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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE:	March 14, 2019
LOCATION:	Department of Consumer Affairs 1625 N. Market Blvd First Floor Hearing Room Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Dr. Albert Wong, Licensee Member, Vice Chair Victor Law, Licensee Member Greg Lippe, Public Member Stan Weisser, Licensee Member Ricardo Sanchez, Public Member
STAFF MEMBERS PRESENT:	Anne Sodergren, Interim Executive Officer Laura Freedman, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General MaryJo Tobola, Senior Enforcement Manager Rob Buckner, Criminal Conviction Unit Manager

1. <u>Call to Order and Establishment of Quorum</u>
Chairperson Allen Schaad called the meeting to order at 9:05AM. A quorum was established.

2. <u>Public Comment on Items Not on the Agenda, Matters for Future Meetings</u>
Chairperson Schaad invited public comment.

Dr. Steven Gray suggested the following items to be considered:

- The enforcement of the statute that requires pharmacies to provide prescription retail prices upon request by the public, however communicated.
- Require pharmacies to provide phone numbers that will directly connect the caller to a pharmacy rather than just a call center.
- Hospitals outsourcing (out of state or out of the country) the required review of hospital orders, in their effort to comply with the Joint Commission's requirement that a pharmacist review the hospital order before the drug is administered to the patient.
- Clarification of enforcement implementation of the two bills which require pharmacists to tell the patient if the retail price of the medication is less than their copayment.

Kim Allen with Sharp Healthcare requested clarification of SB 1447, which addresses the stocking and restocking of automated drug delivery systems (ADDS). Ms. Allen expressed concern that two Business and Professions Code (BPC) sections conflict with each other. Specifically, BPC Code section 4186 states that an ADDS must be stocked by a pharmacist, but BPC Code section 4427.4 allows ADDS to be stocked by a pharmacist, pharmacy technician or intern pharmacist. Ms. Allen opined that in order to maximize the role of a pharmacist in the pharmacy, the restocking of ADDS should be the responsibility of a pharmacy technician.

Chairman Schaad recommended that the board consider, as a future agenda item, a discussion for clarification of the posting of a pharmacist's address of record on the board website.

Board President and Committee Member Victor Law suggested that the board consider, as a future agenda item, the promulgation of statutory change to discipline the common owner of multiple pharmacies in violation of laws or regulations, rather than disciplining each pharmacy.

3. **Approval of the December 20, 2018 Enforcement Committee Minutes**

Chairperson Schaad requested the review and approval of the minutes from the December 20, 2018 Enforcement Committee meeting.

As part of the public comment, Dr. Gray requested that on the bottom of Page 3 of 15, last paragraph, "Health and Safety Code section 4052" be amended to "Business and Professions Code section 4052".

Motion: Approve the minutes with the corrections identified.

M/S: Weisser / Law

Support: 5 Oppose: 0 Abstain: 1

4. **Presentation, Discussion and Consideration of Ethics Course Provisions in California Code of Regulations (CCR), Title 16, Section 1773.5 CCR**

Chairperson Schaad provided background and relevant law. In 2009, CCR section 1773.5 established that when directed by the board, a pharmacist or intern pharmacist may be required to complete an ethics course as a condition of probation, license reinstatement or as abatement for citation and fine. Board approval must first be obtained prior to the commencement of ethics courses.

Chairperson Schaad stated that various healing arts boards were asked by board staff to provide a sample of an approved ethics course, the provider, and the cost.

The Committee heard a presentation from Ms. Leslie Anne Iacopi from the Institute of Medical Quality (IMQ) regarding the content and objectives of IMQ's ethics courses, the cost of each course as well as their measurements for success.

Committee Member Stan Weisser asked what the participant cost is for the IMQ ethics program. Ms. Iacopi stated the cost is $1,995, which includes a full two-day program as well as the follow-up

program consisting of a 6-month progress report and a 12-month final report and includes all post and pre-tests.

Chairperson Schaad asked if students are failed from the ethics program. Ms. Iacopi stated that the course design is not intended to fail students, but rather works with their individual issues and focuses on how each participant can move forward and be a better pharmacist.

Chairperson Schaad asked what type of feedback the students provide to IMQ. Ms. Iacopi stated that upon completion of the 12-month report, the board receives a letter from IMQ which verifies the participants completed the 2-day course and and the contents reported in the 6-month progress report and 12-month final report.

