



California State Board of Pharmacy

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BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

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

DATE: July 24-25, 2018

LOCATION: Department of Consumer Affairs – 1st Floor Hearing Room
1625 N. Market Blvd.
Sacramento, CA 95834

BOARD MEMBERS PRESENT: Victor Law, Licensee Member, President
Gregory Lippe, Public Member, Vice President
Allen Schaad, Licensee Member, Treasurer
Maria Serpa, Licensee Member
Deborah Veale, Licensee Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member
Stanley Weisser, Licensee Member
Lavanza Butler, Licensee Member
Shirley Kim, Public Member

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

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

Tuesday, July 24, 2018

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

President Law called the meeting to order at 12:40 p.m.

Board members present: Victor Law, Maria Serpa, Ricardo Sanchez, Deborah Veale, Allen Schaad, Gregory Lippe, Stanley Weisser, Shirley Kim, Lavanza Butler and Albert Wong.

New board members Maria Serpa and Shirley Kim were sworn in by Chief Deputy Director Christopher Shultz.

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

The board's executive officer Virginia Herold announced her retirement with the following statement.

To my Pharmacy Family,

I have had the pleasure of working for the board since 1990, 16 years as the assistant executive officer and 12 years as executive officer. Over these years, through our combined efforts, we have stepped forward to create a significant and relevant agency aimed at ensuring patients receive the medications and the quality pharmaceutical care they require and deserve. We have accomplished so many things, I hesitate to compile a list in fear of overlooking some of our achievements. To give you some idea of where we once were, I will relate that when I first came to the board, we shared computers, which is an incredibly ancient concept to the way everyone does business today.

It has been my privilege to have held these positions in public health for the years I have. It has been through our combined efforts that we are positioned where we are today – the nation's leading board of pharmacy, and if not the most, certainly among the most significant consumer protection agencies in the country. We are sought out as participants in evolving public health issues, an accomplishment that is noteworthy to acknowledge.

Behind me, the board will be in effective hands with Anne Sodergren, who remain once I leave and while the board determines its future.

Thank you for all your hard work. While the board will continue to address exciting and difficult public health issues relating to such items as opioids, compounding, drug take back and new delivery systems for medications, I know you will be up to challenges that will arise.

I entered public service with sights on emulating consumer advocate Ralph Nader as my career goal. I am humbled to acknowledge that through our efforts, I believe I have succeeded in reaching part of that ambitiousness goal.

Thank you – this has truly been a team effort and I believe a job well done.

The board thanked Ms. Herold for her years of service and dedication to consumer protection.

Pharmacist Joe Grisella asked the board to consider allowing pharmacists and pharmacies who are in the process of being disciplined by the board to speak with board members about their situation before the matter is brought to the attorney general’s office for prosecution. Supervising Deputy Attorney General Joshua Room stated that there would be problems with this approach and recommended placing the item on a future agenda if the board wishes to discuss it further.

III. Approval of the May 2-3, 2018 Board Meeting Minutes

Board member Lippe noted that on page 53 of the minutes the name of the union needs to be corrected to “UFCW.” He also stated that on page 31 of the minutes Dr. Schell’s name needs to be corrected.

Board member Lavanza Butler stated that she also attended the CPhA meeting and it should be noted on page 32 of the minutes.

There were no comments from the public.

Motion: Approve the May 2-3, 2018, board meeting minutes with the corrections noted by the board members.

M/S: Lippe/Sanchez

Support: 8 Oppose: 0 Abstain: 2

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | X | |
| Law | X | | | |
| Lippe | X | | | |
| Munoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | | | X | |
| Veale | X | | | |
| Weisser | X | | | |
| Wong | X | | | |

IV. Approval of the June 6, 2018 Board Meeting Minutes

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

Motion: Approve the June 6, 2018, board meeting minutes.

M/S: Veale/Lippe

Support: 8 Oppose: 0 Abstain: 2

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | | | x | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | | | x | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

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

The board recognized Clifford Wong for 50 years of service as a pharmacist.

VI. Presentation of the Administrative Case Process and Case Resolution Times for Matters Referred to the Office of the Attorney General

Supervising Deputy Attorney General (SDAG) Joshua Room provided a presentation on the disciplinary process. As part of the presentation Mr. Room provided insight into some of the challenges that may impede more swift resolution of disciplinary matters and provided a brief overview of data prepared by the Attorney General regarding workload.

A copy of the presentation is provided following these minutes.

The board recessed for a break at 2:23 p.m. and resumed at 2:39 p.m.

Following the presentation, the board asked why staff does not pursue criminal charges against pharmacists or pharmacies who are diverting drugs. Mr. Room stated that some pharmacists have been criminally charged when there has been significant diversion or patient death. The board's Chief of Enforcement and former DEA agenda Tom Lenox explained the difficulties board staff has in convincing law enforcement and district attorneys to pursue criminal charges. The board asked that staff start tracking when cases are referred to law enforcement for criminal investigation.

Pharmacist Joe Grisela expressed his dissatisfaction with the board's disciplinary process and stated that many cases could be resolved without going to the attorney general's office if the pharmacist was allowed speak with a pharmacist or speak directly with the board members. Mr. Room responded that in all the cases his office has handled the respondent

always has the opportunity to speak with one of the board's inspectors (who are all pharmacists) and sometimes are given warnings to correct the problem prior to the board bringing the case to the AG's office. He added that it would be inappropriate for a respondent to speak with the board directly as doing so would require the board members to recuse themselves if the case was ever brought before them for consideration.

The board recessed for a break at 3:33 p.m. and resumed at 3:46 p.m.

VII. Enforcement and Compounding Committee Related Items

Chairperson Schaad provided a report of the committee's efforts at the June 7, 2018 meeting as follows.

a. Discussion and Consideration of Possible Board Policy Relating to Transparency Involving the Issuance of Citations and Fines

Chairperson Schaad reported that during the April 2018 Enforcement Committee meeting, the committee requested that board staff survey all DCA healing arts boards to determine how each of the boards handles general transparency related to the issuance of citations and fines.

Chairperson Schaad explained that all DCA healing arts boards were surveyed to determine whether each board posted citations and fines issued to licensees on their websites.

Chairperson Schaad stated that the survey showed that 15 of the 18 DCA healing art boards post citations and fines on their website; however, the duration of the postings varies. It should be noted that most boards surveyed are actively using the BreZE System, which may be programmed to upload citations and fines to their respective sites.

Chairperson Schaad reported that the committee reviewed other DCA boards to determine if they post citations and fines, the length of time citations and fines are posted, and whether or not the board participates in the BreZE System.

Chairperson Schaad stated that the committee made a motion to direct staff to identify possible parameters on posting mechanisms and conditions under which citations and fines would be posted for 3 years.

The board discussed the pros and cons of posting citations on its website. The board spoke in support of transparency but expressed concern with posting citations for minor violations that may unnecessarily diminish the public's trust in pharmacists.

Mr. Room noted that if the board posts citations on the website licensees will start appealing even minor citations because they do not want it to appear on the board's website. This will create additional work for staff and may diminish the efficacy of the board's citation and fine program.

The board heard testimony from the public both in support and in opposition to posting the citations on the board's website.

After discussion and hearing public testimony the board decided not to vote on the committee's motion and asked that the Enforcement Committee again re-visit the issue at its next meeting.

b. Discussion and Consideration of Laws and Regulations Related to Petitions for Reduction of Penalty (Reinstatement, etc.) of Disciplined Licenses

Chairperson Schaad explained that Business and Professions Code section 4309 establishes the conditions under which an individual may petition the board for reinstatement of license that has been revoked or suspended. It also establishes the conditions under which a licensee may petition the board for a modification to a penalty, including modifications to probationary terms or early termination of probation. This section further specifies the time frames that must be satisfied before a petition can be considered including:

1. At least three years for reinstatement of a revoked license.
2. At least two years for early termination of probation of three years or more.
3. At least one year for modification of a condition, or reinstatement of a license revoked for mental or physical illness, or termination of probation of less than three years.

