VI. Board Officer Elections

Dr. Gutierrez thanked the board members for their support during her term as president of the board.

Board President

Motion: Elect Victor Law as president of the board.

M/S: Sanchez/Lippe

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Board Vice President

Motion: Elect Gregory Lippe as vice president of the board.

M/S: Law/Weisser

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

Board Treasurer

Motion: Re-elect Allen Schaad as treasurer of the board.

M/S: Weisser/Butler

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

VII. Update from the Department of Consumer Affairs

a. Update on the Salary Category Level Increase for the Position of Executive Officer

Christopher Castrillo, Deputy Director of Board and Bureau Services, reported that the salary level increase was denied by agency. Mr. Castrillo stated that the executive office is open to helping the board appeal the decision.

Mr. Castrillo explained that the department is conducting a study on executive officer salaries for all DCA boards and bureaus. He noted that the last study was completed in 2011. Mr. Castrillo stated that the department will be contracting with an outside vendor to complete the study, which will include an updated duty statement for executive officers and salary comparisons to other states. He reported that the results of the study are expected in January 2019.

Board member Veale asked if the salary level increase was denied because agency wanted a study conducted. Mr. Castrillo responded that no reason was given for the denial.

Board member Weisser asked why the study was being conducted by an outside vendor. Mr. Castrillo explained that they want a nonbiased, third party to conduct a robust study.

The board expressed how important the salary level increase is because of how much the board's workload and oversight have increase in the last few years. They also noted that it is negatively effecting the assistant executive officer's salary.

The board asked when they should appeal the decision. Mr. Castrillo recommended submitting another request after the next executive officer evaluation is completed.

The board again expressed how important a salary level increase is in order to retain and recruit quality executive staff. Mr. Castrillo agreed and stated that the department would assist the board however it can to secure an appropriate salary level for the position of executive officer.

b. Other Items

Mr. Castrillo announced that the department has hired Dennis Cuevas-Romero as the new Deputy Director of Legislation.

Mr. Castrillo reported that the department is conducting Licensing and Enforcement workgroups with expert staff from all boards and bureaus to establish best practices for enforcement and licensing processes.

Mr. Castrillo explained that SB 796 (Hill, 2017, Chapter 600) requires the Department of Consumer Affairs to reconvene the Substance Abuse Coordination Committee (SACC) to specifically review the existing criteria for Uniform Standard #4 related to drug testing. The committee must determine whether the existing criteria for Uniform Standard #4 should be updated and report to the Legislature by January 1, 2019.

Mr. Castrillo explained that the Committee will be comprised of the executive officers of the Department of Consumer Affairs' healing arts boards, a designee of the State Department of Health Care Services, and will be chaired by the Director of Consumer Affairs. He noted that the director may invite individuals or stakeholders who have expertise in the area of substance abuse to advise the Committee.

Mr. Castrillo stated that the next board member orientation trainings would be held in Sacramento on June 6, September 18, and December 5. He also noted that the department is working on holding an orientation in the Los Angeles area.

The board thanked Mr. Castrillo for his update.

VIII. <u>Licensing Committee</u>

a. Discussion and Consideration of Patient Consultation Requirements for Mail Order Pharmacies or Nonresident Pharmacies – Recommendation to Amend Regulations

Chairperson Weisser reported that at prior meetings of the Licensing Committee and of the board, there has been discussion on consultation that is provided to patients who receive medication via mail order or delivery. While acknowledging the benefits of convenience, the board's discussions have included:

- Whether patients are receiving essential information about how to take medications appropriately.

- Whether the current requirements for mail order and nonresident pharmacies are sufficient to ensure patients have access to a pharmacist for consultation.
- Whether a pharmacist is available to assist patients and the pharmacist can be reached upon patient request.
- Whether translation services are available when needed and how patients are advised about such services.
- Whether patients know where to go with complaints.

Chairperson Weisser noted that according to data available to the board, about 25 percent of pharmaceutical sales goes to mail order pharmacies.

Chairperson Weisser explained that the Licensing Committee made the following recommendation at its January 16, 2018, meeting.

> Modify 16 CCR section 1707.2 as provided below.
>
> **1707.2(b)(1)** In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:
>
> **1707.2 (b)(2)(B)** A telephone number shall be provided to the patient from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record. The pharmacists shall be available to speak to the patient no less than six days per week, and for a minimum of 40 hours per week and the call shall be answered by a pharmacist within two minutes.

Chairperson Weisser reported that the committee discussed the proposed modification again at its April 19, 2018, committee meeting.

Chairperson Weisser stated that during the April 19, 2018, committee meeting the board's Chief of Enforcement provided a presentation on complaints received by the board concerning mail order pharmacies. The committee noted that while the data sample used in the presentation was limited, it did illustrate that there are problems with patient interactions and mail order pharmacies, especially regarding how difficult it can be to speak with a pharmacist.

Chairperson Weisser explained that during the meeting the committee discussed the need to balance overregulation with the board's mandate to ensure that patients, who are often required by their insurance to use mail order pharmacies, receive appropriate care.

Chairperson Weisser reported that as part of its deliberations, the committee reviewed 16 CCR section 1707.2. The committee reconsidered if it is realistic to require phone calls in a mail order pharmacy to be answered by a pharmacist within two minutes. The committee also considered if a retail pharmacy that provides delivery services should also be required to have a pharmacist available to answer the

phone within two minutes of a patient calling. Chairperson Weisser stated that members of the public commented that two minutes is an unrealistic time frame, especially considering there is often only one pharmacist on duty in a retail setting and it usually takes the patient a few minutes to ask a question.

Chairperson Weisser reported that after further discussion and additional input from the public, the committee determined that a patient of a mail order pharmacy or a patient who has his or her medications delivered should be able to speak to a pharmacist on the phone within an average of 10 minutes. If the pharmacist will be unable to speak to the patient within 10 minutes, then a return call must be scheduled to occur within one hour. Chairperson Weisser stated that the committee also clarified that customer service representatives, clerks or other ancillary pharmacy staff can still triage calls to determine if patients need help with non-pharmacy related questions (billing, insurance, delivery, etc.).

Chairperson Weisser stated that the committee directed staff to develop draft regulation language to modify 16 CCR section 1707.2 to require that a pharmacist shall be available to speak with a patient within an average of 10 minutes or less or shall schedule a return phone call within one hour, and present it at the May 2018 board meeting for consideration.

Chairperson Weisser explained that following the committee meeting, board staffed work with legal counsel to draft language for the board's consideration (provided below).

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;~~.~~

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:~~(3~~A~~) whenever the prescription drug has not previously been dispensed to a patient; or

(4~~B~~) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.

(b)(1~~2~~) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail, or delivery), a pharmacy shall ensure that ~~the patient receives written notice~~:

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of ~~a~~ the hours of availability and the

telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(C) -A pharmacist~~s~~ shall be available (i) to speak to the patient or patient's agent [during any regular hours of operation], within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one [business] hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2~~3~~) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

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DCA Legal Counsel Laura Freedman stated that staff drafted the language (above) based on the committee's discussion. The board thanked staff and legal counsel for their work and spoke in support of the language.

Representatives from CPhA and Express Scripts spoke in support of the language.

A representative from Kaiser stated that Kaiser supports the goal of the language but has concerns about the ten minutes or less requirement. The representative asked where the requirement to return calls "no less than six days per week" came from. Ms. Herold stated that it is already a statutory requirement for mail order pharmacies to be available six days per week for a minimum of 40 hours per week.

Motion: Approve the proposed amendment to Title 16 CCR Section 1707.2 (as provided below) and initiate the formal rulemaking process. Further, delegate to the executive officer the authority to make any non-substantive changes and clarifying changes consistent with the board's policy direction upon recommendations of the control agencies.

§ 1707.2. Duty to Consult

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all ~~care~~ settings:

(1) upon request; ~~or~~

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment;~~.~~

~~(b) (1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is~~

~~present:~~(3~~A~~) whenever the prescription drug has not previously been dispensed to a patient; or

(4~~B~~) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength, or with the same written directions, is dispensed by the pharmacy.

(b)(1~~2~~) When the patient or patient's agent is not present (including, but not limited to, a prescription drug that was shipped by mail, or delivery), a pharmacy shall ensure that ~~the patient receives written notice~~:

(A) the patient receives written notice of his or her right to request consultation; ~~and~~

(B) the patient receives written notice of ~~a~~ the hours of availability and the telephone number from which the patient may obtain oral consultation from a pharmacist who has ready access to the patient's record.

(C) ~~-~~A pharmacist~~s~~ shall be available (i) to speak to the patient or patient's agent [during any regular hours of operation], within an average of ten (10) minutes or less, unless a return call is scheduled to occur within one [business] hour, (ii) for no less than six days per week, and (iii) for a minimum of 40 hours per week.

(2~~3~~) A pharmacist is not required by this subsection to provide oral consultation to an inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the patient's discharge. A pharmacist is not obligated to consult about discharge medications if a health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

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M/S: Weisser/Veale

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			

Wong	x			

b. Discussion and Consideration of Mail Order Pharmacies or Nonresident Pharmacies Requirements to Notify Patients of the Availability of Translation Services and to Notify Patients of How to File a Complaint with the Board

Chairperson Weisser explained that during the January 16, 2018, Licensing Committee meeting, members discussed concerns regarding mail order patients not receiving translation information as well as notification on how to file a complaint with the board.

Chairperson Weisser reported that during the April 19, 2018, meeting committee members heard testimony from representatives of mail order pharmacies regarding what information is currently provided to patients on the availability of translation services and the number of patients who use the translations services.

Chairperson Weisser stated that after hearing the testimony from the public, the committee determined that more information should be gathered to determine if there is actually a problem with patients not receiving information on translation services. The committee directed board staff to work with some of the large mail order pharmacies to determine how many patients use translation services, what information is currently provided to patients when they receive their medication and how patients are provided the information (paper handouts, emails, website, text, etc.). Chairperson Weisser noted that the committee asked that this information be provided at the next Licensing Committee meeting for discussion and consideration.