Chairperson Schaad asked board staff how course providers are recommended to participants. Interim Executive Officer Anne Sodergren informed the committee that staff suggests programs to licensees that have been used successfully in the past, but licensees are free to locate providers on their own. Providers are then approved by the board if they can demonstrate their program satisfies the requirements of the law.

As part of public comment, Holly Strom shared her support of the IMQ ethics program. Ms. Strom asked the committee what a participant would need to do to get a course provider approved. DCA Counsel Laura Freedman stated that as a condition of probation, staff would approve the course and provider based on the requirement identified in the terms of their probation.

President Law asked Ms. Iacopi if IMQ's student satisfaction evaluations were provided to the board. Ms. Iacopi stated that those surveys were internal, but they could be provided to the board upon request. The committee requested a report of the evaluations be provided to the board annually. Board staff was directed to work with IMQ to obtain annual feedback on student satisfaction.

As part of public comment, Dr. Gray stated his support of the IMQ ethics program. Additionally, Dr. Gray suggested that it would be beneficial for pharmacy students to know what type of disciplinary scenarios result in an ethics course being included as a term of probation. Dr. Gray stated it is the common opinion among pharmacy law educators there is not enough time to teach law and ethics in one course. Dr. Gray expressed concern that at some schools of pharmacy law an ethics course is only a one or two-unit class.

5. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad introduced Board Inspector Steven Kyle. Inspector Kyle presented "How to Prepare for a CA Board of Pharmacy Inspection".

As part of his presentation, Inspector Kyle discussed the following areas: when an inspection or investigation is conducted, designating a pharmacist-in-charge (PIC), responsibilities of a PIC, items

reviewed during a routine pharmacy inspection, and a review of sterile compounding inspections and pharmacy law resources.

Chairperson Schaad requested that questions and comments pertaining to Inspector Kyle's presentation be held until after the next speaker.

6. Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing

Chairperson Schaad welcomed and introduced State Senator Jeff Stone who would be commenting on the implementation of SB 1442.

Senator Stone stated that SB 1442 was introduced by Senator Scott Weiner and himself. He shared his own experiences as a intern pharmacist working with a pharmacist who was shot during a robbery and he shared his experience as a pharmacist, working for Thrifty's in Southern California, tasked with additional retail responsibilities.

Senator Stone stated that SB 1442 was written with the belief that pharmacists should not be working alone, especially at night. He explained that although during the night there are smaller volumes of prescriptions being filled, there are many patients picking up prescriptions and requiring consultations. Senator Stone informed the committee that we now see pharmacists who administer immunizations, dispense naloxone, take blood pressures, take blood sugar levels, while also tending to their own personal issues like using the restroom and taking a break. The Senator shared with the committee that a pharmacist confided in him that he will not go to work while he is taking his diuretic medication because he cannot safely leave the pharmacy to use the restroom. Senator Stone shared that pharmacists have voiced their concern over their increased responsibilities in the middle of the night in these types of retail environments. He expressed his concern that pharmacists are working alone at night, answering telephones, ringing up sales, doing immunizations and dealing with patient demands; he warned it is these types of interruptions of routine which could cause errors.

Senator Stone urged the committee to strongly consider creating a statewide enforcement task force that would conduct after-hour visits and observe activities that happen in pharmacies, especially in the more rural and urban areas, where we see this abuse taking place. Additionally, Senator Stone said some employers are not placing adequately trained personnel in the pharmacy who understand how to work the pharmacy computer system, understand how to answer the patient calls or how to track a prescription. He questioned whether a lay person, without pharmacy training or knowledge, should be left alone in a pharmacy while a pharmacist relieves themselves. Senator Stone stated that there may be unintended consequences of this bill. Further, the Senator continued he and Senator Weiner are willing to address these unintended consequences through future legislation.

Senator Stone concluded with his request that inspection staff review and understand SB 1442 requirements and ensure that it is appropriately implemented throughout the state in the best interest of patient safety and in the best interest of pharmacists who are being pulled in many different directions.

Chairperson Schaad thanked Senator Stone for following up on SB 1442. President Law shared with the Senator that there have been many discussions regarding the implementation of SB 1442; he asked if the Senator would consider amending the law to clarify that pharmacy technicians are required to provide assistance to the pharmacist. Senator Stone agreed that the most logical person who should be with a pharmacist is a pharmacy technician. Additionally, President Law suggested a second amendment that would allow pharmacies to consolidate their late-night hours to specific stores and staff those designated stores with a pharmacists and pharmacy technicians. Mr. Weisser also thanked Senator Stone for his advocacy for the consumers of California.