Chairperson Schaad stated that this section also provides that a petition cannot be considered while the individual is under sentence for a criminal offense, including any period in which the individual is on court-imposed probation or parole. In addition, a petition cannot be considered if there are additional accusations or a petition to revoke probation pending with the board.

Chairperson Schaad explained that in recent years the board has considered such petitions at specially convened board meetings where the primary focus of the agenda is consideration of such petitions. Although the law allows for different adjudication processes, the board's policy in this area is to convene these petition matters as part of a board meeting whenever possible and to have the hearing presided over by an administrative law judge (ALJ). Following the hearings, board members meet in closed session with the ALJ to deliberate on the matters presented during open session hearing. He added that once the board makes its determination, the ALJ drafts the decision on behalf of the board.

Chairperson Schaad noted that in the event a quorum of the board cannot be achieved, the board's policy allows for petitions to be heard by a committee of the board. In such cases, the ALJ will draft a proposed decision for each petition and the decision will then be considered by all members as part of the mail vote process.

Chairperson Schaad explained that under the law, a third option also exists where

petitions are considered by an ALJ independent of the board. In such cases the ALJ renders a proposed decision, which is then considered by all members as part of the mail vote process. (This process is similar to administrative cases.)

Chairperson Schaad stated that in all three scenarios the respondent provides a packet of information and supporting materials intended to provide the board with information in advance of the hearing. Such information includes:

- Personal Information and license history information.
- Letters of recommendation from board licensees.
- Letters of recommendation from citizens.
- Continuing education.

Chairperson Schaad explained that the respondent is also afforded the opportunity to provide oral testimony under oath. In addition to the respondent's testimony, a representative of the Attorney General's Office is present and represents the people of California. The AG's Office is allowed to question the respondent as well as any witnesses. Although not done in all cases, the AG's Office may offer a recommendation to board on the outcome of the petition. Chairperson Schaad noted that technically the board does not have representation in these petitions, and typically board staff does not offer testimony.

Chairperson Schaad reported that since July 1, 2015, the board has considered 41 petitions including 26 petitions for early termination, two petitions for modification of penalty and 13 license reinstatements. He noted added that decisions are not final for all of the petitions heard, but of those where decisions have been rendered, 13 petitions have been approved and 17 petitions have been denied.

Chairperson Schaad reported that when considering reinstatement or reduction of penalty the board may consider factors including, but not limited to, the following:

1. All the activities of the petitioner since the disciplinary action was taken.
2. The offense for which the petitioner was disciplined.
3. The petitioner's activities during the time the license was in good standing.
4. The petitioner's documented rehabilitative efforts.
5. The petitioner's general reputation for truth and professional ability.

Chairperson Schaad stated that to assist in the collection of the relevant information and to provide guidance to potential petitioners, the board has developed petition packets that detail both required and supplemental materials sought from the petitioners and some FAQs about the process.

Chairperson Schaad stated that the criteria established in the law is very general. He explained that during the meeting the committee considered the following items:

1. Is the current process for hearing petitions sufficient, or should the board

- consider reevaluating its policy?
2. Would it be helpful to have board staff testify regarding compliance with terms and conditions of probation, rehabilitative efforts demonstrated by the respondent, public protection concerns, etc.?
 3. Would it be helpful to request additional information in advance of the hearing from the petitioner to aid the board in making its decision?
 4. Does the board wish to establish additional parameters a petitioner must satisfy prior to being eligible to petition the board?
 5. Should a time frame be established that provides clarity on how long a petitioner has to satisfy the requirements set by the board for reinstatement (i.e., pass the NAPLEX, pass the CPJE, pay fines, etc.)?

Chairperson Schaad reported that as part of the committee discussion, staff was directed to release petition materials to members at least 10 days in advance of the meeting. Further, the committee requested that question 15 on the petition application be rephrased.

Chairperson Schaad stated that during the meeting staff also sought guidance from the committee about its interest in amending the statute to include a timeframe for which the provisions of a license a reinstatement must be satisfied. After discussion the committee made a motion to direct board staff to develop statutory language to establish a requirement for a one-year deadline to complete the requirements for reinstatement (such as passing the CPJE).

Chairperson Schaad reported that in response to staff concerns about a lack of guidance on the prioritization of petitions, the committee made a motion to authorize board staff to identify ways to prioritize those probationers that are compliant with their terms of probation and have completed their packet.

Board member Weisser expressed his concern that a pharmacist may not have the time to study and pass the CPJE within a one-year timeframe. Board member Veale also expressed concern with creating additional requirements where none are needed.

Ms. Sodergren explained that there are approximately 30 cases where the board granted reinstatement with conditions that must be met before the license is reinstated (such as passing the CPJE). The challenge for staff is that the law does not currently specify how long someone has to complete the provisions for reinstatement, so the license reinstatement order remains open in perpetuity.

Ms. Sodergren also explained that when the board makes the decision to grant reinstatement they are relying on specific facts, such as completion of continuing education, letters of recommendation, sobriety, etc. As years pass the individual's circumstances many change (for example they may relapse) and the board may want to re-assess the situation before they allow the person to reinstate their license.

After further discussion the board decided not to vote on the committee's motion and instead refer the matter back to the Enforcement Committee for further discussion of

the petition process and refinement of the proposal to create a timeframe to complete the provisions of reinstatement.

Pharmacist Steve Gray spoke in support of returning the item to the Enforcement Committee for further discussion.

c. Discussion and Consideration of Potential Statutory or Regulatory Amendments to Allow a Reverse Distributor to Accept Medications for Destruction in Limited Circumstances from a Previously Licensed Source

Chairperson Schaad explained that BPC section 4040.5 provides the definition of a reverse distributor as an entity that among other functions manages the disposition of outdated or nonsalable dangerous drugs or devices. Note: A reverse distributor is licensed as a wholesaler and must comply with wholesaler requirements unless a specific exemption is provided in the law.

Chairperson Schaad also explained that BPC section 4163 specifies that a wholesaler can only acquire dangerous drugs and devices from a *licensed* source.

Chairperson Schaad reported that during the meeting the committee considered a request from staff to pursue a change in the law that would create a limited exception to allow for a reverse distributor to remove and arrange for the destruction of the drug products for a limited period of time after a license is cancelled, surrendered or terminated.

Chairperson Schaad stated that the committee made a motion to direct board staff to develop a proposal to allow for a reverse distributor to take back some medications.

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

Committee Recommendation (Motion): Direct board staff to develop a proposal to allow for a reverse distributor to take back some medications.

Support: 9 Oppose: 0 Abstain: 1

| | | | | |
|---------|---|--|---|---|
| | | | | |
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | | | X | |
| Law | X | | | |
| Lippe | X | | | |
| Munoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Weisser | x | | | |
| Wong | x | | | |

d. Discussion and Consideration of Current Board Investigation Timeframes and Performance Measures

Chairperson Schaad stated that one of the committee’s strategic goals is to implement processes to shorten the cycle times from the initial investigation to the resolution of cases. Below are benchmarks that are currently measured by board staff.

1. Assignment – Measures the time from the date the complaint is received or initiated.
2. Investigation – Measures the duration from the date the matter is assigned to the date the investigation report is submitted.
3. Review Times – Measures the time from the date the investigation is reviewed until review by the supervisor and second level review is completed.
4. Closure times – Measures the duration from the time the investigation report is reviewed until the case is closed.

Chairperson Schaad reported that the committee discussed the average time frames for the benchmarks provided as part of the meeting materials and discussed different ways to report the data.

Chairperson Schaad stated that the committee did not take action on this item but will continue reviewing workload, including investigation times.