There were no comments from the board of from the public.

c. Update on Implementation of Board-Provided Law and Ethics Continuing Education Courses

Chairperson Weisser explained that a new requirement for pharmacist license renewal is that two of the 30 units of continuing education credit required must be earned by completing a board-provided CE program in law and ethics. This requirement becomes effective for all pharmacist renewals after July 1, 2019. The specific requirement is provided below:

> **1732.5. Renewal Requirements for Pharmacist.**
> (a) Except as provided in section 4234 of the Business and Professions Code and section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
> (b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.
> (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.

Chairperson Weisser reported that board staff has developed a program that covers 2018 new pharmacy laws. This program has been presented live several times and has been taped for placement on the board's website. However, this program does not contain an ethics component.

Chairperson Weisser noted that when the requirements for the CE program were developed, the board did not discuss in depth what it intended to include in an ethics course.

Chairperson Weisser reported that during the committee meeting board staff reported that the "2018 New Pharmacy Law" webinar is in the final stages of development. The webinar will be available on the board's website and will contain quiz questions to ensure that pharmacists are participating in the webinar. Board staff stated that an ethics webinar could be created in a similar format.

Chairperson Weisser stated that during the meeting members of the public asked whether the law and ethics courses must be provided by the board or if courses could be created and provided by an outside entity. Board staff explained that when the board created the requirement in 1732.5, they specifically drafted it so that the two hours of CE on law and ethics must be provided by the board. Chairperson Weisser explained that this ensures that the CE is free to all pharmacists and that the content of the CE comes from the board. Board staff further clarified that subject matter experts could be used to assist the board with creating content for a CE course; however, the course would still be provided by the board at no cost to licensees via the board's website and at live events.

Chairperson Weisser reported that as part of its deliberations the committee reviewed the materials from Dr. Yoshizuka and Dr. Rice and recommended that board staff use them as subject matter experts when creating an ethics CE course.

Chairperson Weisser stated that the committee directed board staff to work with subject matter experts to develop a CE course that focuses on ethical issues that arise in practice and uses board investigations and enforcement actions as examples of what a pharmacist "could/should/would do" when an ethical issue occurs. He noted that the committee will continue to receive updates on the status of this project.

Executive officer Virginia Herold asked the board if the Joint DEA and Board of Pharmacy Training programs should be allowed to count towards the renewal requirements in 1732.5. The board confirmed that as the training contains information on pharmacy law it should be allowed to be used towards the two-hour requirement in 1735.2.

Daniel Martinez stated that CPhA would like to have the option for other entities to provide the courses in addition to the coursed being offered by the board.

d. Update on Implementing Pharmacists Licenses with Photo Identification – Recommendation to Amend Law and Regulations

Chairperson Weisser explained that the board has encountered individuals posing as pharmacists and providing fake licenses for employment purposes. This is a threat to the health, safety and welfare of Californian consumers. He stated that an unlicensed person posing as a pharmacist does not meet the educational and experiential minimum qualifications for licensure and may cause patient harm.

Chairperson Weisser reported that at the July 2017 Licensing Committee meeting, board staff proposed implementing photo identifications for pharmacists. Board staff recommended a phased approach starting with new licensees and gradually adding current licensees based on the licensees' renewal.

Chairperson Weisser stated that at the July 2017 board meeting, the board affirmed the committee's recommendation to proceed with implementing photo identifications for pharmacists by July 2018. The board directed staff to use a phased approach, beginning with newly licensed pharmacists and adding current pharmacists based on their renewal. The board also discussed the need to have the photos updated periodically and have licensees pay the vendor directly for the photo identification.

Chairperson Weisser explained that following the July 2017 board meeting staff determined that while the current pharmacist pocket license states, "Please sign and carry the Pocket License with you" there is no authority to require pharmacists to carry their pocket license on their person. Additionally, the board does not have the authority to require a pharmacist, upon initial licensure or renewal, to pay an additional fee to a vendor for a photo identification without a change in regulation or statute. Chairperson Weisser stated that in light of this information, board staff bought this item back to the committee and recommends implementing a voluntary pharmacist photo identification program while simultaneously pursuing a regulation to make the pharmacist photo identification a requirement in regulation.

Chairperson Weisser explained the process to implement the voluntary program followed by a mandatory program as provided below.

Voluntary Phase with Tracking

The board may begin offering the option for pharmacist photo identification as soon as the contract with the current exam vendor PSI can be amended and the programming and/or manual tracking can be implemented. PSI currently administers the CPJE and will provide for an easy transition. While PSI does not offer biometrics, safeguard measures will be added that will serve a similar purpose for unique identification and verification. PSI offers locations in California and throughout the US for current licensees to take their photograph. Exam candidates would be notified through exam instructions, exam candidate handbooks and the board website. Current pharmacists would be notified through subscriber alerts, the website, and newsletter articles. The board would track when new and current licensed pharmacists obtain photo identification.

Mandatory Phase with Continued Tracking

Upon promulgation of the regulation, the board would require all active pharmacists to maintain a photo identification and to update the photo every 10 years.

Board member Lippe and Schaad expressed their concern with the requirement and questioned if it would actually prevent someone from impersonating a pharmacist. Ms. Veale stated that the committee felt that it would at least create another barrier and would also help the board's inspectors identify staff when they are in a pharmacy.

Ms. Herold noted that the board of registered nursing uses a similar photo identification program.

Board member Law asked if DMV information could be shared with the board to help identify pharmacists. Christopher Castrillo stated that the Department would be willing to assist the board in implementing a photo ID program if needed.

Members of the public stated that creating a photo ID for pharmacists is unnecessary and outdated and recommended that the board look into other ways to use technology to identify pharmacy staff

Ms. Herold stated that even if the board does not decide to implement a photo ID program, staff will work to educate pharmacy owners/managers that they need to take steps to confirm an applicant's ID.

The board took a vote to see if a majority of the members would support implementing a photo ID program as presented. Six board members opposed implementing a photo ID program and only four members supported it.

Following the vote, the board discussed other ways to incorporate technology into the identification of pharmacists, including placing licensees' photos on the board's website. Laura Freedman stated that in order to place photos on the board's website the board would need pursue a change to the Information Privacy Act.

Chairperson Weisser stated that based on the board's vote the entire photo ID program would not move forward.

e. Discussion and Consideration to Amend Business and Professions Code Section 4200(a)(6) Relating to the North American Pharmacist Licensure Examination (NAPLEX) and the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE)

Chairperson Weisser explained that Business and Professions Code (BPC) section 4200 establishes the licensing requirements for a pharmacist. BPC section 4200 (a)(6) requires the board to accept a passing examination score on the NAPLEX and the CPJE on or after January 1, 2004.

Chairperson Weisser stated that BPC section 4200.3 requires the examination process shall be regularly reviewed pursuant to BPC section 139 and meet established

standards and guidelines.

Chairperson Weisser also explained that BPC section 139 establishes occupational analyses and examination validation studies are fundamental components of licensure programs. BPC section 139 requires the Department of Consumer Affairs (DCA) to develop policy regarding examination development and validation, and occupational analysis for all boards, programs, bureaus and divisions under its jurisdiction.

Chairperson Weisser explained that as required by BPC section 139, DCA developed a Licensure Examination Validation Policy (policy). The policy requires boards offering licensure examinations to conduct an occupational analysis every five years so that a detailed content outline (DCO) may be developed based on current professional practice. From the DCO, the licensure examination is developed. He noted that the policy also outlines requirements for ensuring validation of the licensing examination.

Chairperson Weisser stated that the board currently administers the CPJE as one of the required examinations for licensure in California as a pharmacist. Pharmacist licensure candidates must obtain a passing score on both the CPJE and NAPLEX prior to being licensed as a pharmacist.

Chairperson Weisser reported that every five years, as part of the occupational analysis, the profession of pharmacy in California is reassessed. The analysis includes a review of job-related critical tasks and the knowledge, skills and abilities necessary to practice pharmacy in California. He explained that based on the reassessment of the profession, the DCO is updated to ensure the licensure examination reflects current pharmacy practice in California.

Chairperson Weisser reported that recently board staff has noticed a trend of pharmacist applicants having passed the NAPLEX and/or the CPJE more than five years ago. Because the occupational analysis is conducted every five years, a passing score from more than five years ago does not demonstrate that the applicant has met the minimum qualifications based on current practice standards. For example, the most recent occupation analysis of the CPJE was completed in 2014; therefore, if a candidate passed the CPJE in 2012, the passing score no longer represents a demonstration of minimum competency in 2018.

Chairperson Weisser explained that the intent of BPC sections 4200, 4200.3 and 139 is to ensure that an applicant is issued a pharmacist license relatively soon after receiving a passing score on both the CPJE and NAPLEX. However, pursuant to BPC section 4200, the board may license a pharmacist licensure candidate who has passed the NAPLEX and CPJE on or after January 1, 2004. As currently written, BPC section 4200 is not aligned with the intent of BPC section 139 and DCA's Licensure Examination Validation Policy, as passing scores are being accepted in accordance with statute without regard to when the most recent occupational analysis was conducted.

Chairperson Weisser stated that board staff reached out to the DCA's Office of Professional Examination Services (OPES) regarding this issue. OPES advised board staff that an examination score is only valid during the current occupational analysis

and examination content.

Chairperson Weisser noted that the board currently has 44 applicants who passed the CPJE over five years ago. Additionally, the board has 256 applicants who passed the NAPLEX over five years ago and do not hold a pharmacist license in another state. He stated that if the board amends the regulations, it would result in these applicants having to retake the CPJE and/or NAPLEX.

Chairperson Weisser explained that during the committee meeting members discussed the importance of having applicants demonstrate that they have met the minimum competency requirements to practice pharmacy in California at the time of application for licensure. The committee noted that the practice of pharmacy has changed drastically in the past few years and an exam from 2004 would not reflect the current practice standards in 2018.

Chairperson Weisser stated that the committee also discussed only accepting a NAPLEX passing score from the current occupational analysis *unless* the applicant is currently licensed as a pharmacist in another state.

Chairperson Weisser reported that the committee reviewed the process of conducting an occupational analysis every five years, including a review of job-related critical tasks and the knowledge, skills and abilities necessary to practice pharmacy.

Chairperson Weisser stated that the committee heard testimony from faculty of Chapman University School of Pharmacy stating that the only way to ensure that applicants have the appropriate knowledge to practice pharmacy is to have them pass the CPJE and NAPLEX during the current content outline.