7. <u>Presentation on the Board's Routine Pharmacy Inspections</u>

Chairperson Schaad invited committee and public comments regarding the presentation of routine pharmacy inspections presented earlier by Inspector Kyle.

Mr. Weisser asked Inspector Kyle if he was satisfied with the amount of consultation being provided to patients. Inspector Kyle answered, in his observation, consultation is not enough of a standard practice.

Committee Member Albert Wong suggested that Inspector Kyle's presentation be provided on the Board's website for viewing. Ms. Sodergren confirmed that a video of this module would be provided on the board website.

President Law encouraged pharmacy students to view this module in order to learn inspection expectations.

As part of the public discussion, Joe Grasela asked if out of state pharmacies are inspected. Ms. Sodergren clarified that some out-of-state pharmacies are inspected; outsourcers and sterile compounding are inspected but authority out-of-state is limited. Mr. Grasela stated that he believes that there are many compounding pharmacies that are sending prescriptions into California that are non-sterile and not compliant with California laws. He suggested that the National Association of Boards of Pharmacy conduct out-of-state California inspections. Counsel Laura Freedman suggested that this could be considered as a future agenda item. Mr. Gray asked if inspections are conducted during nights, weekends and/or holidays. Inspector Kyle confirmed that visits are conducted during nights, weekends and/or holidays, as they relate to the investigation. Additionally, Mr. Gray stated that in the area of cite and fines many pharmacy owners are paying the fines for their PICs who are found in violation, which defeats the purpose of sanctioning that specific employee for their mistake. President Law re-stated that his earlier suggestion to cite the owner of the pharmacy.

The committee paused for break at 11:05 a.m. and returned at 11:21 a.m.

8. <u>Discussion and Consideration of Senate Bill 1442 (Wiener, Chapter 569, Statutes of 2018) Relating to Community Pharmacies Staffing</u>

Chairperson Schaad provided information regarding SB 1442 which prohibits pharmacists from working alone. At the last committee meeting, the committee directed staff to work with counsel to research DEA requirements and to determine whether a background check for non-licensed personnel would be required under the Code of Federal Regulations (CFR) or whether the board should develop such a requirement. Ms. Sodergren informed the board that Title 21 CFR section

1301.90, which discusses the non-practitioner screening procedures for employees, had been provided for their review.

As part of public comment, Title 21 CFR section 1301.76 which is the basis for section 1301.90, was provided to the committee by Dr. Gray. Dr. Gray clarified that section 1301.76 applies to institutional practitioners, meaning hospitals, pharmacies and wholesalers. As part of public comment, a pharmacist working in a retail store stated that, in his experience, the staff sent to assist in retail pharmacies currently lack the training, knowledge and pharmacy skills necessary to assist the pharmacist or customers. Additionally, it was suggested that when inspectors conduct inspections, a copy is made of the employee schedules to verify who is assigned to the pharmacy to verify compliance with SB 1442.

Dr. Wong voiced his concern that pharmacies are unwilling or unable to staff appropriately. Dr. Wong stated he believed that Primary Benefit Manager (PBM) reimbursements are the root of this inability to staff appropriately.

Ms. Sodergren informed the committee that she is aware of at least one complaint alleging non-compliance with SB 1442.

Dr. Gray stated that with the approval of remote dispensing pharmacies, pharmacists will be required to supervise the pharmacy technicians at the remote dispensing pharmacy, in addition to their responsibilities at their actual pharmacy location. With the increased pharmacist responsibility there could be security issues in addition to concerns regarding consultation and service.

9. <u>Update on and Discussion of Board's Citation and Fine Program</u>

Chairperson Schaad stated that Goal 2.1, of the board's Strategic Plan calls for evaluation of the board's citation and fine program.

Chairperson Schaad explained that the chair report details several provisions of pharmacy law that govern the board's citation and fine program. During the discussion, Chairperson Schaad hoped to focus on two areas: post evaluation of order of abatement provisions since the board's May 2018 meeting and review of the policy considerations and guidance staff have been provided, by both the president and vice president, as it relates to completed citations issued with a fine of $2,000 or greater.