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

e. Discussion of the Presentation of the Administrative Case Process and Case Resolution Times for Matters Referred to the Office of the Attorney General

Chairperson Schaad stated that this item was covered earlier in the meeting. There were no comments from the board or from the public.

f. Discussion and Consideration of Implementation Strategy for Anticipated Statutory Changes to Incorporate USP Compounding Chapters

Chairperson Schaad reported that during its May 2018 board meeting, members voted to pursue a statutory proposal to incorporate USP compounding chapters into the board’s requirements for compounding drug preparations. As part of its discussion, the board noted that two of the compounding chapters, <795> and <797>, are in the revision process by USP and USP <800> has been finalized but is not yet in effect.

Chairperson Schaad provided an update on the status of USP chapters 795, 797 and 800 as provided below.

Chapter 795

The proposed revisions for USP <795> were released in March 2018 and an open microphone session was held on April 20, 2018. In addition, on May 1, 2018, Chapter 795 was formally published in *Pharmacopeial Forum* for review and public comment. The public comment period will close on July 31, 2018, and USP indicates that its intended publication date is June 1, 2019 with an anticipated official implementation date of December 1, 2019.

Chapter 797

The proposed revisions to USP <797> will be pre-posted by USP on July 27, 2018 and will be formally published on September 4, 2018. An open microphone session will be held on September 5, 2018 and the public comment period will close on November 20, 2018. The intended publication date for this chapter is June 1, 2019, with an anticipated official implementation date of December 1, 2019.

Chapter 800

This chapter is in its final form, with an expected official implementation date of December 1, 2019 (to coincide with the anticipate official dates for Chapters 795 and 797).

Committee Discussion and Action

Chairperson Schaad stated that as the revisions for the respective chapters are finalized, it is anticipated that staff will complete a comprehensive review of the new requirements and provide recommendations to the board about necessary changes to the board's regulations. Further, the board's current regulation requirements related to hazardous drug compounding will also need to be reassessed to determine what if any action is necessary.

Chairperson Schaad reported that as part of its discussion the committee heard from members of the public on readiness to meet the December 1, 2019, requirements in USP 800. Based on the information received, it appears that independent retail sterile compounding pharmacies will be compliant with USP 800 requirements by December 1, 2019. The committee requested that information on readiness by other sterile compounding pharmacies be provided at future meetings.

Chairperson Schaad explained that in response to public comment and in recognition of the large impending policy work that will be required after finalization of the USP Chapters, President Law has bifurcated the Enforcement and Compounding Committee into two committees. He added that information on this transition will be provided during the next Enforcement Committee Meeting scheduled for September 8, 2018.

President Law announced that Stanley Weisser would be the chair of the Compounding Committee and Maria Serpa, Allen Schaad, Shirley Kim would be members.

A representative from CPhA spoke in support of the board's statutory proposal to

incorporate USP compounding chapters into the board’s requirements for compounding drug preparations.

Board member Veale asked if the board should submit comments on the USP chapters. After discussion the board agreed that if there are specific sections of the USP chapters that are of concern, then the board should submit comments.

The board heard public comment supporting the board submitting comments on the USP chapters. Additionally, CPhA and Dyna Labs offered to work with the board on drafting comments.

Chairperson Schaad stated that the comment period closes in November and expressed concern that the board will not have time to get comments approved by the full board prior to submission.

Ms. Veale recommend authorizing the Compounding Committee chair to work with board staff to draft and submit comments on behalf of the board. Ms. Herold noted that the board has used this model in the past to submit comments to the FDA when the comment period closed before the full board could review them.

Motion: Authorize the chair of the Compounding Committee to work with staff to review USP chapters 700, 795 and 800 and submit comments if nessecary.

M/S: Veale/ Weisser

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

g. Discussion and Consideration of the Board’s Enforcement Statistics

Chairperson Schaad reported that during the meeting, the committee reviewed enforcement statistics. As part of the committee’s discussion, staff was directed to incorporate additional reporting elements into future enforcement statistics including:

- Proof of Abatement Orders
- Average Investigation Time
- Strategic Goal Measures
- Cease and Desist orders issued for Unlicensed Activity

Chairperson Schaad stated that some of these changes have been incorporated and are reflected in the three-year comparison statistics provided in the Executive Officer's Report. He noted that the additional elements will be brought to the committee for review and consideration during its next meeting.

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

h. Future Committee Meeting Dates

Chairperson Schaad announce the following committee meeting dates.

- September 5, 2018
- December 13, 2018

VIII. Presentation on the Open Meetings Act and Conflict of Interest

Board attorneys Laura Freedman and Kelsey Pruden provided DCA's refresher training with an overview of several laws and policies that govern the board and its members as a state body, as an entity within a larger department, and how the various laws and policies relate to the board's mission to protect the public and satisfy good government practices in the process. Their presentation covered:

- (1) the Bagley-Keene Open Meeting Act requirements;
- (2) for enforcement or disciplinary matters, the Administrative Procedure Act's requirements about (a) disqualification in voting and (b) ex parte communications;
- (3) the Political Reform Act, spotting financial conflicts of interests and what to do when questions arise; and
- (4) the department's Incompatible Activity Policy and appearance concerns.

Wednesday, July 25, 2018

President Law called the meeting to order at 9:02 a.m.

Board members present: Victor Law, Ricardo Sanchez, Deborah Veale, Allen Schaad, Gregory Lippe, Stanley Weisser, Shirley Kim, and Lanza Butler.

Note: Albert Wong and Maria Serpa arrived at 9:10 a.m.

Reappointed board member Ricardo Sanchez was sworn in by Chief Deputy Director Christopher Shultz.

Board member Weisser thanked Giny for her service by reading the following statement.

“I think Giny’s announcement caught many of us by surprise yesterday. While we the board will more formally recognize Giny when her retirement date nears, I want to take a few minutes to thank Giny not only for her many years of dedicated service to the board, but also to the state of California. Giny has worked tirelessly for this board for over 25 years. California consumers are much better off because of her efforts. It would be a very difficult task to list all of her achievements. Her work on patient consultation regulations and on e-pedigree and most recently sterile compounding and outsourcing facilities are just a few in a long list. Giny’s efforts embody the board’s vision statement of “healthy Californian’s through quality pharmacists care.” I am sure I speak for many as well as myself when I say: “Giny, a sincere thanks to you for everything you have done for the board and for the citizens of California.””

President Law stated that a committee would be created to begin the search for a new executive officer.

The board briefly returned to agenda item VIII to finish the presentation on the Open Meetings Act.

IX. Update from the Department of Consumer Affairs

Patrick Le welcomed the board’s two newest members, board member Serpa and board member Kim. He also thanked executive officer Herold for her years of service following her retirement announcement.

Patrick Le provided an update on the DCA leadership call that occurred on June 25, 2018. The call had over 30 participants in that call which included board presidents, vice presidents, chairs, vice chairs and some advisory committee members. During the call, DCA provided updates on pro rata, Assembly Bill 2138, the executive officer salary study and the regulatory process improvements. The Department plans to host another leadership teleconference call in the near future, with the next date to be announced.

Patrick Le provided some background and some updates on DCA’s Licensing and Enforcement Workgroup activities. On April 10, the Department hosted its first licensing and enforcement workgroup meeting. With over 60 staff in attendance, the Department convened executive officers, bureau chiefs and key licensing and enforcement staff and began to identify business processes that will strengthen boards and bureaus in the areas of licensing and enforcement. Since then, the workgroups continued to meet monthly to discuss specific ideas to innovate in the areas of licensing and enforcement – whether process efficiencies or collaboration. In June, the licensing workgroup heard from Dr. Joseph Morris, executive officer of the Board of Registered Nursing, and learned about BRN’s cloud drive and ways the platform can streamline license application processing.