Chairperson Weisser reported that as part of its deliberation the committee also discussed the need to allow a grace period after a content outline expires to give an applicant who passed the exam at the very end of the current content outline time to complete the application process with the board.

Chairperson Weisser explained that the committee directed staff to draft language to amend its regulations to only accept a CPJE passing score during the current occupational analysis and exam content. Additionally, the committee directed staff to draft language to amends its regulations to only accept a NAPLEX passing score from the current occupational analysis *unless* the applicant is currently licensed as a pharmacist in another state.

Chairperson Weisser reported that following the committee meeting, board staffed work with legal counsel to draft language based on the committee's direction (below).

Ms. Sodergren noted that this proposal would require a statutory change.

Proposal to Amend Section 4200 of the Business and Professions Code as follows:

4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees

(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

(2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or

(B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.

(3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.

(4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.

(5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.

(6) Has passed the North American Pharmacist Licensure Examination ~~and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.~~ and satisfies one of the following:

(A) (i) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and (ii) holds an active pharmacist license in another state or territory of the United States;

(B) Has passed a version of the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(7) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.

(b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.

(c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

The board discussed the proposed language and agreed that applicants must demonstrate that they have the current knowledge and abilities to practice pharmacy in California and that the way to ensure this is to require that applicants pass the CPJE and NAPLEX during the current content outline. Ms. Veale reminded that board that if you are licensed in another state an applicant would not need to retake the NAPLEX before applying to the board.

A pharmacist spoke in support of the language and thanked the board for creating the

NAPLEX exemption for pharmacists who are licensed in other states.

Motion: Pursue a statutory amendment to Section 4200 of the Business and Professions Code as follows.

> **4200. Pharmacist License Requirements: Age; Education; Experience; Examination; Proof of Qualifications; Fees**
> (a) The board may license as a pharmacist an applicant who meets all the following requirements:
> (1) Is at least 18 years of age.
> (2) (A) Has graduated from a college of pharmacy or department of pharmacy of a university recognized by the board; or
> (B) If the applicant graduated from a foreign pharmacy school, the foreign-educated applicant has been certified by the Foreign Pharmacy Graduate Examination Committee.
> (3) Has completed at least 150 semester units of collegiate study in the United States, or the equivalent thereof in a foreign country. No less than 90 of those semester units shall have been completed while in resident attendance at a school or college of pharmacy.
> (4) Has earned at least a baccalaureate degree in a course of study devoted to the practice of pharmacy.
> (5) Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Section 4209.
> (6) Has passed the North American Pharmacist Licensure Examination ~~and the California Practice Standards and Jurisprudence Examination for Pharmacists on or after January 1, 2004.~~ and satisfies one of the following:
> (A) (i) Has passed the North American Pharmacist Licensure Examination on or after January 1, 2004, and (ii) holds an active pharmacist license in another state or territory of the United States;
> (B) Has passed a version of the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.
> (7) Has passed a version of the California Practice Standards and Jurisprudence Examination for Pharmacists that, at the time of application for licensure, was based on an occupational analysis that either remains current or was replaced no more than [one year] prior.
> (b) Proof of the qualifications of an applicant for licensure as a pharmacist shall be made to the satisfaction of the board and shall be substantiated by affidavits or other evidence as may be required by the board.
> (c) Each person, upon application for licensure as a pharmacist under this chapter, shall pay to the executive officer of the board the fees provided by this chapter. The fees shall be compensation to the board for investigation or examination of the applicant.

M/S: Weisser/Sanchez

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

f. Discussion and Consideration of Renewal Requirements for Individual Licenses and Facility Licenses – Recommendation to Amend Regulations

Chairperson Weisser explained that currently the board's regulations outline specific renewal requirements for pharmacists, pharmacy technicians, designated representatives, pharmacies, nonresident wholesalers and nonresident pharmacies. Specifically, these licensees are required to indicate if they have been disciplined by any governmental agency since their last renewal. For example, pharmacists must answer the following question on their renewal application.

> "Since you last renewed your license, have you had any license disciplined by a government agency or other disciplinary body; or, have you been convicted of any crime in any state, the USA and its territories, military court of foreign country?"

Chairperson Weisser stated that as the board's regulatory jurisdiction continues to grow, the renewal requirements for the new license types listed below were not drafted to include the same discipline disclosure.

- designated representative-3PL
- designated representative-vet
- designated representative-reverse distributor
- designated paramedics
- nonresident third-party logistics provider
- nonresident outsourcing

Chairperson Weisser explained that board staff is recommending simplifying its regulations to consolidate the renewal requirements for licenses issued to a premise as well as the licenses issued to individuals. He noted that this approach would allow for the incorporation of new licenses that will be implemented in the future and follows the same format as the approach the board approved for the abandonment of applications at the February 2018 board meeting.

Chairperson Weisser reported that the committee agreed with the staff's recommendation to consolidate the renewal requirements for licenses into two categories: licenses issued to individuals and licenses issued to a premises.

Chairperson Weisser stated that as part of its deliberation the committee noted that using this approach will ensure that any future licensing types will have the same renewal requirements without having to modify any regulations.

Chairperson Weisser noted that during the meeting the committee heard testimony from the public supporting the proposal.

Chairperson Weisser stated that the committee directed staff to draft language to consolidate the renewal requirements for licenses issued to a premises as well as the licenses issued to individuals and present it at the May 2018 board meeting for consideration.

Chairperson Weisser reported that following the committee meeting, board staff work with legal counsel to draft language based on the committee's direction (provided immediately following these minutes).

The board reviewed the draft language and spoke in support of consolidating the renewal requirements.

Motion: Amend Title 16, California Code of Regulations 1702, 1702.1, 1702.5 and repeal 1702.2 as provided at the May 2018 board meeting (and immediately following these minutes).

M/S: Weisser/Law

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

g. Discussion and Consideration of Continuing Education Requirements for an Advanced Practice Pharmacist – Recommendation to Amend Regulations

Chairperson Weisser explained that BPC section 4233 establishes the continuing

education requirements for an advanced practice pharmacist. He added that BPC section 4231 establishes the pharmacist renewal requirements, which include the required 30 hours of continuing education as well as language to place a pharmacist license on inactive status for failing to comply with the renewal requirements.

Chairperson Weisser reported that as of December 13, 2016, the board began accepting applications for advanced practice pharmacists and shortly thereafter in 2017 began issuing advanced practice pharmacist licenses to those that met the licensure requirements.

Chairperson Weisser stated that an advanced practice pharmacist is required to complete an additional 10 hours of continuing education each renewal cycle in addition to the 30 hours required by BPC 4231.

Chairperson Weisser reported that currently, BPC 4233 does not include the same renewal requirements for advanced practice pharmacists as required for pharmacists pursuant to BPC 4231. Specifically, pursuant to BPC 4231, if a regular pharmacist submits the renewal application and renewal fee but does not certify on the renewal application that he or she has completed 30 hours of continuing education, the board has the authority to place the pharmacist on inactive status. He explained that BPC 4233 was not written in this manner, and as a result the board is unable to place an advanced practice pharmacist who does not certify that he or she has completed the required continuing education on inactive status.

Chairperson Weisser stated that board staff recommends amending the board's regulations to specify that at the time of renewal, the advanced practice pharmacist must provide to the board the renewal application, renewal fee and certify that he or she has completed 10 additional hours of continuing education. Additionally, staff recommends that if an advanced practice pharmacist is unable to provide proof of completing 10 hours of continuing education when audited, his or her license should be placed on inactive status.

Chairperson Weisser reported that during the meeting committee members discussed the continuing education requirements for an advanced practice pharmacist at the time of renewal.

Chairperson Weisser stated that the committee agreed with staff's recommendation to require that at the time of renewal, an advanced practice pharmacist must provide to the board the renewal application, renewal fee and certification that he or she has completed 10 additional hours of continuing education.

Chairperson Weisser also stated that the committee also determined that if an advanced practice pharmacist is unable to provide proof of completing 10 hours of continuing education when audited, his or her license should be placed on inactive status.

Chairperson Weisser reported that the committee directed staff to draft language to require that at the time of renewal, an advanced practice pharmacist must provide to

the board the renewal application, renewal fee and certification that he or she has completed 10 additional hours of continuing education.

Chairperson Weisser stated that following the committee meeting, board staffed work with legal counsel to draft language based on the committee's direction which is provided below.

§ 1732.5. Renewal Requirements for Pharmacists and Advanced Practice Pharmacists.

(a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.
(c) Each applicant for renewal of an advanced practice pharmacist license shall submit proof to the board, that the applicant has (i) renewed the pharmacist license pursuant Section 4231 of the Business and Professions Code, and (ii) completed 10 additional hours of continuing education in the prior 24 months.
(d) If an applicant submits the renewal application of an advanced pharmacist and payment of the renewal fee but does not submit proof to the board that the licensee has completed the additional 10 hours of continuing education, or if as part of an investigation or audit conducted by the board, an advanced pharmacist fails to provide documentation substantiating the completion of continuing education as required, the board shall cancel the active advanced pharmacist license and issue an inactive advanced pharmacist license in its place. A licensee with an inactive advanced pharmacist license issued pursuant to this section may obtain an active advanced pharmacist license by paying the renewal fees due and submitting proof to the board that the licensee has completed the additional 10 hours of continuing pharmacy education.

(~~c~~ e) All pharmacists and all advanced practice pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course.
Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4231, ~~and~~ 4232, and 4233 Business and Professions Code.

The board discussed the need to have advanced practice pharmacists provide proof of completion of the 10 additional hours within six months. Ms. Sodergren asked if the intent is for an advanced practice pharmacist to provide proof of completion of the 10 hours of CE within six months of being randomly audited by board staff. The board

discussed the fact that regular pharmacists do not provide proof of their CE when they renew their license, they simply sign to certify that they have completed the CE. Proof of completion is only required when a pharmacist has their CE randomly audited by board staff.

The board asked what happens if a regular pharmacist does not have proof of CE when they are randomly audited. Ms. Herold explained that his or her license is inactivated and in order to re-activate the license they must complete the required CE and pay the renewal fee.

President Gutierrez asked if there is a time limit for a regular pharmacist to complete the CE to re-activate his or her license. Ms. Herold responded that there is no time limit, however he or she cannot practice until he or she comes into compliance and a license is cancelled after five years of not being renewed.