Chairperson Schaad directed the committee to the citation and fine data in the chair report. The data provided in the report demonstrated that orders of abatement are used with a far greater frequency than in previous years. This is consistent with the board's direction. Whereas, in 2016/17 about 1% of citations were issued with an abatement order, this year about 20% contain such an order. It appears abatements acceptance is relatively low.

Ms. Sodergren explained that typically when issuing an order of abatement, the board is giving the respondent a period of time in which to complete the abatement before the citation is completed, therefore, it would be helpful if staff could provide another follow up report to see if the actual abatement rate is higher because of the compliance period.

President Law informed the committee that since he and Vice President Greg Lippe have been reviewing citations, the number of citations has decreased.

As part of public comment, members of the public expressed concern regarding the expenditure of Cite and Fine monies. In relation, a member of the public asked why the board was not just part of the State General Fund. Supervising Deputy Attorney General (SDAG) Joshua Room provided the following clarification: the board is a Special Fund Agency and does not receive General Funds. Fines collected by the board are not the board's to spend, as special authorization is required to spend those funds, therefore, there is no financial incentive to collect additional fines because the board has no idea whether it will be allowed to spend those funds.

Ms. Sodergren recommended that further discussion regarding these budgetary issues could be discussed as an agenda item at the Organizational Committee. Vice President Lippe agreed to the recommendation.

10. Discussion and Consideration on Efforts to Reduce Investigation Times and Case Resolutions

Chairperson Schaad informed the committee that Goal 2.1, of the board's Strategic Plan seeks to implement processes to shorten the cycle times from investigation to resolution of cases, with special focus on prioritized critical cases, to minimize patient harm and enhance consumer protection.

Chairperson Schaad stated that for several meetings the committee has been discussing investigation closure times and receiving updates on current data. Included in the chair report for review are pending investigation case historical and current data as well as case closure data.

Chairperson Schaad informed the committee that in the review of the Age of Pending Field Investigations , he noted a significant decrease in the number of pending investigations over 1 year, which shows progress. Additionally, a review of the Age of Field Cases Closed also reflects improvement in overall investigation time for cases that are closed. He recommended that the committee continue to monitor this progress.

President Law thanked staff for reducing investigation time. He noted that cases sent to board members by mail vote are also more current.

Chairperson Schaad thanked the staff for responding to direction by the committee. He stated that the board has heard the professions concern with efficiency and increased transparency in the discipline program.

11. Discussion on Attorney General Annual Report on Accusations Prosecuted for Department of Consumer Affairs Client Agencies

Chairperson Schaad stated that Goal 2.5 of the board's Strategic Plan is to evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.

As required by law, the Office of the Attorney General (AG) is required to publish data annually on certain disciplinary matters. Chairperson Schaad invited SDAG Joshua Room to provide a brief presentation on the AG's Report.

SDAG Room informed the committee that this is the second reporting year for the Annual Report. This is an effort by the legislature to collect data on how quickly cases are progressing. SDAG Room reported that numbers are improving overall. He explained that Board of Pharmacy cases do not move as quickly due to complexity, number of respondents in each case, which slows down the progress. SDAG Room stated right now it is taking about six months for a case to go from receipt of the case at the AG's office to the filing of the Accusation with the goal being to get that time down to three months. The overall goal is to get Board of Pharmacy in and out of the AG's office within one year.

President Law inquired about the suspension of a license when a licensee is subject to a criminal case. SDAG Room confirmed that the process to suspend in such a case would be initiated pursuant to Penal Code section 23 (PC23). SDAG Room confirmed that the board has pursued PC 23 suspensions, whenever possible.

Ms. Sodergren stated the board attempts to obtain an Interim Suspension Order (ISO) when the PC 23 is not an option.

No public comment.

12. Discussion and Consideration of AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction
a. Consideration of Possible Regulations
b. Consideration of Possible Statutory Changes

Chairperson Schaad informed the committee that AB 2138 places restrictions on the acts and convictions the board can consider when reviewing an applicant's criminal history, and had been previously discussed.

DCA Counsel Laura Freedman provided a brief overview of the bill. She stated that AB 2138 primarily changes the board's ability to deny an application. The bill contains two different provisions related to substantial relationships and rehabilitation.