Patrick Le provided an update on the Substance Abuse Coordination Committee. On April 23rd, the Department reconvened the Substance Abuse Coordination Committee. Per SB 796, the Committee has been tasked with examining Uniform Standard #4 related to drug testing standard for substance-abusing licensees in a Diversion Program or in programs that have adopted the Uniform Standards. The committee is tasked with determining if the existing criteria needs to be updated based on a recent development in testing research and technology, and report to the legislature by January 1, 2019. Per statute, the committee is made up of the healing arts boards executive officers, and designate from the Department of Health Care Services, and is chaired by the Director of the Department of Consumer Affairs. At its last meeting in June, the committee examined Uniform Standard #4 and took an in-depth look at drug testing methodologies, research, and technological advancements. The committee heard from a panel of industry and medical experts in the field of rehabilitation, toxicology, and laboratory science. The committee voted to adopt some technical changes to Uniform Standard #4, and decided to further examine the issue of testing frequency at its next meeting.

Board member Weisser stated that the board is concerned with the high testing frequency. Ms. Herold stated that as the board's representative at these meetings she has expressed the board's concerns. Mr. Le stated that this will be an ongoing discussion at the next meeting.

Patrick Le provided the additional dates for Board Member Orientation Training for 2018. The next two trainings will be on September 18 and December 5, with additional dates to be announced soon. These are one-day training in Sacramento which details the important functions and responsibilities of board members. Taking the training is required for board members, and must be taken within one year of appointment or reappointment to a board.

Patrick Le provided an update on the Department's effort to improve the timeframes for regulatory packages. The Department changed its processes in late 2016 to improve the quality of the regulations it submitted to the Office of Administrative Law, and reduce the number of disapproved files. The Department reports that since September 2016, there was steady improvement in the disapproval rate, going from a 21.8% percent disapproval rate in the first half of 2017, to only 7.6% being disapproved between July 2017 and February of 2018. In 2018, there have been 0 disapprovals. The Department recognized that the timeframes for review have also increased in that time.

In order to reduce review timelines without sacrificing quality, the Department has been implementing new processes. The first is training to improve the knowledge base of those writing regulations. To that end, DCA offered three separate training classes to regulation staff in November 2017, April 2018, and May 2018 to better equip staff with preparing rulemaking files and cut down on the level of scrutiny needed to review packages.

Secondly, the Department has been cutting layers of review, particularly the ones who were identified as not harming the quality of the rulemaking files. Third, the Department has done some internal restructuring, consolidating review functions to reduce the amount of time lost due to transferring files throughout the Department. Fourth, the Business, Consumer Services and Housing Agency hired a new attorney to help improve review of

regulations. Finally, the Department is implementing a computer tracking system – a DCA-wide regulation tracking system that will better manage time and track packages.

DCA Fiscal Officer Taylor Schick reviewed the distributed cost allocations and DCA's 2018 Report to the Legislature that was provided in the board meeting materials.

Mr. Schick explained that the main way that the department equitably distributes the department's administrative costs across all boards and bureaus is by using authorized position counts to create a ratio.

The board asked if all board's and bureaus pay for BreZE even if they do not use the program. Mr. Schick explained that effective July 1, 2018 only programs who are actively using BreZE are paying for the system.

The board thanked Mr. Schick and Mr. Le for their updates.

X. Executive Officer's Report

a. Update on Substance Abuse Prevention Billboard

Ms. Herold reported that at its February 2018 meeting, the board approved a design chosen by the Communication and Public Education Committee for a billboard to raise awareness about drug abuse prevention. Board Member Ryan Brooks' firm, Outfront Media, has agreed to donate five billboards for the project – two in Northern California, one in Central California, and two in Southern California.

Ms. Herold stated that also at the February meeting, the committee reported that staff is revamping the drug abuse prevention page on the website. The new page will have a fresh look and contain updated resources for drug abuse information and treatment. Eventually, the billboard image will be displayed on the website as a link to the new drug abuse prevention page.

Ms. Herold reported that board staff and Outfront Media are working to finalize a no-cost contract for the project. Staff is working with DCA's Business Services Office (BSO), which is responsible for preparing and processing all contracts for the board, to finalize the contract.

Ms. Herold added that in the meantime, staff has updated the drug abuse information on the board's website. The new webpage is cleaner and visually more interesting, with logos identifying organizations and resources. It also includes an embedded video of the board's public service announcement about prescription drug abuse.

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

b. Update on the Substance Abuse Coordination Committee Meeting Held 6/27/18

Ms. Herold stated that as Mr. Le reported the second meeting of the Substance Abuse Coordination Committee was held on June 27, 2018. During this meeting, the committee held discussions about the various modes to test for abstinence and ensure adherence to treatment requirements, including when a participant has a need to leave the state (e.g., to settle an estate outside the USA).

Ms. Herold noted that frequency of testing especially for the first year of program participation where the testing frequency is 52 to 104 times a year was also discussed. She added that there will likely be at least one additional meeting of the SACC to focus on testing frequencies for program participants.

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

c. Report on the Certification of the CURES System by the CA Department of Justice and Resulting Changes

Ms. Herold reported 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 (Lara, Chapter 708)), and at least every four months thereafter if therapy with the controlled substances is ongoing. She noted that these provisions can be found in Health and Safety Code section 11165.4.

Ms. Herold stated that the board released a subscriber alert on 5/16/18 to inform pharmacists about the requirements for prescribers to check CURES before prescribing these medications.

Ms. Herold reviewed CURES data for January through May 2018 (provided in the board meeting materials). The board was pleased that so many pharmacists are using CURES. Ms. Herold stated that there is still room for improvement, but the board has done significant outreach to inform pharmacists of the requirements and encouraging them to use CURES.

d. Update on the Board's 2018 Pharmacy Law Continuing Education Webinar

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 CA 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 reported that board staff has developed a program that covers 2018 new pharmacy laws. Board staff worked with DCA's SOLID Training and Development Unit to create a free video webinar that integrates a live presentation on pharmacy law by the executive officer, with quiz questions intended to monitor participation and learning objectives. Upon completion pharmacists will be awarded one hour of CE toward the fulfillment of the requirement in 1732.5(b) and will have the ability to print a certificate of completion for their records. Ms. Herold announced that the webinar will be available on the board's website in early August.

Ms. Herold stated that board staff will begin developing another webinar focusing on pharmacy ethics to fulfill a part the second hour of CE required by 1732.5(b). Additionally, once the 2018 legislative year is over, staff will develop a 2019 pharmacy law component to this series.

Ms. Herold explained that the Communication and Public Education Committee at its next meeting will discuss a means to award one hour of CE for reading the board's newsletter, *The Script*.

Ms. Herold also noted that the board agreed to allow licensees to use two of the six hours awarded for attendance at the Prescription Drug Abuse Presentations as fulfillment of the CE requirement for a renewal period.

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

e. Update on the Board's Naloxone Certification Webinar

Ms. Herold explained that at the February 2018 Board Meeting, the board approved a recommendation by the Communication and Public Education Committee to create a webinar course for pharmacists to furnish naloxone, which reverses opioid overdose. The webinar would provide one hour of CE credit to satisfy the training requirement for furnishing naloxone under the board's protocol in CCR section 1746.3. The board also approved materials for the webinar created by Dr. Talia Puzantian of Keck Graduate School of Pharmacy and Dr. James Gasper of California Department of Health Care Services.

Ms. Herold reported that staff has been working with DCA's SOLID Training and Development Unit to create the free webinar that will be available on the board's website. SOLID is preparing the webinar PowerPoint for ADA compliance. Staff is developing a script for voice-over that will accompany the webinar. Pharmacists who view the full webinar will be able to print out a certificate of completion.

Ms. Herold stated that because of SOLID's workflow – including development of a law and ethics webinar for the board – the naloxone webinar is expected to be completed in late summer.

Ms. Herold noted that the Communication and Public education committee will be considering if the board should scale back the naloxone protocol to encourage more pharmacists to provide naloxone. Mr. Schaad stated that recently other state boards of pharmacy have scaled back their naloxone requirements.

Board member Lavanza Butler stated that she would like to coordinate with board staff to hold another DEA and Board of Pharmacy Joint training in the LA area.

f. Staff Development and Training Update

Ms. Herold reported that to ensure ongoing knowledge and competency in compounding, all board inspectors are completing another three-day in-person training through Clinical IQ. In order to take this training, inspectors are required complete a 40-hour webinar training program.