The board stated that the renewal requirements should be the same for both advanced practice pharmacists and regular pharmacists.

After further discussion, the board decided that additional review of both the advanced practice pharmacist and regular pharmacists renewal requirements was needed. Chairperson Weisser asked board staff to review the requirements and have language prepared for the next committee meeting.

h. Licensing Statistics

Chairperson Weisser stated that the licensing statistics were provided in the board meeting materials for the period of July 2017 to March 2018.

There were no comments from the board or from the public.

i. Future Committee Meeting Dates

Chairperson Weisser announced the following committee meeting dates.

- June 26, 2018
- September 26, 2018

The board recessed for lunch at 1:00 p.m. and resumed at 2:00 p.m.

IX. Enforcement and Compounding Committee

Chairperson Schaad provided a summary of the committee's efforts at the April 3, 2018, committee meeting as follows.

a. Report on the Presentation by the University of California San Diego on Its Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)

Chairperson Schaad explained that in July 2017, the board heard and discussed the results of the University of California, San Diego (UCSD), experimental study involving the use of ADDS technology to dispense new and refill medications to employees in an area nonadjacent to a pharmacy counter. He added that this study required a waiver of California Code of Regulations, title 16, section 1713, to allow first-time fills to be dispensed via an ADDS machine not adjacent to a pharmacy counter.

Chairperson Schaad stated that during the July 2017 board meeting, the board also approved an extension of the UCSD study for another 12 months (July 26, 2017 to July 25, 2018); additionally, the board requested that data provided to the board include a distinction between new prescriptions (as defined by law) and previously dispensed prescriptions.

Chairperson Schaad reported that during the committee meeting Jan Hirsch, BPharm, PhD and UCSD researcher, provided a presentation updating the committee on the status and direction of UCSD's experimental program regarding access to medications from an ADDS.

Note: A copy of the PowerPoint presentation was provided in the board meeting materials.

Chairperson Schaad explained that no action was required by the board and that the presentation was being provided consistent with the board's request to receive an update on the study after the extension of study was granted.

There were no comments from the board or from the public.

b. Presentation, Discussion and Consideration of the Board's Citation and Fine Program

Chairperson Schaad stated that members of the board's regulated public have a misconception about board member involvement in the issuance of citation and fines.

Chairperson Schaad explained that as part of the board's efforts to increase transparency regarding the board's citation and fine program a presentation on the program was provided at the committee meeting.

Chairperson Schaad explained that the committee found the presentation to be very insightful and asked board staff to provide the presentation for the full board.

As requested Anne Sodergren and Julie Ansel provided a presentation on general enforcement information, board investigations and specific information about citations and fines issued by the board during 2017.

A copy of the presentation is provided following these minutes.

During the presentation, the members expressed concern that board members are not involved in the cite and fine program and asked that staff continue to collect data on the cite and fine program and periodically provide updates to the board. Board

staff offered to work with the board president and enforcement committee chair to refine the data so that it provides useful information to the board.

Members of the public asked if board inspectors work with other law enforcement agencies when they uncover criminal activity. Ms. Herold responded that the board does reach out to law enforcement agencies; however, they are often not interested in getting involved in what they consider to be "lower-level cases."

A pharmacist noted that other states often take action on a pharmacist's licenses based on a citation issued by the California Board of Pharmacy. Ms. Herold explained that citations are not considered discipline and she regularly provides an explanation of this in writing to other state boards of pharmacy. She added that she also discusses this at national meetings to educate the other boards on how citations are issued in California.

Raffi Simonian, pharmacist and former board member, stated that based on the presentation it is clear that board staff is fulfilling the board's consumer protection mandate. He also recommended that the board develop a dashboard for the data so members can determine where they would focus efforts to better protect consumers.

c. Discussion and Consideration of Disclosure of Enforcement Actions, Including Citation and Fines

Chairperson Schaad stated that one area where board members should be transparent is in enforcement actions involving themselves (whether they are directly or indirectly involved). He added that board members should determine whether recusal from a vote or discussion should occur based on the real or possible appearance of self- interest. For example, an enforcement matter involving a board member could influence a member's objectivity in future decision making when the case involves fact patterns similar to his or her enforcement matter.

Chairperson Schaad reported that at the December 2017 committee meeting, a motion was made to recommend to the full board that board member involvement in disciplinary or administrative action would be reported in the Organizational Development Report.

Chairperson Schaad explained that at the January 2018 board meeting, the board members voted to send this issue back to the committee for further discussion and reconsideration.

Chairperson Schaad reported that at the committee meeting board staff provided information about how other DCA boards are handling transparency in the area of citations, fines and disciplinary actions for all licensees. He added that some boards disclose citations as an attachment to license searches. Chairperson Schaad noted that the degree of disciplinary transparency varies amongst the individual boards.

Chairperson Schaad explained that during the meeting the committee was informed that currently, the board posts items related to discipline but citations and fines are

not disclosed.

Chairperson Schaad reported that after discussion, the committee directed board staff to survey all healing arts boards to examine how each healing arts board handles transparency in all areas of discipline. The results will be brought back to the next committee meeting.

Chairperson Schaad stated that the committee also asked that the agenda item for the next committee meeting be changed to reflect that the committee would be discussing general transparency in reporting citation and fines for all licensees, not just for board members.

There were no comments from the board or from the public.

d. Update on the Substance Abuse Coordination Committee, and the Department of Consumer Affairs' Reconvening of It Pursuant to Business and Professions Code Section 315

Chairperson Schaad explained that Senate Bill 1441 (Ridley-Thomas, Chapter 548) established in the Department of Consumer Affairs the Substance Abuse Coordination Committee (SACC). The bill required the SACC to formulate uniform and specific standards in specified areas that each healing arts board would be required to use in dealing with the substance-abusing licensees.

Chairperson Schaad stated that Senate Bill 796 (Hill, 2017, Chapter 600) requires the Department of Consumer Affairs to reconvene the SACC to specifically review the existing substance abuse testing criteria, known as Uniform Standard 4. He also stated that the committee must determine whether the existing criteria should be updated and provide a report to the Legislature by January 1, 2019.

Ms. Herold explained that she is a member of the SACC panel. She reported that the first SACC meeting was held on April 23, 2018. Ms. Herold stated that the discussion focused on the frequency at which blood and/or urine are tested for substance-abusing licensees. She added that another meeting will be held and the discussion on testing frequency will continue.

Ms. Sodergren explained that the committee also discussed the pros and cons of the different types of testing and the various frequencies for testing.

Ms. Herold and Ms. Sodergren stated that they will continue to report back to the board on the outcomes from the meetings. The board asked that it item be discussed at the next Enforcement Committee meeting.

There were no comments from the public.

e. Discussion and Consideration of the Pew Charitable Trust's "State Oversight of Drug Compounding" Report

Chairperson Schaad explained that the Pew Charitable Trusts' drug safety project has identified more than 50 reported compounding errors or potential errors from 2001 to 2017 linked to 1,227 adverse events—undesirable experiences associated with the use of a medical product—including 99 deaths. Because many such events may go unreported, this number is likely to be an underestimation.

Chairperson Schaad reported that the committee was informed that in November 2013, Congress passed and President Barack Obama signed into law the bipartisan Drug Quality and Security Act (DQSA), which established clear lines of oversight accountability for two categories of businesses that can compound drugs. While the majority of states have taken action to strengthen sterile compounding oversight policies since the outbreak, it is essential to follow through with strong implementation and enforcement of these laws and rules—including the federal DQSA.

Chairperson Schaad stated that the Pew Charitable Trusts "State Oversight of Drug Compounding" Report is intended to highlight the significant progress on public health policy that has occurred and to identify the most fruitful opportunities for action to help ensure a safe supply of compounded drugs. He added that this remains a period of flux for drug compounding oversight; a number of states have pending policy changes, and implementation of the federal DQSA is ongoing.

Chairperson Schaad noted that California is one of the 10 states that are compliant with USP.

Chairperson Schaad reported that the committee directed staff to share the Pew Charitable Trusts "State Oversight of Drug Compounding" Report with the Medical Board and Veterinary Medical Board, in order to support oversight.

Chairperson Schaad stated that the committee made a motion to advocate for changes at the federal level to allow for compounding for office use, consistent with the board's regulations.

Ms. Herold explained that she will have the opportunity to advocate for the board's position on the Pew Report at a national meeting on Compounding that USP is holding at the end of May.

Ms. Lippe asked if the board has a policy for advocating board positions to other state and federal entities. Ms. Herold explained that there is no policy, but whenever there is an opportunity to speak at national events she advocates for the board.

The board discussed developing materials that outline the board's positions on important topics that board members can provide to stakeholders and representatives at the state and federal level.

Ms. Herold agreed that it would be beneficial for the board to proactively reach out to advocate for consumer protection. President Gutierrez recommended that staff work with the board president and vice president to create a fact sheet on board positions.

Ms. Herold stated that staff would work on developing a "top five" fact sheet on important board issues and bring it to a future committee meeting.

Note: The board did not vote on the committee motion.

f. Matters Related to United States Pharmacopeia (USP) Chapter 797, USP 800, and Other USP Chapters Related to Compounding

1. Anticipated Release of Updates and Impact on the Board's Regulation of Pharmacy

Chairperson Schaad reported that the proposed revisions for USP Chapter 795 were released in March 2018 and an open microphone session was held on April 20, 2018. On May 1, 2018, Chapter 795 will be formally published in *Pharmacopeial Forum* for review and public comment. He noted that the public comment period on USP 795 will close on July 31, 2018.

Chairperson Schaad explained that USP Chapter 797 will be formally published in the *Pharmacopeial Forum* for review and public comment on September 4, 2018. An open microphone session on Chapter 797 is scheduled for September 5, 2018. He added that the public comment period for Chapter 797 will close on November 30, 2018.

Chairperson Schaad stated that as part of a larger discussion, the committee was advised of the proposed changes to USP Chapters 795 and 797.

Chairperson Schaad reported that the committee briefly reviewed the proposed changes to Chapter 795 and noted that further modifications would be made to the chapter. The committee asked staff to draft a summary of the proposed changes to be discussed at the next committee meeting.

Chairperson Schaad reported that board staff participated in the open microphone session on April 20, 2018, and noted that it appears that Chapter 795 may establish practice guidance but may not be strictly enforced.