Ms. Sodergren stated that AB 2138 reduces the opportunity for the board to consider some of the criminal activities that people engage in as a cause for discipline or denial of a license. The trigger in the statute is no longer necessarily substantial relationship, there is a hard deadline on when we can no longer consider the criminal activity. Ms. Sodergren informed the committee that the discussion today is whether AB 2138 is consistent with the board's mandate. Although the policy was decided and the bill was enacted, this committee previously discussed this legislation and directed staff to see if there are opportunities to request changes to the statute. Also, Ms. Sodergren added, as part of the statute, the board is required to make changes to the board's substantial relationship regulations and make updates to the pharmacy technician application form to conform with the law.

Chairperson Schaad stated that based on the draft language recommendations, statutory changes would allow the following:

1. Consideration of convictions of felony financial crimes;

2. Consideration of acts that would be grounds for denial of a federal registration to distribute controlled substances;
3. Consideration of acts that involve fraud in violation of state or federal law related to healthcare.
4. Consideration of convictions related to identify theft;
5. Consideration of convictions related to the sale of counterfeit products.

SDAG Room clarified that as of July 1, 2020, the conviction or the end of incarceration would have to have occurred within seven years of the application date, in order for the conviction to be considered for denial or discipline. There are certain exceptions which are not subject to the seven-year period such as serious felonies and sex crimes. Additionally, there are various other types of crimes, for specific agencies, that are not subject to the seven-year limitation, for example, financial crimes for the Fiduciaries Board. SDAG Room explained that a proposed amendment would put the Board of Pharmacy among the boards with the financial crime exception. Additionally, this proposed amendment would carve out a special set of crimes just for the pharmacy board, which would allow the board to continue to use in the consideration of denials and discipline.

Ms. Sodergren suggested drafting language to also allow the board to consider an applicant's criminal history, if they have something within the allowable seven years and history previous to that.

SDAG Room clarified, if someone has a lengthy criminal history, for example, 12 convictions leading up to eight years ago, then they have a period of legality, then they have one more conviction from three years ago; for purposes of their application, under the current law we would only be allowed to consider three years ago.

SDAG Room recommended the committee consider all amendments presented and after deciding which amendment to pursue, staff should seek an author for the amendments agreed upon by the board.

Motion: Committee recommended the board seek an author to make the statutory amendments, as included in the meeting materials, and include language specific to criminal history.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of the committee discussion, DCA Counsel Laura Freedman reviewed proposed draft language and options for regulatory amendments that would conform to AB 2138.

Motion: Approve draft regulations to include Section 1 with optional language, subdivision (c) and for Section 2, include Option A, without the variation. Make any non-substantive changes consistent with policy.

M/S: Lippe/Weisser

Support: 6 Oppose: 0 Abstain: 0

As part of public comment, concerns were raised regarding the consideration of crimes committed in other states, and whether the National Practitioner Data Bank (NPDB) could still be reviewed in the consideration of applications SDAG Room clarified that this regulation will have no effect on the process, just the criteria used consider an applicant for disciplinary action or denial.

Holly Strom of Strom & Assoc. asked if the applicant would need to disclose a conviction on the application. SDAG Room clarified the applicant would no longer be required to disclose, although the applicant could voluntary disclose and show rehabilitation.

13. <u>Presentation and Discussion on Disciplinary Guidelines</u>

Chairperson Schaad, informed the committee that as required by CCR section 1760, the board uses its Disciplinary Guidelines when considering disciplinary action. He stated that it is his intent to dedicate time at the next several meetings to discuss the current guidelines and determine what, if any, changes should be recommended to the full board for consideration.

Chairperson Schaad invited SDAG Room to provide a summary on the Disciplinary Guidelines.

The Disciplinary Guidelines are adopted and are therefore mandatory. They must provide guidance to the board in the decision of disciplinary actions. SDAG Room reviewed the various sections and categories in the Disciplinary Guidelines and informed the committee of the Uniform Standards.

Ms. Freedman clarified that the Uniform Standards speak only to substance-using licensees and the specific criteria were created by a specific organization of executive officers for healthcare.

Ms. Sodergren stated that when the board was considering the Disciplinary Guidelines at the policy level, the committee identified which of those standards should be included in the Disciplinary Guidelines. There were different types of directions within the Standards: directions to the board itself, directions to board staff on testing frequency recommendations, directions to respondents on what their requirements would be and directions for those boards who have a recovery program. As policy makers, the committee included in the guidelines those that were incumbent upon the respondent to satisfy.