Ms. Herold added that to ensure better and more consistent inspections in California, the board offered pharmacy consultants in the Department of Public Health the opportunity to join in the training sessions with the board's inspectors. Board staff noted that eight staff members from the Department of Public Health are taking the training sessions.

The board spoke in support of the continued training of the board's inspectors in order to keep them current on emerging pharmacy issues and to ensure consistency in the board inspections.

Ms. Herold stated that in the future board members will be given an opportunity to take the 40-hour compounding webinar training.

Ms. Herold explained that in order to foster a more collegial work environment as the board continues to grow, in recent months board staff has attended team building sessions led by trainers in DCA's SOLID Office.

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

g. Update on the Relocation of the Board's Office

Ms. Herold explained that for the past year board staff has been working with DCA and the Department of General Services to locate new office space that can accommodate the board's significant growth.

Ms. Herold reported that recently, the board signed a lease for new office space located at 2720 Gateway Oaks Drive Suite, approximately three miles from our current

location. The tentative start date of the lease is February 1, 2019; however, that date could be impacted by construction timelines, necessary approvals, etc.

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

h. Update on the July Issue of *The Script*

Ms. Herold reported that the second newsletter of 2018 was published in mid-July. The cover story explores potential health risks to consumers who shop for prescription drugs on the internet, and how pharmacists can educate their patients about buying medications online. She noted that this article has been shared with other healing arts boards in DCA. Other newsletter articles report on ways to help reduce medication errors, new board regulations related to disciplinary guidelines and beyond use dates for compounded drug medications, and tips for wholesalers on how to prepare for inspections and how to report suspicious orders of controlled substances.

Ms. Herold stated that the next issue of *The Script* will focus on the reconciliation regulation and the importance of catching drug losses early.

The board thanked staff for the improvement in the quality of *The Script* layout and articles.

i. Information on the Department of Health Care Services Grant for Drug Take Back Programs

Ms. Herold reported that she is working with the California Department of Health Care Services on a possible grant to provide reimbursement for drug take back services. This project is in the early development phases and more information will be provided as it becomes available.

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

j. Report on the 2018 USP Workshop on Safe Compounding

Ms. Herold reported that in May she attended a USP workshop to address compounding issues entitled: Inaugural USP Workshop on Evolution and Advances in Compounding. Ms. Herold stated that she provided a presentation “Advancing Quality Compounding, the State Perspective.”

Ms. Herold reported that in the presentation she described the board’s requirements, inspections conducted, and the learning experiences of moving to implement portions of USP 800 and its huge impact on pharmacy building standards.

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

k. Report on the National Association of Boards of Pharmacy Development of Recommended Parameters Regarding Suspicious Order Notification from Wholesalers

Ms. Herold reported that she was invited to work with the National Association of Boards of Pharmacy on the development of parameters to trigger suspicious order notifications by wholesalers to state boards of pharmacy involving irregular sales of controlled substances by wholesalers to pharmacies.

Ms. Herold explained that in 2017, California and other states enacted provisions to require wholesalers to add to federal notification requirements a provision for state reporting when wholesalers receive suspicious orders from pharmacies. However, what constitutes “suspicious” is not clearly defined. She explained that the definition of suspicious orders currently includes, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

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

I. Changes to the California Department of Corrections’ Drug Distribution Model

Ms. Herold reported that enacted as part of the trailer bills to the state’s 2018/19 budget is a bill that altered the manner in which the state’s prisons handle and provide prescription medication to inmates. The general plan is to use a clinic-based model with ADDS machines to provide medication to the state’s prison population one dose at a time. Ms. Herold noted that this is expected to result in an increase hundreds of licenses and registrations.

The board asked that representatives from the Department of Corrections provide a presentation on the new drug distribution model at the next Licensing Committee meeting.

There were no comments from the public.

m. Report of Multi-Year Comparisons of Licensing and Enforcement Statistics

Enforcement Statistics

Ms. Herold noted that the board meeting materials contained a three-year comparison of data for the board’s enforcement operations. She explained that a review of the three-year comparison reveals the board completed about 229 more investigation in FY 2017/18 versus FY 2015/16, about an 8 percent increase, and the overall total of investigations pending decreased by 16 percent.

Ms. Herold stated that detailed enforcement statistics were provided in the board meeting materials.

Ms. Veale asked why there was a drop of interim suspension orders. Ms. Herold responded that they are only used when there is an immediate public risk that requires the pharmacy to close in order to protect the public.

Ms. Veale noted that there was also a drop in the number of pharmacy technicians on probation. Ms. Herold explained that often technicians decide to surrender their license once they realize how stringent and expensive probation can be.

Licensing Statistics

Ms. Herold reported that in fiscal year 2017/2018, the board received 16,459 applications for licensure, issued 11,067 new licenses and renewed 64,644 licenses. In addition, licensing staff processed 15,264 change notices, responded to 34,858 email inquiries and answered 7,784 phone calls. She noted that the board's overall licensing population at the end of the fiscal year was 139,640.

Ms. Herold stated that detailed licensing statistics were provided in the board meeting materials.

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

n. Update on Status of Board Sponsored Legislation Related to Fees for Government Owned Facilities

Ms. Herold explained that in 2017 as part of the enactment of SB 443 (Hernandez, Chapter 547), a discussion occurred with the Department of Finance about why the board exempts government facilities from having to pay licensure fees. In a subsequent discussion with the board, the board opted to end this subsidy in the future.

Ms. Herold reported that this year, Senator Hill has agreed to add provisions to SB 1480. However, the Department of Finance asked the board not to pursue the bill this year and reintroduce it during the next legislative cycle.

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

o. Report on the FDA Approval of Seizure Medication Containing Cannabidiol and the Implementation of AB 710 (Wood)

Ms. Herold stated that Epidiolex was approved by the FDA on June 25, 2018.

Note: A copy of the FDA's statement was provided in the board meeting materials.

Ms. Herold explained that the Drug Enforcement Administration (DEA) now has 90 days to schedule the medication. The product will also need to be rescheduled under the state's controlled substance act in those states that control marijuana and its compounds in Schedule I.

Ms. Herold reported that in California, Governor Brown signed AB 710 on July 9 which addresses this drug. Below is a description of AB 710 from the Legislative Counsel's Digest:

Existing law, the California Uniform Controlled Substances Act, classifies controlled substances into 5 designated schedules, with the most restrictive limitations generally placed on controlled substances classified in Schedule I, and the least restrictive limitations generally placed on controlled substances classified in Schedule V. Existing law designates cannabis in Schedule I. Cannabidiol is a compound contained in cannabis.

Existing law restricts the prescription, furnishing, possession, sale, and use of controlled substances, including cannabis and synthetic cannabinoid compounds, and makes a violation of those laws a crime, except as specified.

This bill, if one of specified changes in federal law regarding the controlled substance cannabidiol occurs, would deem a physician, pharmacist, or other authorized healing arts licensee who prescribes, furnishes, or dispenses a product composed of cannabidiol, in accordance with federal law, to be in compliance with state law governing those acts. The bill would also provide that upon the effective date of one of those changes in federal law regarding cannabidiol, the prescription, furnishing, dispensing, transfer, transportation, possession, or use of that product in accordance with federal law is for a legitimate medical purpose and is authorized pursuant to state law.

Existing law, the Medicinal and Adult-Use Cannabis Regulation and Safety Act, regulates the cultivation, processing, and sale of medicinal and adult-use cannabis within the state.

This bill would expressly exclude from regulation under that act, any medicinal product composed of cannabidiol approved by the federal Food and Drug Administration and either placed on a schedule of the federal Controlled Substances Act other than Schedule I or exempted from one or more provisions of that act.

This bill would declare that it is to take effect immediately as an urgency statute.