Chairperson Schaad explained that it is anticipated that the final versions of chapters 795 and 797 will be available June 1, 2019.

Chairperson Schaad stated that as the chapters become finalized staff will provide the committee with summary documents highlighting the changes and any staff recommendations for consideration. He also encouraged the public to participate in the comment periods for USP 795 and USP 797.

2. Discussion and Consideration of Statutory Proposal to Require USP Compliance in Pharmacy Law

Chairperson Schaad stated that for several years this committee and the board have discussed the regulation of sterile and nonsterile compounding and most

recently hazardous compounding. The results of these discussions were comprehensive regulations promulgated to ensure compounded drug preparations are safe. He added that although not totally consistent, relevant USP chapters covering compounding served as part of the framework for these regulations.

Chairperson Schaad reported that during the February 2018 board meeting, counsel was directed to research the feasibility of incorporation USP standards into the board's regulation of compounding practice rather than creating its own requirements.

Chairperson Schaad explained that the committee discussed the following at its April 3, 2018, meeting:

- Whether the board could adopt USP 797.
- Whether USP 795, 797 and 800 could all be included.
- Whether, following adoption, regulations would be used to identify higher California standards.

Chairperson Schaad stated that the committee heard comments from the public that not all chapters of USP are relevant to compounding of drug preparations and that it may be unclear which sections of USP would require compliance.

Chairperson Schaad reported that the committee directed staff to draft a statutory proposal to incorporate USP into the board's requirements for compounding of drug preparations.

Chairperson Schaad explained that following the meeting, board staff and counsel drafted the following proposed statutory language.

> **Add Section BPC 4122.5 as follows:**
> The compounding of drug preparations for furnishing, distribution, or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

Daniel Martinez stated that CPhA supports the board pursuing a statutory proposal to incorporate USP into the board's requirements. He added that CPhA would recommend adding the language to BCP 4108 and including references to USP 795, 797 and 800. Ms. Sodergren explained that the reason that the chapters are not specifically listed is because USP 795, 797 and 800 reference other chapters and the board wants to be sure that these additionally referenced chapters are also included. She also noted that the language was drafted to mirror federal law which does not list the specific USP 795, 797 and 800.

Mr. Martinez explained that CPhA is also requesting that the board add the following statement at the end of the language. He stated that the reason they want to add the statement so that any additional requirements that the board adds are based on scientific reasoning.

> "Nothing in this section shall prevent the board from adopting regulations requiring additional standards for compounding drug preparations as long as the board provides the reasoning that can be substantiated with scientific evidence for doing so."

Board member Weisser expressed his disagreement with adding the additional statement and explained that when the board takes action and creates regulations they do so using facts and experts in the field. Mr. Martinez stated that the perception is that there was no scientific basis for some of the compounding language that the board drafted. President Gutierrez responded that it is important to consider that there is some controversial scientific reasoning behind some of the sterile compounding practices and the board had to consider what was safest for consumers. She added that the board had multiple discussions on the language where stakeholders and experts were allowed to provide input.

Rick Rhoads, from University Compounding, thanked the board for adopting a statutory proposal to incorporate USP into the board's requirements for compounding of drug preparations. He added that California is by far the best state when it comes to regulating sterile compounding; however, there are some areas where the board's regulations differ from the USP chapters.

President Gutierrez reminded the board and the public that the reason the board drafted regulations was because initially the board was advised by legal counsel that it could not adopt the USP chapters. She explained that the legal opinion has changed and the board is now proposing the incorporation of USP into the board's requirements.

President Gutierrez and Chairperson Schaad stated that they would recommend approving the language as approved by the Enforcement Committee.

Jennifer Partridge, compounding pharmacist, spoke in support of the committee's recommended language. She also provided examples of sections of the board's regulations that differ from USP. The board stated that adopting USP into the board's requirements will eliminate any inconsistencies.

A pharmacist stated that he was part of an expert committee for the drafting of the USP chapters in 2013. He explained that even within the development of the USP chapters there were differing opinions based on scientific research.

Motion: Approve the proposed statutory language as provided below.

> **Add Section BPC 4122.5 as follows:**
> The compounding of drug preparations for furnishing, distribution,

or use in California must be done consistent with standards established in the latest edition of the United States Pharmacopeia-National Formulary chapters on pharmacy compounding, including all relevant testing, and quality assurance. This does not, however, prevent the board from adopting regulations requiring additional standards for compounding drug preparations.

M/S: Gutierrez/Munoz

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

g. Enforcement Statistics

Chairperson Schaad briefly reviewed the enforcement statistics as provided in the board meeting materials.

There were no comments from the board or from the public.

h. Future Committee Meeting Dates

Chairperson Schaad announced that following Enforcement Committee dates for 2018:

- June 7, 2018
- September 5, 2018
- December 13, 2018

X. Executive Officer's Report

Ms. Herold announced that she was recently informed that the board will have the ability to accept credit card payments by the end of 2018.

a. Biannual Report of the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) Examination Statistics and the North American Pharmacist Licensure Examination (NAPLEX)

Ms. Herold explained that the examination scores for the California Practice Standards and Jurisprudence Examination for Pharmacists (CPJE) and North American Pharmacist Licensure Examination (NAPLEX) are released twice a year, generally in spring and fall.

Ms. Herold stated that the Semi-Annual CPJE statistical report for October 2017 through March 2018 reflects that the overall pass rate for the CPJE is 51.8 percent. The pass rate for graduates from the California schools of pharmacy is 63.60 percent. The overall pass rate for the NAPLEX is 88.5 percent.

CPJE: Overall Pass Rates		
	Frequency	**Percent**
Fail	419	48.2
Pass	451	51.8
Total	870	100.0

NAPLEX: Overall Pass Rates		
	Frequency	**Percent**
Fail	91	11.5
Pass	702	88.5
Total	793	100.0

5 Year Comparison of CPJE and NAPLEX Pass Rates (Percentage)					
	CPJE			**NAPLEX**	
	Fail	**Pass**		**Fail**	**Pass**
April 2013 – Mar. 2014	19.9	80.1		4.5	95.5
April 2014 – Mar. 2015	21.3	78.7		4.3	95.7
April 2015 – Mar. 2016	21.6	78.4		5.8	94.2
*April 2016 – Mar. 2017	34.6	65.4		10.1	89.9
April 2017 – Mar. 2018	29.7	70.3		7.9	92.1

Mr. Schaad asked how the exam questions are developed. Ms. Herold provided a high-level overview of the exam development process.

Mr. Schaad and Mr. Weisser expressed concern with the lower pass rate.

A pharmacy professors stated that pharmacy schools focus much of their curriculum on California pharmacy law.

Raffi Simonian, pharmacist and former board member, stated that when he was on the board he participated in the exam development and noted that there is a robust process in place to ensure the validity of each exam question. He added that it is always a challenge to test the competency of students based solely on an exam.

Mr. Weisser asked if the caliber of student is changing because there are more pharmacy schools. A pharmacy professor stated that the students are very dedicated to their education.

Ken Schell, former board member and faculty at UCSD school of pharmacy, stated that most students who initially fail the exam go on to pass it on their second attempt. He added that some students have trouble focusing on studying the law section.

Mr. Schaad recommended that board staff and the competency committee review the pass rates for the exam over the last several years to identify trends.

Ms. Herold noted that each board member can sit in on the competency committee meetings (which are not open to the public) to see how the exam is developed.

b. Report on the California Pharmacists Association's 2018 Western Pharmacy Exchange

Ms. Herold reported that the California Pharmacists Association's annual meeting, Western Pharmacy Exchange, was held in San Diego on April 13-15, 2018.

Ms. Herold reported that she and board Members Victor Law and Cheryl Butler attended. Ms. Herold added that she provided the board's "2018 Pharmacy Law Update" twice during the meeting, and she staffed an information booth on two days with Chief of Enforcement Tom Lenox and Inspector Chris Woo.

Mr. Martinez stated that CPhA received a lot of positive feedback on Ms. Herold's presentation and the staff working in the board's booth.

c. Update on the Controlled Substance Utilization Review and Evaluation System (CURES)

Ms. Herold explained that as of March 31, 2018, there were 41,787 dispensers and 135,415 prescribers registered in CURES.

Ms. Herold noted that as the data below reflects, pharmacists remain the primary users of the system:

- 729,892 patient activity reports were run by pharmacists in March 2018. This reflects 57 percent of all patient activity reports run that month (1,244,505).
- Pharmacists accessed CURES 299,288 times in March 2018. This reflects 59 percent of the 505,727 total times the system was accessed.

Ms. Herold reviewed the table below, which illustrates the number of prescriptions reported into CURES for the first three months of 2018.

Prescriptions Reported Into CURES, January March 2018	
Schedule II Medications	4,795,866
Schedule III Medications	862,548
Schedule IV Medications	4,917,610

Ms. Herold explained that the California Department of Justice certified the CURES 2.0 system on April 2, 2018. This also means that on October 2, 2018, prescribers will be required, with some exceptions, to check CURES before prescribing Schedule II, III or IV drugs to a patient for the first time (pursuant to provisions enacted in 2016 by Lara, Chapter 708). She noted that these provisions can be found in Health and Safety Code section 11165.4.

Board member Butler asked if pharmacists who are not practicing still have to maintain their registration with CURES. Ms. Herold confirmed that if their licenses is active they must maintain their registration with CURES.

d. Ratification of Trainings That Satisfy the Law and Ethics Continuing Educations Requirements

Ms. Herold explained that a recent change in continuing education requirements mandates that effective July 1, 2019, at least two of the 30 units required for pharmacist license renewal be obtained by participation in a board-provided continuing education course. The specific requirement is provided below:

> **§1732.5 Renewal Requirements for Pharmacists**
> (a) Except as provided in Section 4234 of the Business and Professions Code and Section 1732.6 of this Division, each applicant for renewal of a pharmacist license shall submit proof satisfactory to the board, that the applicant has completed 30 hours of continuing education in the prior 24 months.
> **(b) At least two (2) of the thirty (30) hours required for pharmacist license renewal shall be completed by participation in a Board provided CE course in Law and Ethics. Pharmacists renewing their licenses which expire on or after July 1, 2019, shall be subject to the requirements of this subdivision.**
> (c) All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course

Ms. Herold stated that during prior meetings, the board has agreed to allow the following board provided programs to count towards the required two hours of law and ethics.