Ms. Freedman informed the committee that DCA was the head of the organization that created the Uniform Standards.

President Law stated that the current process consists of an inspector completing a report and forwarding the file to a supervising inspector with a recommendation for cite and fine or referral to the AG's Office. President Law stated that previous discussions have recommended that the board should have a process to screen cases before they are issued a cite and fine or referral to the Attorney General's Office. President Law stated that only cases of the most serious nature should be referred to the AG's office.

Ms. Strom and Jenny Partridge expressed support of a more thorough review process.

The committee paused for lunch break at 1:05p.m. The committee returned and called the meeting back to order at 1:38p.m.

14. Presentation by the California Pharmacists Association on a Proposal to Modify the Board's Current Enforcement Process

Chairperson Schaad introduced Danny Martinez, Government Relations and External Affairs for the California Pharmacists Association (CPhA). Mr. Martinez introduced Veronica Bandy, CPhA President.

Mr. Martinez presented "Proposal for a Pharmacy Advisory Committee". Mr. Martinez's presentation included a review of the Board of Pharmacy's Enforcement Process, CPhA's proposed changes to the Enforcement Process, and the proposal of a Pharmacy Advisory Committee.

As part of the presentation, Mr. Martinez's proposed that prior to initiation of the formal disciplinary process (referral to the AG's office), the board should permit licensees to go before a consortium of their practicing peers in order to help the board prioritize serious issues from less significant issues. Mr. Greg Lippe informed the presenter that the charge of the board is the protection of consumers and to recommend a consortium of only pharmacists is in opposition to the whole idea behind the board.

Mr. Martinez shared a proposed flowchart of the intake, investigation and outcomes process. Ms. Sodergren and SDAG Room expressed concern that the flowchart provided did not match the process suggested in the proposal. Mr. Martinez stated that the flowchart would need to be corrected in order to match his proposal and he informed the committee that his proposal is open to changes and suggestions.

Mr. Martinez stated that the Medical Board of California (Medical Board) has a process similar to the CPhA proposal, where a practicing licensee conducts a review of the investigation and provides a recommendation on whether they should proceed. If the evidence is not clear, it is sent to a second expert reviewer. SDAG Room provided clarification to the presenter that the Medical Board uses internal staff experts, as well as external experts; internal experts are employees of the Medical Board. Additionally, SDAG Room stated some agencies like the Dental Board, Medical Board and Veterinary Board employ in-house consultants to determine standards of care issues because they do not have subject matter experts on staff like the Board of Pharmacy. SDAG Room further stated that in-house consultants' sole mission is to determine whether there is enough of a possibility of a deviation from the standard of care that it should be sent out for an expert review; they are not making recommendations on whether a board or staff should pursue a case. Mr. Martinez stated that the information he was providing today was confirmed on the Medical Board website.

Mr. Martinez stated that the proposal is a hybrid of the Medical Board process as well as the process used by the Maryland Pharmacy Board.

Mr. Martinez stated to the committee that CPhA would like to recommend that board staff work with CPhA to modify this process to something to which the committee is comfortable.

President Law inquired, regarding the Maryland Pharmacy Board, where their review committee sits in the CPhA proposed model. Mr. Martinez stated that the committee, mandated by statute, sits at the beginning when the accusation is filed.

As part of the committee discussion, members expressed various areas of concern. Firstly, the charge of the board is the protection of consumers; to recommend a consortium of only pharmacists is in opposition to that concept. In addition, the membership criteria for CPhA's proposed advisory committee would exclude retired licensees who are still active members in the pharmacy profession. Mr. Weisser expressed his disappointment in the model proposed by CPhA.

SDAG Room presented a few possible legal objections to the CPhA proposal:

1) Committee members would have access to confidential information generally only shared with board staff who are subject to criminal and civil penalties for the potential release or abuse of private information.
2) The proposal could be considered a violation of statute or an unconstitutional delegation of this body's authority to another body. Creating the committee would require a statutory amendment.
3) By what process is a board of thirteen members going to appoint a subcommittee of five members?
4) The board has been previously briefed on anti-trust possibilities of treading to close to the line of having licensees exclusively policing other licensees under the North Carolina Dental Board case. If the board, which has been consciously constituted of professional and public members, were to delegate some portion of its authority to a subcommittee made up exclusively of members of the profession, who might have competitive interests involved in any case, the risks of liability, under the North Carolina case, would increase significantly. Other possible requirements like insisting on the president or executive officers be pharmacists, would put the members of the board in greater jeopardy for a trust violation.