The board discussed the medical use of cannabis and its derivatives. Mr. Room noted that any pharmacy that is registered with the DEA would be unwise to provide cannabis-based products because at the federal level it is still illegal.

Ms. Herold stated that staff will continue monitoring the actions taken by the FDA and DEA and will bring the item to a future meeting when more information is available.

The board recessed for a break at 11:00 a.m. and resumed at 11:10 a.m.

XI. Organizational Development Committee

a. Budget Update/Report

Fiscal Year 2017/2018

President Law reported that fiscal year 2017/2018 ended on June 30, 2018. However, the final FY 2016/2017 numbers are not yet available. He stated that a final budget report will be provided at the next board meeting.

President Law reviewed the below summary table of the revenue for the first eleven months of the fiscal year.

| Source | Amount | Percentage |
|----------------|---------------|-------------------|
| Licensing | \$22,428,200 | 90% |
| Citation Fines | \$1,720,900 | 7% |
| Cost Recovery | \$699,100 | 3% |
| Interest | \$98,500 | 0% |

President Law reported that as of fiscal month eleven, the board expended \$19,856,000, which is approximately 85% of its authorized budget of \$23,370,000. He reviewed the largest expenditure categories as detailed in the table below.

| Source | Amount | Percentage |
|---------------|---------------|-------------------|
| Personnel | \$13,719,200 | 69% |
| Prorata | \$2,168,900 | 11% |
| Enforcement | \$2,486,700 | 13% |

President Law reviewed the following summary of the fund condition report prepared by the department.

| Fiscal Year | Fund Balance | Months in Reserve |
|--------------------|---------------------|--------------------------|
| 2017/2018 | \$9,095,000 | 4.1 |
| 2018/2019 | \$6,415,000 | 2.8 |
| 2019/2020 | \$3,213,000 | 1.4 |
| 2020/2021 | -\$515,000 | -0.2 |
| 2021/2022 | -\$4,769,000 | -2.0 |

President Law stated that when the board receives the final budget information, staff has been authorized to work with the Vice President to 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.

Fiscal Year 2018/2019

President Law reported that the new fiscal year started July 1, 2018. The Board's authorized expenditures for the year are \$25,280,000. He noted that detailed budget information is not yet available but will be provided at the next quarterly board meeting. There were no comments from the board or from the public.

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

b. Board Member Reimbursement and Attendance Information

President Law explained that board members may seek reimbursement for travel expenses and per diem payments. It is important to note that these figures only represent hours and travel expenses where reimbursement was sought. He added that it is not uncommon for board members to waive their per diem payments or only request partial reimbursement of travel expenses.

President Law reported that as part of the end-of-year accounting process, the payment of all travel claims has been stopped until the State Controller's Office updates the electronic program used for the reimbursement of travel expenses. Once the system has been updated for the new fiscal year, all board member travel claims will be paid. He stated that a final report of reimbursements will be provided at the next board meeting.

President Law stated that the detailed reimbursement and board member attendance information was provided in the meeting materials.

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

c. Discussion and Consideration of Authorizing Continuing Education for Pharmacists and Pharmacy Technicians Participating in the Pharmacy Technician Occupational Analysis Survey

President Law reported that the Board is conducting an occupational analysis for the license category of pharmacy technician pursuant to Business and Professions Code section 139. As a part of the occupational analysis, surveys are sent to pharmacists and pharmacy technicians to determine what duties and types of knowledge bases are required to be a pharmacy technician in California.

President Law explained that in order to increase the response rate for surveys, board staff is recommending that a pharmacist or pharmacy technician who completes the survey be awarded 2 hours of continuing education. Board staff has reached out to the entities that offer the two pharmacy technician certification programs accepted in California – PTCB and ExCPT. President Law note that both entities have agreed to accept continuing education offered by the board for this purpose.

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

Motion: Award two hours of continuing education credits to pharmacists and pharmacy technicians upon completion of the Pharmacy Technician Occupational Analysis Survey.

M/S: Law/Weisser

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | X |
| Butler | X | | | |
| Khan | | | | X |
| Kim | X | | | |
| Law | X | | | |
| Lippe | X | | | |
| Munoz | | | | X |
| Sanchez | X | | | |
| Schaad | X | | | |
| Serpa | X | | | |
| Veale | X | | | |
| Weisser | X | | | |
| Wong | X | | | |

President Law announced that in order to educate pharmacy students on the board’s disciplinary process and the pitfalls that can result in licensure discipline, the board will be holding all future petitioner board meetings as schools of pharmacy.

Board member Schaad requested that committee members be provided meeting minutes following the committee meetings. Ms. Herold responded that staff would provide draft minutes to the committee members following each meeting.

XII. Legislation and Regulation Committee

Part 1: Legislation for Discussion and Consideration Report

a. Board Sponsored/Originated Legislation

1. AB 1751 (Low) Controlled Substances: CURES Database

Version: As amended July 5, 2018

Status: Senate Appropriations

Board Position: Support

Summary: This measure will allow the Department of Justice to enter into an agreement with an entity operating an interstate data sharing hub for purposes of interstate sharing of controlled substances reporting information and also require DOJ to promulgate regulations outlining access to and the use of information within CURES.

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

Recent Updates: This measure was recently amended. The proposed amendments go far beyond the initial policy goal of the board as well as the measure itself (sharing controlled substances dispensing history across state lines) Further amendments were incorporated that would allow a health care provider or a pharmacy who is employed by an insurer or PBM to access CURES for the stated purpose of adjudicating a claim. According to information received, this amendment is intended to allow insurers and PBMs to serve as another gatekeeper in the prescribing and dispensing of controlled substances. Staff notes it is the role of the regulator to safeguard against inappropriate prescribing and dispensing habits and is a core function of our mandate as well as the mandate of prescriber board.

Chairperson Lippe explained that because of the recent amendments, per the board's policy, he authorized changing the board's position from support to oppose unless amended to remove PBM access to CURES.

Ms. Herold explained that the amendments were added without consultation with the board and there is significant concern with allowing PBMs to access patient information using CURES.

Pharmacist Steve Gray explained that PBMs are federally required to employ pharmacists to manage patient therapy and medication adherence. He stated that the PBMs would use the CURES data to manage therapy. Mr. Lippe noted that the bill states that the PBMs would be using CURES to adjudicate a claim, not to manage patient therapy.

Mr. Room stated that PBMs would already have access to all claims, so they wouldn't need access to CURES to manage therapy or adjudicate claims. Dr. Gray responded that CURES would show if a patient is paying cash for controlled substances.

Mr. Weisser expressed his concern that PBMs would not be using CURES information solely for the purpose of medication therapy management and asked if there were any privacy concerns that the board should consider. Mr. Room stated that under both federal and state law there are allowances for sharing medical information for the purposes of adjudicating claims.

Ms. Herold stated that California law will soon require prescribers to check CURES before they write a prescription. The reason the board wants to expand the program across state lines is to provide prescribers with as much information as possible when they are caring for the patient. Ms. Herold stated that there is no reason to allow PBMs to access CURES and other states do not grant them this access.

Mr. Room again noted that the language seems to be very specific in granting PBMs access for the purposes of claim adjudication, not medication therapy management.

Pharmacist Robert Stein stated that the purpose of CURES is to ensure proper patient care not to adjudicate claims.

Daniel Martinez stated that CPhA supports the board’s change in position and added that they will also be changing their position to oppose unless amended.

Ms. Freedman recommended that the board validate the position that Chairperson Lippe took.

Motion: Approve changing the board’s position to Oppose Unless Amended to remove PBMs access to CURES for the purpose of adjudicating claims.

M/S: Weisser/Sanchez

Support: 9 Oppose: 0 Abstain: 1

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | | | x | |
| Weisser | x | | | |
| Wong | x | | | |

2. AB 1752 (Low) Controlled Substances: CURES Database

Version: Introduced January 3, 2018

Status: Referred to Assembly Business and Professions Committee

Board Position: Support

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.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification.

