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

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE:	December 20, 2018
LOCATION:	Department of Consumer Affairs 1625 N. Market Blvd First Floor Hearing Room Sacramento, CA 95834
COMMITTEE MEMBERS PRESENT:	Allen Schaad, Licensee Member, Chair Albert Wong, Licensee Member, Vice Chair Victor Law, Licensee Member Stan Weisser, Licensee Member Ricardo Sanchez, Public Member
STAFF MEMBERS PRESENT:	Virginia Herold, Executive Officer Anne Sodergren, Assistant Executive Officer Laura Freedman, DCA Staff Counsel Joshua Room, Supervising Deputy Attorney General MaryJo Tobola, Senior Enforcement Manager

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

Chairperson Allen Schaad called the meeting to order at 10:05 a.m. A quorum was established.

2. Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Member of the public, Jason Cain, on behalf of Laura Churns from Alberstons Companies, expressed concern about the lack of clarification provided to licensees on the compounding regulations related to the "batch" definition and staff pharmacist competency for sterile compounding, as well as the lack of clarification to inspectors for consistent enforcement. Mr. Cain requested that the committee consider rescinding all enforcement related regulations between January 1, 2017, when the regulations became effective, through the date in which they are clarified.

3. Discussion and Consideration of Implementation Strategies for Chaptered Legislation

Chairperson Schaad stated that at the October Board and September Enforcement Committee meetings members of the public suggested that the legislation passed in this

year's legislative session be brought to the committee for discussion.

a. AB 2086 (Gallagher) (Chapter 274, Statutes of 2018) Controlled Substances: CURES Database

Chairperson Schaad informed the committee that this bill allows prescribers to request a list of patients for whom they are listed as being the prescriber in the CURES database.

Board staff suggested that the committee consider whether a pharmacist working under a collaboration practice agreement may similarly obtain a list of patients where he/she is listed as the prescriber. Additionally, board staff stated that the Department of Justice (DOJ) CURES database can accommodate such a request, as long as an individual has a DEA number.

As part of the public discussion, Robert Stein of KGI School of Pharmacy stated that it is his understanding that CURES either allows an individual to be a prescriber or a dispenser, not both. Pharmacist Steve Gray stated prescribers have historically been unable to obtain a list.

Board staff will confirm that individuals who are prescribers and dispensers may obtain a list, as long as they have a DEA number. Additionally, staff will obtain clarification from DOJ on what format the list will be provided (i.e. paper, electronic, email, etc..)

b. AB 2783 (O'Donnell) (Chapter 589, Statutes of 2018) Controlled Substances: Hydrocodone Combination Products: Schedules

Chairperson Schaad informed the committee that this measure reclassifies specific hydrocodone combination products as Schedule II controlled substances, making California law consistent with federal law.

As part of the public discussion, Mr. Gray stated not all mid-level practitioners, such as physician assistants and nurse practitioners are aware of the change to Schedule II. Additionally, he stated nurse practitioners may not be aware of the difference between federal and state schedules. In his opinion, the problem exists in that pharmacists are filling prescriptions from prescribers who may not have DEA approval to prescribe that particular schedule of drug. Mr. Gray suggested that the board have a discussion with the boards who regulate all mid-level practitioners to inform them of these changes.

Board staff will advise those boards whose practitioners' prescribing abilities are affected by this law.

c. AB 2789 (Wood) (Chapter 438, Statutes of 2018) Health Care Practitioners: Prescriptions: Electronic Data Transmission

Chairperson Schaad informed the committee that this law requires that by January 1, 2022, all written prescriptions, issued by licensed prescribers in California, be issued as an electronic transmission prescription (e-prescription). Also, by January 1, 2022, all pharmacies, pharmacists, or other practitioners authorized to dispense or furnish a medication must have the capability to receive an e-prescription.

Chairperson Schaad provided a list of exemptions, which included:

- Any medication prescribed under Health & Safety Code §11159.2 (for use by hospice or terminally ill patients)
- Technological/electrical failure making transmission problematic
- Prescription that will be dispensed outside of California
- Issued by hospital emergency department or urgent care clinic AND the patient resides outside of California, or outside the geographical area of the hospital
- The patient is indigent or homeless
- The prescription is issued when a patient's pharmacy is closed
- Prescription issued by veterinarians
- The prescription is for eyeglasses or contact lenses
- The prescriber and dispenser are the same entity
- Any time e-prescribing would cause a delay in therapy
- Prescription is not covered by the National Council for Prescription Drug Programs' SCRIPT standard

The committee discussed who is responsible for ensuring that prescribers provide e-prescriptions to pharmacists. Ms. Virginia Herold confirmed that the board would not provide regulatory oversight to prescribers for this new law. Ms. Herold stated she is confident that pharmacists will work with prescribers in educating them of this new requirement.

As part of the public discussion, Mr. Stein stated that there are concerns regarding a 2017 DEA letter which states that pharmacists could forward unfilled electronic prescriptions from pharmacy to pharmacy, including Schedule II. However, there is no mechanism to do that. Additionally, Mr. Stein requests clarification of the terms "forwarding" and "transferring" as they pertain to CCR section 1717(e). Ms. Herold requested Mr. Stein provide a copy of the 2017 DEA letter to the board.