SDAG Room stated he disagreed with Mr. Martinez's implication that the investigations performed by inspectors were somehow inferior due to an assumption incompetence, bias or inability to act as a jury of peers for their peers. SDAG Room stated most inspectors are dragged reluctantly to the conclusion that a member of their profession has failed the standards. Mr. Martinez stated that the proposal was not indicative of any feeling of biased or lack of confidence in the inspectors. He stated the intent of the proposal was to allow for discussion.

President Law stated that the proposal presented by CPhA was a concept that could be further developed. President Law explained that as the pharmacy profession progresses, there are different areas of specialization such as long-term care and Advanced Practice

Pharmacists (APH). Many cases come to an inspector's attention, he stated that the board cannot possibly have inspectors who are experts in all fields. President Law provided an example of an inspector who may have expert-level experience at a hospital pharmacy but may not have experience in a retail pharmacy. President Law stated there might be a place for the use of peer expertise in these particular areas to advise the board in decision making. President Law stated that he hopes to see in the future that as more difficult case come before the board, a way that the board can use different areas of expertise for Long-Term Care or APH. For example, if there is something wrong with an APH he hoped that there would be an APH expert to determine exactly if a practice is safe or just a simple mistake that may have just due to a lack of education. He stated looking forward it may not be a bad idea to explore this concept and expedite the process. President Law clarified that the proposal is a screening process and the final vote would still come to this board for consideration.

Ms. Freedman informed the committee that as an option the board has the authority pursuant to the BPC to hire subject-matter experts to assist and when they encounter a situation where the staff does not have the necessary expertise.

Mr. Weisser voiced his confidence in the level of diversity among the and backgrounds of inspectors as well as with the diversity of their training received at the board.

Dr. Wong stated that based on the possible breach of confidentiality, he proposed a committee of inspectors to review and approve recommendations, as opposed to a committee of persons outside of the board.

A member of the public stated that the proposed process would allow a licensee an opportunity to explain their side of the story to committee members before being sanctioned. Additionally, he informed the committee that the states of Iowa, Texas and Florida all allow licensees the opportunity to be heard. Another member of the public emphasized the specific need to seek pharmacists who are experts in the area of collaborative drug therapy pharmacy, to consult and guide the process; he suggested there are more areas in which investigators and board members need guidance, due to lack of in-house experience.

Ms. Sodergren stated that this year, the board has referred about 150 cases to the AG's office.

DCA Counsel Kelsey Pruden, provided the committee members with an overview of the review process for the State of Texas. SDAG Room stated that other than the inclusion of a board member, the Texas process is the same as California. SDAG Room explained that every administrative case offers the licensee the opportunity to seek settlement by communication with the AG's office to arrange a settlement conference with Office of Administrative Hearings.

President Law asked if the board could pay for per diem experts. SDAG Room confirmed that the board could hire experts and has already done so in the past

The committee heard comment from Lauren Walmsey of Walgreens who serves on the Arizona Pharmacy Board. She informed the board that in Arizona all disciplinary matters start at a sub-committee level discussion, made up of a public member, a pharmacy technician and two practicing pharmacists who are all board members appointed by the Governor. The committee makes a recommendation on the discipline and the full board decides how to move forward. An investigator conducts an investigation, an investigation summary is written, the summary is reviewed by the committee, and then a recommendation is made by the committee. The committee may recommend dismissing the case, formal discipline, or suggest continuing education. SDAG Room clarified that in AZ there is no requirement for a pleading to be filed prior to discipline. Ms. Walmsey responded that each state has a variety of ways to handle disciplinary cases, pursuant to each state's statutes.

As part of the public discussion, a community pharmacist, stated that if a licensee was afforded the right to present testimony prior to disciplinary action, it would allow for a learning opportunity to identify barriers and discuss what tools or assistance are available to correct the violation as well as open lines of communication between the board and licensees. Another member of the public called attention to the inconsistency of disciplinary actions for similar violations; she supported the idea of using expert consultants before determining formal disciplinary action.