Daniel Martinez reported that CPhA has changed their position from oppose

unless amended to support.

There were no comments from the board.

3. AB 2086 (Gallagher) Controlled Substances: CURES Database

Version: Amended April 3, 2018

Status: Senate Floor-Second reading

Board Position: Support

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.

Recent Updates: This measure has not been amended since last brought before the board.

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

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

Version: Amended April 11, 2018

Status: Senate Appropriations Suspense file

Board Position: Support

Summary: This bill would reclassify specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

Recent Updates: This measure has not been amended since last brought before the board.

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

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

Version: Amended July 3, 2018

Status: Senate Appropriations

Board Position: Support

Summary: This bill would require by January 1, 2022, all written prescriptions issued by licensed prescribers in California be issued as an electronic transmission prescription (e-prescription). By January 1, 2022 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 use counterfeit prescriptions, thus decreasing unsupervised access to medication.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification as well as extend the effective date which was previously January 1, 2021.

Mr. Weisser asked if this bill would affect patients who get their medications online or from Canada. Ms. Herold responded that as most patients do not have a prescription when they purchase drugs online or from Canada this bill would not affect them.

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

Status: Assembly Appropriations

Board Position: Support

Summary: This bill is sponsored by the board. The measure will repeal the general Automated Drug Delivery System (ADDS) registration 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, leased, owned 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 California 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 or lease 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 (APDS) that are used to dispense medication to patients. 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. Lastly, this bill would require the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024.

Staff Comments: This measure is board sponsored and includes the provisions approved by the board during its January 2018 meeting. The board discussed this measure at the May 2 meeting and board staff have continued to work closely with the author’s office and interested parties to ensure that the provisions of the bill are in line with the board’s policy decision. In its current form, the bill would exempt ADDS from licensure that are used in hospitals to provide access to drugs that are administered to patients.

Paige Tally asked why re-inspection would be necessary if a machine is simply being replaced in the same location. Ms. Herold stated that the board would want to verify that the new machine has the same security features as the original machine. She added that she would discuss this with the author's office.

b. Legislation Impacting the Practice of Pharmacy or the Board's Jurisdiction with a Board Established Position

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

Version: Amended June 25, 2018

Status: Senate Appropriations

Board Position: Support if amended

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. The Board voted to support this measure if amended with an additional provision that would require disclosure to the board any relationship between a pharmacy and a SNF.

Recent Updates: The author was made aware of the board's position and suggested amendment and, as yet, has not included this in the bill.

A representative for the California Counsel for the Advancement of Pharmacy stated that they support the bill and also supports the board's suggested amendments.

There were no comments from the board.

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

Version: Amended April 2, 2018

Status: Senate Appropriations

Board Position: Oppose

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: The board 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 DCA to more robustly protect consumers. Creating barriers or limiting information the board can consider when making a licensing decision and enforcement action could undo gains the board has made in this area and significantly undermine the board's consumer protection mandate.

Recent Updates: Amendments to the measure have removed some of the more restrictive provisions of the bill but do not make sufficient changes to remove the board's opposition. Multiple boards in the DCA similarly oppose the measure.

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

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

Version: Amended June 6, 2018

Status: Senate Floor

Board Position: Support

Summary: This bill would allow law enforcement agencies throughout the state to acquire Naloxone from a pharmacy, *wholesaler, or manufacturer* 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.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification that a wholesaler or manufacturer may also provide an opioid antagonist to law enforcement agencies.

Mr. Weisser asked what the price of Naloxone is currently. Ms. Herold stated that it has gone up due to increased demand.

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

Version: Amended June 27, 2018

Status: Senate Appropriations

Board Position: Support

Summary: This bill would grant authority to clinics to furnish dangerous drugs to several entities, pharmacies to dispense drugs without a prescription and the board to waive any requirement in the relevant chapter during a state of 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 clinics 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.

Recent Updates: Amendments made to this measure after the May Board meeting now extend the policy beyond response to declared disasters by expanding the conditions under which a clinic can provide medications to someone other than a patient. Board staff has requested clarification from the author's office on this provision.

Ms. Sodergren reported that staff met with the author's office and determined that their intent was to have the measure only apply when there is an emergency. She stated that staff is working with them to draft the language so that it reflects their intent.

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

Version: Amended June 21, 2018

Status: Assembly Appropriations Committee

Board Position: Oppose unless amended

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 recommend offering amendments to remove (c)(1) and (2) as the Board already has the authority to cite and fine for noncompliance with regulations. Board established an OUA position, with the desired amendment being to make optional the requirement for a pharmacy to carry safe storage products.

Recent Updates: Following recent amendments to the measure, the executive officer worked with committee chair to establish a neutral position on this measure. That position is being brought to the board for ratification.

Chairperson Lippe explained that because of the recent amendments, per the board's policy, he authorized changing the board's position from oppose unless amended to neutral.

Daniel Martinez reported that because the bill had been amended to make the display of safe storage products optional for independent pharmacies CPhA changed their position to support.

Ms. Freedman recommended that the board validate the position that Chairperson Lippe took.

Motion: Approve changing the board's position to neutral.

M/S: Veale/Butler

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

Following the vote, it was noted that the bill still makes the display of safe storage products mandatory for chain pharmacies (defined in the bill as more than four locations). Because many of the members thought that is was optional for *all* pharmacies when the vote was taken, the board decided to re-vote.

Motion: Reconsider the previous vote.

M/S: Lippe/Sanchez

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

Motion: Approve changing the board’s position to neutral.

M/S: Veale/Sanchez

Support: 5 Oppose: 4 Abstain: 1

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | | | x | |
| Law | | x | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | | x | | |
| Veale | | x | | |
| Weisser | | x | | |
| Wong | x | | | |

6. SB 1442 (Wiener) Pharmacies: Staffing

Version: Amended June 21, 2018

Status: Assembly Appropriations

Board Position: Support

Summary: This bill specifies that a community 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: When this measure was before the Senate Business, Professions, and Economic Development Committee, concern was raised about independent pharmacies and the possible negative impact to such businesses. Since then, the measure has been amended to exempt independent, government owned, and hospital pharmacies. The board heard testimony at the May board meeting and voted to take a Support position.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification of the types of pharmacies included, who may assist a pharmacist, and the situations in which this rule may not apply.

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

c. **Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction without a Board Established Position**

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

Version: As amended April 18, 2018

Status: Senate Appropriations

Summary: This measure would reduce the number of authorized security printers approved by the DOJ to three. 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.

Recent Updates: This measure has not been amended since last brought before the board.

Chairperson Lippe reported that the committee did not take a position on this bill. There were no comments from the board or from the public.

2. AB 1998 (Rodriguez) Opioids: Safe Prescribing Policy

Version: As amended July 2, 2018

Status: Senate Appropriations

Summary: By July 1, 2019, every health care practitioner authorized to prescribe Schedule II and Schedule III opioids must adopt a safe prescribing protocol, as specified, including a requirement that a prescription for Naloxone or other opioid antagonist be offered when prescribing opioids to patients that meet specified criteria. This bill requires CDPH to report to the legislature annually on data relating to such prescriptions issued in California.

Staff Comments: The board has routinely supported and focused efforts on combatting prescription drug abuse.

Recent Updates: Recent amendments to this measure now include a hospital pharmacy and therapeutics committee as an entity required to develop a safe prescribing protocol.

Board member Veale asked if a safe prescribing protocol was being developed for the entire state. Ms. Sodergren responded that it will not be a statewide protocol, it is intended to be facility specific.

The board decided not to take a position on AB 1998.

There were no comments from the public.

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

Version: Amended May 25, 2018

Status: Senate Appropriations

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.

Recent Updates: Staff will work with the author's office to do double joining language with the board's ADDS bill, SB 1447.

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

Board member Weisser stated that he supports the use of automated drug delivery systems in 340B clinics.

Board member Schaad explained that this bill applies to federally funded outpatient clinics that are not supported by hospitals. He stated that he supports the bill because the use of the machines in 340B clinics will help ensure that patients can obtain their medications quickly and at a better price.