- 2018 Pharmacy Law Update. This program has been provided live multiple times and has been recorded for placement in the future on the board's website.
- 2018 Pharmacy Ethics Update. This program is currently being developed by board staff.
- Joint DEA and Board of Pharmacy Prescription Drug Abuse Seminar.

Ms. Herold noted that the Communication and Public Education Committee is working on developing a program to provide one hour of CE for reading *The Script*.

Ms. Herold asked the board to confirm that it does **not** want attendance of a board or committee meeting to fulfill the law and ethics requirement. The board confirmed that attending a board or committee meeting should not count towards the fulfillment of the law and ethics requirement.

e. Report on Activities Relating to Internet Sales of Prescription Drugs and Opioids

Ms. Herold reported that she continues to be involved in activities that focus on educating consumers on the dangers of purchasing drugs online and finding ways to make it safer for consumers to purchase medications from the internet. This includes her participation as a member of the National Associations of Boards Of Pharmacy's (NABP) .pharmacy (pronounced dot pharmacy) executive board.

Ms. Herold also reported that she has been working with the Alliance for Safe Online Pharmacies to develop public information about the dangers of purchasing drugs online in order to save money on prescription medication. This group develops information and discusses the dangers of seeking drugs from such locations as "Canada Drugs" with policymakers.

f. Personnel Update

Ms. Herold reviewed the personnel update as provided in the board meeting materials. There were no comments from the board or from the public.

The board recessed to closed session at 5:00 p.m.

Thursday May 3, 2018

President Gutierrez called the meeting to order at 9:03 a.m. Board members present: Gregory Lippe, Albert Wong, Deborah Veale, Allen Schaad, Lavanza Butler, Victor Law, Amy Gutierrez, Valerie Munoz, Ricardo Sanchez and Stanly Weisser.

XII. Organizational Development Committee

a. Budget Update/Report

President Gutierrez reported that the new fiscal year started July 1, 2017. The board's authorized expenditures for the year are $23,370,000.

President Gutierrez stated that as the board was advised during the February 2018 board meeting, the state has transitioned to a new statewide Accounting and Budgeting system known as Fi$Cal. The Department went "live" in the Fi$Cal system on July 10, 2017. She noted that although there are some delays, as of fiscal month seven the board has received $14,843,000 in revenue. A summary of the revenue is provided below.

Revenue Sources		
Source	**Amount**	**Percentage**
Licensing	$13,167,400	89%
Citation Fines	$1,116,500	8%
Cost Recovery	$499,200	3%
Interest	$59,900	0%

President Gutierrez explained that as of fiscal month seven, the board expended $12,241,000, which is approximately 52% of its authorized budget. The largest expenditure categories are detailed below.

Expenditures		
Source	**Amount**	**Percentage**
Personnel	$8,618,600	71%
Prorata	$1,393,700	12%
Enforcement	$1,262,500	10%

President Gutierrez stated that as the board begins to receive more budget details, staff will assess the fund condition to determine what, if any, action is necessary to address what appears to be a reduction of the board's fund.

There were no comments from the board or from the public.

b. Board Member Reimbursement and Attendance Information

President Gutierrez explained that board members may seek reimbursement for travel expenses and per diem payments. She stated that it is important to note that these figures only represent hours and travel expenses where reimbursement was sought. It is not uncommon for board members to waive their per diem payments or only request partial reimbursement of travel expenses. President Gutierrez noted that a chart of the board member reimbursement was provided in the board meeting material.

President Gutierrez stated that a report of the board member attendance was provided in the board meeting materials for review.

There were no comments from the board or from the public.

c. Future Board Meeting Dates

President Gutierrez reported the following board meeting dates.

2018 Board Meeting Dates

- June 6, 2018 – Petitioner Board Meeting
- July 24-25, 2018
- September 6, 2018 – Petitioner Board Meeting
- October 23-24, 2018
- December 12, 2018 – Petitioner Board Meeting

Proposed 2019 Board Meeting Dates

- January 30-31, 2019
- May 7-8, 2019

- July 24-25, 2019
- November 5-6, 2019

Proposed 2019 Petitioner Board Meeting Dates

- March 25, 2019
- June 25, 2019
- September 10, 2019
- December 17, 2019

There were no comments from the board or from the public.

The board recessed for a break at 9:10 a.m. and resumed at 9:15 a.m.

X. Petitions for Reinstatement of Licensure of Other Reduction of Penalty Time Certain: May 3, 2018, 9:00 a.m.

Administrative Law Judge Theresa Burrell presided over the petitions for reduction of penalties for University Compounding Pharmacy (PHY 45631 and LSC 99018) and Joseph Grasela (RPH 40868).

The board recessed to Closed session at 12:00 p.m. and returned to open session at 12:30 p.m.

XIII. Legislation and Regulation Committee

The Legislation and Regulation Committee will convene a meeting immediately prior to the board meeting on May 2, 2018. The board will receive a summary of the committee's efforts, as well as updates, for discussion and action as necessary.

Part 1: Legislation for Discussion and Consideration Report

a. Board Sponsored/Originated Legislation

1. SB 1447 (Hernandez) Pharmacy: Automated Drug Delivery Systems: Licensing

Chairperson Lippe provided the following information on SB 1447.

Version: Amended April 17, 2018

Status: Senate Business, Professions and Economic Development

Summary: This bill would repeal the general ADDS provisions and the additional conditions for an ADDS located in a licensed clinic or a health facility. The bill instead would prohibit an ADDS from being installed or operated in the state unless specified requirements are met, including a license for the ADDS issued by the board to the holder of a current, valid, and active pharmacy license. The bill would limit the placement and operation of an ADDS to specified locations, including the licensed, pharmacy holding that ADDS license, a licensed health facility, a licensed clinic, or a specified medical office.

The bill would require the pharmacy holding the ADDS license to own the ADDS and the drugs and devices located within it, and would require that pharmacy to supervise the operation of the ADDS. The bill would prescribe specified stocking and transfer requirements for those drugs and devices. The bill would require the pharmacy holding the ADDS license to provide training on the operation and use of that ADDS to specified individuals and would require the pharmacy to complete periodic self-assessments. The bill would require additional conditions for automated patient dispensing systems, as defined. The bill would also authorize a pharmacy inspector employed by the board to enter the location, or proposed location, of an ADDS to inspect the location pursuant to these provisions.

Staff Comments: This measure is board sponsored and includes the provisions approved by the board during its January 2018 meeting. This proposal has been amended to better mesh with existing law.

Paige Tally stated that the California Counsel for the Advancement of Pharmacy has no formal position. She noted that they are concerned that the required inspections may cause a delay and have a negative impact on patients' quality of life. Ms. Herold stated that board staff will work with stakeholders to minimize the impact on patient care.

A representative from Kaiser stated that they support the bill. He added that Kaiser's only concern is that consultation is required for refills. Ms. Herold explained that the language was drafted incorrectly by legislative counsel; there is no requirement for consultation for refills.

2. <u>AB 1751 (Low) Controlled Substances: CURES Database</u>

Chairperson Lippe provided a summary of AB 1751 as follows.

Status: Referred to Assembly Public Safety Committee

Board Position: Support

Summary: This measure will allow the Department of Justice to enter into an agreement with an entity operating an interstate data share hub for purposes of interstate sharing of controlled substances reporting information.

Staff Comments: The board is the originator of this measure. The board established a support position on this measure during the February board meeting.

Daniel Martinez stated that CPhA supports SB 1751.

There were no comments from the board.

3. <u>AB 1752 (Low) Controlled Substances: CURES Database</u>

Chairperson Lippe provided a summary of AB 1752 as follows.

Version: Introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

Summary: This measure expands CURES reporting to also include Schedule V controlled substances and reduces the time frame for reporting to the CURES system to one working day.

Staff Comments: The board is the originator of some of the provisions included in this measure. During the board's February 2018 meeting, the Board voted to take a position of Support for this measure. Since that time, the measure was amended to remove the authority of the board to, through regulation, add additional medications that would be tracked in the CURES database.

Board member Weisser asked why the bill was amended to remove the authority of the board to, through regulation, add additional medications that would be tracked in the CURES database. Ms. Herold responded that the California Medical Association took an Oppose Unless Amended Position to remove that authority. She added that the board currently does not have the authority to add additional medications.

The board asked the executive officer to reach out to the Medical Board to ask if they would be willing to allow the board to have joint authority with them to add drugs to the CURES database.

Daniel Martinez stated that CPhA has a Support if Amended position. He explained that CPhA is concerned with the 24-hour CURES recording requirement in the bill.

Note: Board member Schaad left the room at 12:45 p.m.

4. <u>AB 2086 (Gallagher) Controlled Substances: CURES Database</u>

Chairperson Lippe provided a summary of AB 2086 as follows.

Version: Amended April 3, 2018

Status: Re-Referred to Assembly Appropriations Committee

Summary: Allow prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

Staff Comments: The board is the originator of this bill. During the July 2017 Board meeting it was discovered that a statutory change was needed in order to allow prescribers to access reports in CURES.

Chairperson Lippe reported that the committee made a recommendation to support AB 2086.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Support AB 2086.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser	x			
Wong	x			

5. AB 2783 (O'Donnell) Controlled Substances: Hydrocodone Combination Products: Schedules

Chairperson Lippe provided a summary of AB 2783 as follows.

Version: Amended April 11, 2018

Status: Re-Referred to Assembly Appropriations Committee

Summary: Reclassify specific hydrocodone combination products as Schedule II controlled substances.

Staff Comments: This is the board's measure that was initially intended to reconcile California state schedules with the federal schedules as approved by the board at its January 11, 2018, meeting. Although this bill does not go that far, this change does begin the reconciliation.

Chairperson Lippe reported that the committee made a recommendation to support AB 2783.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Support AB 2783.

Support: 9 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad				x
Veale	x			
Weisser	x			
Wong	x			

6. AB 2789 (Wood) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Note: Board member Schaad returned to the meeting at 12:55 p.m.

Chairperson Lippe provided a summary of AB 2789 as follows.

Version: Amended April 3, 2018

Status: Assembly Appropriations

Summary: Require by January 1, 2021, all prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription). By January 2, 2021 all pharmacies, pharmacists or other practitioners authorized to dispense or furnish a prescription must have the capability to receive an e-prescription.