President Law acknowledged that board members are not always provided the opportunity to hear the licensees side of the case. He stated the committee is trying to determine a process which helps the profession and protects the consumer.

Mr. Weisser stated that when presented with the opportunity to vote on a case he reviews all materials provided and he is given the option to agree, disagree and/or comment. Mr. Lippe stated that the board policy is that if two members object then the case is brought back to the board.

Ms. Freedman confirmed with committee members that the committee requests a future discussion on how the enforcement program is structured.

The committee directed board staff to work with the chair of the committee to explore alternative solutions.

DCA Counsel suggested that the committee request a future discussion on how the enforcement program is structured. President Law agreed and directed board staff to research other state enforcement models and continue the discussion on disciplinary matters

15. **Review of Final Report Submitted by University of California San Diego's Experimental Program Regarding Access to Medications from an Automated Drug Delivery System (ADDS) (Pursuant to California Code of Regulations, Title 16, Section 1706.5)**

Ms. Sodergren informed the committee that the study will end in June 2019 and the board should expect to receive a final report in Fall 2019.

16. **Discussion and Consideration of Proposed Changes to Self-Assessment Forms Incorporated by Reference in Title 16, California Code of Regulations, Section 1715 and 1784**

Chairperson Schaad informed the committee that CCR section 1715 establishes the requirements for completion of the pharmacy and hospital pharmacist self-assessment forms. CCR section 1784 establishes a similar requirement for completion of a wholesaler self-assessment. In all cases, the self-assessment is a compilation of relevant laws that are intended to allow for the entity to self-evaluate compliance with various provisions of law. Because the various forms are incorporated by reference in the respective regulation sections, a regulation change is necessary whenever the forms require update. The proposed revisions incorporate recent changes to pharmacy law.

Motion: Recommend to the board approval of the draft self -assessment forms.

M/S: Weisser/Sanchez

Support: 6 Oppose: 0 Abstain: 0

17. **Discussion and Consideration of Title 16, California Code of Regulations, Section 1715.6 Related to the Reporting of Drug Losses**

Chairperson Schaad stated that as part of the committee's discussion on the development of its inventory reconciliation requirements, the requirement to report drug losses was discussed. He explained an owner is required to report any loss of a controlled substance, including the amount and strength. This report must be made to the board within 30 days.

Previous discussions noted the difference between California Law and DEA reporting requirements. Included in the chair report was data for both types of loss reports for several fiscal years and the first six months of FY 2018/19. Also included was a breakdown of the number of reports received based upon the loss in dosage units. Ninety-one percent of loss reports indicated a loss of less than 100 dosage units.

President Law acknowledged that the number of drug losses has reduced significantly but noted concern over the 17 cases identified with over losses over 10,000.

As part of public comment, Dr. Gray stated he has been asked about the new regulation regarding inventory and reconciliation every quarter and for every controlled substance. He stated the implication is that on all the other controlled substances, Schedules III, IV and V, there also must be a reconciliation. If they have to report every missing tablet, it means each time they do a reconciliation on that many products, they would have something missing. If there is no ability to say if a loss is significant then pharmacies would rather wait once every two years to inventory Schedules III, IV and V. He requested that the committee revisit the process of reporting drug losses to do what DEA does and establish criteria for reporting a loss, which varies depending on the schedule of the controlled substance. Paige Talley of CCAP, encouraged the committee to determine a definition of "significant loss" in numbers.

Ms. Freedman advised the committee that the board would have to describe what significant means to the board and create standards.

Ms. Sodergren suggested, and the board agreed, that staff would survey a couple other states for their drug loss reporting requirements and research the types of drugs that are in that 1 to 100 dosage units threshold.

Dr. Wong asked if a drug loss could be submitted electronically. Ms. Sodergren stated that the board is working on an interface to submit losses electronically.

Mr. Weisser left the meeting at 3:24 p.m.

18. **Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask An Inspector Program**

This item was moved to the next committee meeting.

19. **Discussion and Consideration of Board's Enforcement Statistics**

Chairperson Schaad informed the committee that they have been provided a copy of the enforcement statistics reflecting data from July 1, 2018, through February 28, 2019.

The committee agreed to review the data, and if they have any questions, they would be addressed at the next committee meeting.

20. **Future Meeting Dates**

Chairperson Schaad stated that the next meetings are scheduled for July 2, 2019 and September 25, 2019.

The meeting adjourned at 3:31 p.m.