Pharmacist Steve Gray expressed concern that not only indigent patients would receive the drugs because the clinics serve *all* patients, not just the indigent. Mr. Weisser responded that there is nothing prohibiting non-indigent patients from using federally funded clinics. Ms. Sodergren added that hospitals similarly provide services to both indigent and non-indigent patients.

Board member Maria Serpa expressed concern with the complexity of the bill. She explained that as there is another bill dealing with automated drug delivery machines this bill may cause confusion.

President Law noted that 340B drugs are not owned by the pharmacy, whereas the provisions in SB 1447 require that the drugs used in the machines be owned by a pharmacy. Ms. Veale stated that since SB 1447 only applies to machines stocked with pharmacy owned medications she would support AB 2037 because it will ensure that 340B clinics can use automated drug delivery machines stocked with drugs that are not owned by the pharmacy.

Board member Weisser again expressed his support of the bill as it will improve the efficiency of providing medication to indigent patients in 340B clinics.

President Law asked if the 340B machines would still require consultations. Ms. Herold confirmed that the same consultations requirements would apply to these machines.

Motion: Support AB 2037.

M/S: Weisser/Schaad

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

4. AB 2486 (McCarty) Opioid Prevention and Rehabilitation Act

Chairperson Lippe reported that this bill would not be moving forward this year.

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

5. SB 212 (Jackson) Solid Waste: Pharmaceutical and Sharps Waste Stewardship

Version: Amended June 18, 2018

Status: Assembly Appropriations Committee

Summary: This bill would establish the Pharmaceutical and Sharps Waste Stewardship program in California. This statewide program will be established by the manufacturers of covered drugs, as defined, and will provide convenient receptacles for the return of pharmaceuticals and sharps.

Staff Comments: Staff has worked with the authors and CalRecycle and continues to provide technical assistance. Board staff will be prepared to discuss this measure in more detail should the committee/board so choose. As written, staff believe compliance with the board's drug take back regulations would still apply, and the board would remain responsible for enforcement of those provisions.

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

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

6. SB 1021 (Wiener) Prescription Drugs

Version: Amended June 14, 2018

Status: Assembly Appropriations

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 co pay. This measure was brought to the board in May and no position was established.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification.

Chairperson Lippe reported that the committee recommends taking a support position on the bill.

Ms. Veale stated that the board should not take a position on this bill as the board does not regulate drug pricing.

Chairperson Lippe stated that this bill protects consumers by ensuring that they are getting the best price on their medication which will lead to better medication adherence.

Motion: Support SB 1021.

M/S: Lippe/Butler

Support: 8 Oppose: 0 Abstain: 2

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | | | x | |
| Weisser | x | | | |
| Wong | | | x | |

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

Version: Amended June 28, 2018

Status: Assembly Appropriations

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 measure was brought to the board in May and no position was established.

Recent Updates: Amendments to the measure do not indicate change in policy but rather provide clarification.

Chairperson Lippe reported that the committee is recommending a support position on the bill.

Mr. Weisser stated that the intent of this bill is very noble, but he questioned the practicality of collecting medication information from unconscious or memory impaired patients.

Ms. Veale stated that this is best practice for a hospital but expressed concern with *requiring* a hospital to obtain an accurate medication profile for each high-risk patient.

Board member Serpa stated that it is often legislation that prompts hospitals to provide the funding needed to implement a new program. She explained that even if a program is considered “best practice” resources will not be provided unless it becomes *required* due to legislation.

Pharmacist Steve Gray spoke in support of the bill.

Mr. Weisser asked if the California Hospital Association has a position on the bill. Ms. Herold stated they support this bill.

President Law spoke in support of the bill as it will improve patient care.

Motion: Support SB 1254.

M/S: Lippe/Butler

Support: 10 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | x | | | |
| Khan | | | | x |
| Kim | x | | | |
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Weisser | x | | | |
| Wong | x | | | |

Note: Ms. Butler left the room at 1:13 p.m. after the vote.

Part 2: Regulations for Discussion and Consideration

d. Board Readoption of Emergency Regulation Related to Compounding

Summary of Regulation:

This re-adoption amends the board’s regulations regarding the establishment of compounding beyond use dates on an emergency basis.

Timeline:

- Approved by Board: May 6, 2018
- Submitted to DCA for Pre-Notice Review: May 17, 2018
- 5-Day Public Notice: May 30, 2018 – June 6, 2018
- Submitted to OAL: June 7, 2018
- Approved by OAL: June 18, 2018

Chairperson Lippe reported that the re-adoption was effective upon approval by OAL on June 18, 2018. The current expiration date for the emergency regulation is September 18, 2018.

Note: The adopted text is posted on the board’s website and can be obtain using the following link - - http://www.pharmacy.ca.gov/laws_regs/approved_regs.shtml.

Chairperson Lippe explained that the emergency readoption approved by the board in May will expire September 18, 2018. Non-emergency regulations will be filed with OAL on August 3, 2018. He stated that a 45-day public comment period will end September 17, 2018. After the 45-day comment period DCA must perform their post review. Chairperson Lippe further explained that it is necessary to adopt the emergency regulations once more so that they will stay in effect until the non-emergency regulations can be promulgated by OAL.

Motion: Readopt the emergency regulation.

M/S: Veale/Lippe

Support: 9 Oppose: 0 Abstain: 0

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Brooks | | | | x |
| Butler | | | | x |
| Khan | | | | x |
| Kim | x | | | |

| Board Member | Support | Oppose | Abstain | Not Present |
|--------------|---------|--------|---------|-------------|
| Law | x | | | |
| Lippe | x | | | |
| Munoz | | | | x |
| Sanchez | x | | | |
| Schaad | x | | | |
| Serpa | x | | | |
| Veale | x | | | |
| Weisser | x | | | |
| Wong | x | | | |

Note: Ms. Veale left the room at 1:15 p.m. following the vote.

e. Board Approved to Initiate Rulemaking - Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

Chairperson Lippe provided a brief update on each of the following regulations. No action was taken by the board and there were no comments from the public.

Note: Ms. Butler returned at 1:17 p.m. and Ms. Veale returned at 1:19 p.m.

- Proposed Regulations to Amend Title 16, California Code of Regulations (CCR), Sections 1735.1, 1735.2, 1735.6, 1751.1, and 1751.4, Related to Compounding
- Proposed Regulations to Amend Title 16 CCR Sections 1780-1783, et seq. Related to Third-Party Logistics Providers and Dangerous Drug Distributors
- Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage
- Proposed Regulations to Amend Title 16 CCR Section 1746.3 Related to the Naloxone Fact Sheet
- Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts
- Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs
- Proposed Regulations to Add Title 16 CCR Section 1793.9 Related to Remote Dispensing Technicians
- Proposed Regulations to Amend Title 16 CCR Section 1706.2 Related to Abandonment of Applications
- Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs
- Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, 1702.5 Related to Renewal Requirements

f. Board Approved to Initiate Rulemaking – Documents Returned to the Board for Corrections to be Made by Staff

Chairperson Lippe provided a brief update on the following regulation. No action was taken by the board and there were no comments from the public.

- Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

g. Board Approved to Initiate Rulemaking – Documents Being Prepared by Board Staff for Pre-Notice Review

Chairperson Lippe provided a brief update on each of the following regulations. No action was taken by the board and there were no comments from the public.

- Proposed Regulations to Amend Title 16 CCR Section 1735.2 to Update the Compounding Self-Assessment Form 17M-39
- Proposed Regulations to Amend Title 16 CCR Section 1784 to Update Self-Assessment Form 17M-26
- Proposed Regulations to Amend Title 16 CCR Section 1707.2 Related to Mail-Order Pharmacy Consultation

President Law adjourned the meeting to closed session at 1:30 p.m.

President Law returned the meeting to open session at 2:15 and adjourned the meeting at 2:17 p.m.