Staff Comments: The board is the originator of this bill. During the January 2018 board meeting, the board discussed how the abuse of pharmaceutical drugs has skyrocketed in the United States over the past decade and has led to the current opioid epidemic. E-prescribing can address the opioid epidemic by substantially reducing the opportunities for persons to steal, alter, “doctor shop,” or counterfeit prescriptions, thus decreasing unsupervised access to medication

Chairperson Lippe reported that the committee made a recommendation to support AB 2789.

Representatives from CPhA spoke in support of the bill.

NACDS spoke in support of the bill and offered to work with the board to draft an amendment to mandate e-prescribing for all prescriptions and to create consequences for prescribers who are not in compliance.

The board stated that it will be difficult to mandate consequences for other healing arts practitioners.

Board member Munoz stated that there is already a federal requirement that will require electronic medical records for all practitioners in the next few years. The board directed the executive officer to look at the time frames for the federal requirements and consider if the e-prescribing time frames should coincide.

Committee Recommendation (Motion): Support AB 2789.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction

1. AB 1753 (Low) Controlled Substances: CURES Database

Chairperson Lippe provided a summary of AB 1753 as follows.

Version: As introduced January 3, 2018

Status: Referred to Assembly Public Safety Committee

Summary: This measure would limit the number of authorized security printers approved by the DOJ to three effective January 1, 2020. Further, this measure would require security forms to contain a unique serialized number that must be reported to CURES and would establish reporting requirements to the DOJ on the delivery of security forms to a prescriber.

Staff Comments: The author arrived at the number of printers based on input from the Department of Justice.

Chairperson Lippe reported that the committee did not take a position on the bill.

There were no comments from the board or from the public.

2. AB 1953 (Wood) Skilled Nursing Facilities: Disclosure of Interests in Business Providing Services

Chairperson Lippe provided a summary of AB 1953 as follows.

Version: As introduced January 29, 2018

Status: Referred to Assembly Health Committee

Summary: This bill would require disclosures by an applicant for a license to operate a skilled nursing facility or by a skilled nursing facility licensee relating to an ownership or control interest of 5% or more in a corporation, sole proprietorship, or partnership, that provides, or is proposed to provide, any service to the skilled nursing facility.

Staff Comments: More information regarding related party transactions and skilled nursing facilities will be available soon. Board staff recommends that amendments be offered to require a similar disclosure by anyone applying for a pharmacy license. This additional provision would support the intent of this legislation by also highlighting any relationship between a pharmacy and a SNF.

Chairperson Lippe reported that the committee took a position of support if amended to require a similar disclosure by anyone applying for a pharmacy license.

Daniel Martinez stated that CPhA does not have an official position on the bill and stated that CPhA would like to see the amendment in writing before it takes a position.

Board member Weisser asked if the board is opposed to a pharmacy having partial ownership of skilled nursing facility. Ms. Sodergren explained that the board has found fraud in some cases where a pharmacy, skilled nursing facility and wholesaler all have the same ownership. She added that board staff is not opposed; however, staff would like to be notified so that they can verify that the ownership structure is appropriate.

Committee Recommendation (Motion): Support AB 1953 if amended to require a similar disclosure for anyone applying for a pharmacy license.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x

Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

3. AB 2037(Bonta) Pharmacy: Automated Drug Delivery Systems

Chairperson Lippe provided a summary of AB 2037 as follows.

Version: Introduced February 6, 2018

Status: Referred to Assembly Business, Professions and Consumer Protection

Summary: Allow a pharmacy to provide pharmacy services to outpatients in an entity covered under Section 340B through the use of an automated drug delivery system (ADDS)

Staff Comments: This measure is similar to last year's SB 528 (Stone). The board established a support if amended position on that measure. As part of its request, the board requested that the provisions not be limited to just 340B clinics. The board's amendments were not incorporated into the measure last year and the measure ultimately stalled in committee.

Chairperson Lippe reported that the committee did not take a position on AB 2037 and directed staff to work with the author's office to modify the language so that it conforms with SB 1447.

4. AB 2138 (Chiu/Low) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Version: Amended April 2, 2018

Status: Assembly Business and Professions Committee hearing April 24, 2018

Summary: This bill would place significant limits on the Board's enforcement process including limits on when a board can deny, revoke or suspend a license based on a conviction or other act and limits on the length of probation. It also limits the Board's timeframe to decide on a petition to modify probation to 90 days.

Staff Comments: Board staff has significant policy concerns that this measure will negatively impact the board's ability to thoroughly review and consider criminal arrests and/or convictions of applicants and licensees. The policy being put forth in this measure runs contrary to the board's consumer protection mandate as well as efforts by the Legislature to strengthen the ability of programs within the DCA to more robustly protect consumers. Creating barriers or limiting information the board can consider when making a licensing decision and enforcement action will undo gains the board has made in this area and significantly undermine the board's consumer protection mandate.

Chairperson Lippe reported that the committee is recommending an oppose position on AB 2183.

Board member Weisser asked what the intent of the bill is. Ms. Herold explained that the author does not want there to be a "lifetime ban" on someone who has previous criminal convictions from entering a profession.

Committee Recommendation (Motion): Oppose AB 2183.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

5. AB 2256 (Santiago) Law Enforcement Agencies: Opioid Antagonist

Chairperson Lippe provided a summary of AB 2256 as provided below.

Version: Introduced February 13, 2018

Status: Assembly Public Safety

Summary: Allow law enforcement agencies throughout the state to acquire Naloxone from a pharmacy without a prescription if it is exclusively for use by employees of the agency who have completed training in administering an opioid antagonist and acquisition and disposition records are maintained by the law enforcement agency for three years.

Staff Comments: This bill is consistent with the board's policy to support the availability and use of naloxone as an important tool to reduce deaths caused by opioid overdose.

Chairperson Lippe reported that the committee is recommending supporting AB 2256.

CPhA, National Association of Chair Drug Stores and the California Retailers Association spoke in support of AB 2256.

Committee Recommendation (Motion): Support AB 2256.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

6. AB 2409 (Kiley) Professions and Vocations: Occupational Regulations

Chairperson Lippe provided a summary of AB 2409 as provided below.

Version: Amended April 16, 2018

Status: Assembly Business and Professions

Summary: Establishes the right of a person to engage in a lawful profession without being subject to an occupational regulation that imposes a substantial burden on that right. Included within this right is the right to not have the person's criminal record, delinquent taxes, or student loan payments be used as grounds for an automatic denial of a license. Authorizes a person to petition a board to review an occupational regulation for compliance with the above rights. Authorize a person with a criminal record to petition a board at any time for a determination of whether the person's criminal record will automatically disqualify the person from obtaining a license from the board and would specify the criteria a board is allowed to use in making that determination.

Staff Comments: This bill failed Assembly B&P and will be reconsidered by committee. Board staff has concerns that establishing a statutory right to a

license is counter to the board's consumer protection mandate. Staff notes that last year the board was successful in negotiating an amendment to changes in the deferred entry of judgment program by excluding some of the provisions from applying to healing arts licensed professional. Board staff suggests that similar amendments be requested and if not accepted the board change its positions to an oppose position.

Chairperson Lippe reported that the committee is recommending opposing AB 2409.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Oppose AB 2409.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

7. AB 2576 (Aguiar-Curry) Emergencies: Healthcare

Chairperson Lippe provided a summary of AB 2576 as follows.

Version: Amended April 25,2018

Status: Assembly Appropriations

Summary: Expands the emergency provisions to authorize a clinic licensed by the Board to purchase drugs at wholesale for administration or dispensing to patients, to furnish dangerous drugs or devices in reasonable quantities without a prescription during a federal, state, or local emergency.

Staff Comments: The board currently has authority to issue temporary permits as well as a process to waive certain requirements in the event of a declared natural disaster. Many of these provisions currently only apply to a pharmacy. It appears that allowing greater flexibility for clinic licenses would be consistent with the board's policy of ensuring displaced patients have ready access to

prescription medications. Board staff provided technical input to reconcile the provisions with current law.

Chairperson Lippe reported that the committee is recommending supporting AB 2576.

CPhA spoke in support of the bill.

Committee Recommendation (Motion): Support AB 2576.

Support: 10 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale	x			
Weisser	x			
Wong	x			

8. AB 2859 (Caballero) Pharmacy: Safe Storage Products

Chairperson Lippe provided a summary of AB 2859 as follows.

Version: Amended April 12, 2018

Status: Assembly Appropriations Committee

Summary: Require community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products within the pharmacy.

Staff Comments: This measure appears consistent with the board's policy to combat the opioid epidemic. Board staff recommends offering amendments to remove (c)(1) and (2) as the board already has the authority to cite and fine for noncompliance with regulations.

Chairperson Lippe reported that the committee was concerned that the safe storage products are not really tamper proof and requiring their use has the unintended consequence to making it easier to identify controlled substances for diversion.

Daniel Martinez explained that the sponsor of the bill is the manufacturer of the safe storage containers. He stated that CPhA has an opposed position on the bill.

Committee Recommendation (Motion): Oppose AB 2576 Unless Amended to make the displaying of the tamper proof products optional.

Support: 8 Oppose: 2 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad		x		
Veale	x			
Weisser	x			
Wong		x		

9. AB 2863 (Nazarian) Pharmacy: Prescriptions: Pharmacy Benefit Manager: Cost

Chairperson Lippe provided a summary of AB 2863 as follows.

Version: Amended April 11, 2018

Status: Assembly Business & Professions

Summary: This bill would limit the amount a health care service plan, health insurer, or pharmacy benefit manager may require an enrollee or insured to pay at the point of sale for a covered prescription to the lesser of the applicable cost-sharing amount or the retail price.

Staff Comments: This measure seems to be consistent with the board's consumer protection mandate by ensuring the consumer be charged the lesser amount for their prescriptions.

Chairperson Lippe reported that the committee is recommending supporting AB 2863.

Board member Veale asked why the board is taking a position on this bill as the board is not involved in drug pricing.

Board member Schaad stated that this is an ethical issue. A pharmacist should be allowed to tell a patient if his or her prescription is available at a cheaper price.

Ms. Veale asked how the consumer is being protected by being informed of a lower price. Mr. Schaad responded that it allows the patient to make an informed decision about his or her medications.

Daniel Martinez stated that CPhA supports the bill. He added that cheaper drug prices lead to better medication adherence and access to care.

Committee Recommendation (Motion): Support AB 2863.

Support: 9 Oppose: 0 Abstain: 1

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez	x			
Schaad	x			
Veale			x	
Weisser	x			
Wong	x			

10. SB 1021 (Wiener) Prescription Drugs

Note: Board members Sanchez and Schaad left the meeting at 1:36 p.m.

Chairperson Lippe provided a summary of SB 1021 as provided below.

Version: Amended April 16, 2018

Status: Senate Health Committee

Summary: This bill would eliminate the sunset date on provisions of AB 339 (Gordon, 2015).which, added Section 1342.71 to the Health & Safety Code, capping monthly copays at $250 total per patient; preventing discrimination against patients with specific conditions, by ensuring that all of the drugs for a given disease could not be placed in the most expensive tier; and extending all protections to plans in the large employer market as well as the individual and small employer coverage markets, of January 1, 2020.

Staff Comments: Amendments made in Senate Health Committee added language similar to AB 2863 capping the co pay amount at the retail price if it is lower than the copay.

Ms. Sodergren explained that the sponsor of the bill is intending to make the provisions in Health and Safety Code section 1342.71 permanent by eliminating the sunset date. She added that the author informed staff that the board would not have any part of enforcing the provisions; it will be handled by the Department of Managed Care and the Department of Insurance.

Daniel Martinez stated that CPhA supports the bill as capping copays will lead to better access to medications.

After discussion, the board did not take a position on SB 1021 and asked staff to further research the provisions in the bill and bring a recommendation back to the next board meeting.

11. SB 1109 (Bates) Controlled Substances: Schedule II Drugs: Opioids

Chairperson Lippe provided a summary of SB 1109 as follows.

Version: Amended April 4, 2018

Status: Senate Health

Summary: This measure contains provisions relating to education of opioid use. Specifically related to our board, it would require a warning label on all Schedule II controlled substances.

Staff Comments: This bill was recently amended in committee and the resulting amendments have not been published. Generally, the amendments will remove the requirement for the board to promulgate emergency regulations regarding an opioid warning label, as well as no longer requiring the minor and parent/guardian to sign a statement upon being informed of the risks of opioid use, rather require a consultation by the prescriber, and requiring the use of the Opioid fact sheet by the Centers for Disease Control by schools and sports organizations.

Chairperson Lippe reported that the committee is recommending opposing SB 1109 unless it is amended to remove the labeling requirement. He explained that the committee was concerned that the required label would have the unintended consequence of making it easier to identify controlled substances for diversion.

CPhA and Kaiser stated their opposition to this bill.

The board determined that while it opposed the labeling requirement, the bill contains other provisions regarding counseling and education that the board supports.

Committee Recommendation (Motion): Oppose SB 1109 unless it is amended to remove the labeling requirement. Direct staff to explore other labeling

options while preserving the education and consultation provisions of the measure.

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad				x
Veale			x	
Weisser	x			
Wong	x			

12. SB 1229 (Stone) Pharmacists: Opioid Medications: Consultation

Chairperson Lippe reported SB 1229 is not moving forward this year.

13. SB 1240 (Stone) Prescription Drugs: CURES Database

Chairperson Lippe reported that SB 1240 is not moving forward this year.

14. SB 1254 (Stone) Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

Note: Board member Wong left the room at 1:50 p.m.

Version: Amended April 2, 2018

Status: Senate Business, Professions and Economic Development

Summary: This bill would require a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge of the patient. The criteria for determining whether a patient is high risk will be established by each hospital. Additionally, this measure would allow for this duty to be performed by a pharmacy technician or a pharmacy intern, if they have successfully completed training and proctoring by a pharmacist and where a quality assurance program is used to monitor competency.

Staff Comments: This measure is being brought to the committee to seek input on the policy of the measure. The board previously heard a presentation on a study underway at Cedars Sinai regarding high risk patients. This bill was

amended on April 23, 2018 to add a provision that the board may adopt rules to carry out the provisions of the bill.

Chairperson Lippe reported that the committee discussed the bill but did not take a position. He asked the members if they wished to discuss taking a position on SB 1254 and they indicated that they supported the committee's decision to not take a position.

There were no comments from the public.

15. SB 1286 (Pan) Pharmacy Technicians

Chairperson Lippe reported that SB 1286 will not be moving forward.

16. SB 1373 (Stone) General Acute Care Hospitals: Minimum Levels of Pharmaceutical Staff

Chairperson Lippe reported that SB 1286 will not be moving forward.

17. SB 1442 (Wiener) Pharmacies: Staffing

Note: Board member Wong returned at 1:56 p.m.

Version: Amended April 2, 2018

Status: Senate Appropriations

Summary: Specify that a pharmacy shall not require a pharmacist employee to engage in the practice of pharmacy unless the pharmacist is assisted at all times by another employee as specified.

Staff Comments: This measure recently passed out of the Senate Business, Professions, and Economic Development committee. As part of the committee's discussion, concern was raised about independent pharmacies and the possible negative impact to such businesses.

Chairperson Lippe reported that the committee recommended opposing SB 1442 unless it is amended to exempt hospitals.

President Gutierrez explained that the committee discussed the difficulty that hospitals often have keeping a pharmacy staffed for 24 hours and that is the reason that the committee recommended exempting hospitals.

Board member Butler spoke in strong support of the bill. She explained that pharmacists are under a lot of stress due to understaffing and it creates a risk to consumers.

Board member Weisser noted that the historically the board doesn't take a position on staffing and labor issues. Ms. Butler again stated that this bill goes beyond staffing; it is about protecting patients from pharmacists who are understaffed and may make errors.

A retail pharmacist shared with the board his day-to-day work schedule and how difficult understaffing makes caring for patients.

Daniel Martinez stated that CPhA received many complaints from pharmacists about the dangers of understaffing. He stated that they are working with the author's office to determine if the author would be willing to amend the bill to allow the additional personnel to be a pharmacy technician.

Ms. Veale asked why pharmacies with fewer than four pharmacists are exempt from this bill. Chairperson Lippe explained that amendment was not made by the board. Ms. Munoz stated that she supports the exemption for smaller pharmacies because they often are located in rural or medically underserved communities and mandating staffing levels may have the unintended consequence of forcing these pharmacies to close.

Amber Parrish-Bauer, political director for UFCW Western States Counsel (sponsor of the bill), thanked the board for its discussion. She noted that following the committee meeting they will discuss the committee's recommendation to exempt hospital pharmacies with the author.

Ms. Parrish-Bauer stated that the main focus of the bill is to protect consumers by ensuring that pharmacies are appropriately staffed to provide patient care.

Ms. Parrish-Bauer read a letter from Senator Wiener (author of the bill) that asked for the board's support of SB 1442.

The National Association of Chain Drug Stores and The California Retailers Association stated their opposition to SB 1142 because it will have the unintended consequence of shutting pharmacies down if they cannot meet the staffing requirements.

The secretary treasurer for UFCW Local 135 spoke in strong support of the bill and noted that staffing issues cannot be resolved through union bargaining because many pharmacies are non-union.

Note: The issue of board members voting on legislation sponsored by their employer was raised during the meeting. DCA staff counsel analyzed the issue and concluded that as long as the board member does not have a financial conflict of interest nothing would prohibit a member from voting on legislation that is sponsored by his or her employer.

Committee Recommendation (Motion): Support SB 1142 if amended to exclude hospitals.

Support: 4 Oppose: 1 Abstain: 3

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			
Gutierrez			x	
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad				x
Veale			x	
Weisser				
Wong			x	

Part 2: Regulations for Discussion and Consideration

Chairperson Lippe explained that the only regulations that require action from the board is are the Proposed Regulations to Amend Title 16 CCR sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding

Chairperson Lippe explained that this regulation formally amends the board's regulations regarding the establishment of compounding beyond use dates as they relate to sterile and nonsterile compounded drug preparations. Additionally, this regulation allows for the use of a double filtration system.

Chairperson Lippe reported that as part of the discussion during the Enforcement and Compounding Committee meeting, the committee made the recommendation to readopt the emergency regulations given the delay in the promulgation permanent regulation.

Chairperson Lippe stated that the emergency regulations expire on June 18, 2018. He explained that without readoption of the emergency regulations, there will be significant adverse impact to patients related to the current requirement for the establishment of beyond use dates for nonsterile compounded drug preparations.

Note: At the time of the meeting the emergency regulation was under review by the DCA Budget Office.

There were no comments from the board or from the public.

Committee Recommendation (Motion): Re-adopt the emergency regulations.

Support: 8 Oppose: 0 Abstain: 0

Board Member	Support	Oppose	Abstain	Not Present
Brooks				x
Butler	x			

Gutierrez	x			
Khan				x
Law	x			
Lippe	x			
Munoz	x			
Sanchez				x
Schaad				x
Veale	x			
Weisser	x			
Wong	x			

President Gutierrez adjourned that meeting at 2:41 p.m.

Individual & Facility Renewals
Draft Regulation Text
Title 16, California Code of Regulations

Amend § 1702. Pharmacist Renewal Requirements.

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.
(1) A pharmacist~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.
(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).
(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).
(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).
(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.
(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.
(d) As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with any continuing education requirements to renew his or her pharmacist or advanced pharmacist license as required by section 1732.2.
(e) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.
Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend § 1702.1. ~~Pharmacy Technician~~ Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual other than a license as a pharmacist or an advanced practice pharmacist.

(a) An individual licensee ~~pharmacy technician~~ applying~~icant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The individual ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The individual ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, ~~apharmacy technician applicant~~ the individual shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, ~~a pharmacy technicianapplicant~~ the individual shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4038, 4115, 4202, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal § 1702.2. Designated Representative Renewal Requirements.

~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~

~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~

~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~

~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~

~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~

~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~

~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.~~

~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

~~Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.~~

Amend § 1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy~~.

This section applies to a renewal application submitted by a licensed premises or facility.
(a) As a condition of renewal, an applicant seeking renewal of a premises or facility license ~~as a nonresident wholesaler or as a nonresident pharmacy~~ shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. ~~An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.~~ Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.
(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation, or public reprimand or reproval.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.