Also during the public discussion, Mr. Gray, requested clarification of the Health and Safety Code that permits the transfer of any valid prescriptions between pharmacists as it relates to CCR section 1717(e), which limits transferring to refilled prescriptions only. Additionally, Mr. Gray informed the committee there are prescribers who have capability to transfer electronically, but their systems do not meet DEA requirements.

Board staff was directed by the committee to work with counsel on the limitations that exist within the regulation and bring back a recommendation to the committee.

d. SB 1447 (Hernandez) (Chapter 666, Statutes of 2018) Pharmacy: Automated Drug Delivery Systems and AB 2037 (Bonta) (Chapter 647, Statutes of 2018) Pharmacy: Automated Patient Dispensing Systems

Chairperson Schaad informed the committee that these measures establish requirements for automated drug delivery system (ADDS) registration requirements with a licensing program that recognizes the different uses for such a device. The measure establishes definitions for the two different functions of ADDS: Automated Unit Dose System (AUDS) for administration to patients and Automated Patient Dispensing System (APDS) for dispensing directly to the patients.

Specifically, effective July 1, 2019, this measure prohibits an ADDS from being installed, leased, owned or operated in California unless specific requirements are met. One requirement specifies an ADDS license will only be issued to the holder of a valid and active California pharmacy license. The bill expands the locations for placement and operation of an ADDS to specific locations, including the licensed pharmacy issued the ADDS license, a licensed health facility, a licensed clinic, or a specific medical office. Further, this measure requires the pharmacy issued the ADDS license to own or lease the ADDS machine and own the drugs and devices located within it. The measure requires the pharmacy to supervise the operation of the ADDS. This measure details specific stocking and transfer requirements for the ADDS, requires the pharmacy issued the ADDS license to provide training on the operation and use of that ADDS to specific individuals, and requires the pharmacy to complete periodic self-assessments. The bill requires additional conditions for ADDS used to dispense medication to patients. The bill authorizes 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 measure requires the board to report to the legislature regarding the regulations of ADDS machines on or before January 1, 2024, as part of the board's Sunset evaluation process.

Chairperson Schaad informed the committee that under the provisions of the law, drugs can be stored for a period of up to 48 hours in a secured room within the ADDS location (BPC§4427.4(f)). Chairperson Schaad asked if the committee/board should consider providing more specific storage and recordkeeping requirements?

As part of the public discussion, Mr. Gray asked the board to consider, when an APDS is being stocked by a pharmacist, that drugs may be stored in a secure location, on site, which only the pharmacist can open. Mr. Gray noted that there are similar provisions for deliveries that happen after a pharmacy is closed. Sara Lake, Director of Regulatory Affairs for Asteres, Inc. stated there should not be any circumstance when drugs should not be delivered from the pharmacy directly to the secured machine.

Board staff informed the committee that the legislation, as enacted, allows for the consideration of medication storage outside of any ADDS machine. Staff suggested that the board sponsor legislation, to amend this statute in order to tighten the storage restrictions to apply only to an AUDS, not to an APDS.

The committee directed board staff to research options and present a few policy recommendations to the committee at a later time.

Ms. Anne Sodergren stated that under the provisions of the law, an incident involving an APDS where a complaint, error, or omissions has occurred shall be reviewed as part of the pharmacy's quality assurance program (BPC § 4427.6(i)). Ms. Sodergren asked the committee/board to consider requiring such quality assurance reviews to be separately reported to the board. If so, the board could develop regulations to require the reporting of such incidents to be sent to the board, which would allow the board to collect data to accurately report to the legislature in 2024.

During the public discussion, Mr. Gray stated his support of the development of regulations and urged the committee to provide clear language which would separate this requirement to report incidents from the quality assurance review requirement.

Motion: Direct board staff to work with the committee chair in developing regulation language for consideration regarding the mandatory reporting of Quality Assurance reports to the board. Proposed language will be brought to the January board meeting.

M/S: Weisser/Wong

Support: 5 Oppose: 0 Abstain: 0

Following the vote a member of the public asked for clarification regarding under what conditions an ADDS machine may operate in a licensed clinic. Ms. Herold stated that Section 4186 details conditions under which an ADDS can operate in a licensed clinic. Mr. Gray voiced concern about 4180 Clinics that currently own and operate their own ADDS machines. Mr. Gray requested clarification of implementation of Section 4186 with 4180 Clinics.

SDAG Joshua Room stated that an ADDS in a clinic must be controlled by a pharmacist, but does not have to be owned by a pharmacy.

e. <u>AB 2753 (Low) (Chapter 479, Statutes of 2018) Controlled Substances: CURES Database</u>

Chairperson Schaad informed the committee that this law reduces the number of authorized security printers approved by the DOJ. Further, this measure requires security prescription forms to contain a unique serialized number that must be reported

to CURES and establishes reporting requirements to the DOJ on the delivery of security prescription forms to a prescriber.

Ms. Herold stated that Health & Safety Code section 11162.1 establishes provisions of this law. The board has requested delayed implementation from DOJ, since the actual approved forms will not yet be available by the January 1, 2019 effective date. Providers do not yet have these serialized forms. Effective January 1, 2019 a prescriber may be prescribing on a non-compliant form.

SDAG Room confirmed that printers will not be able to provide compliant forms to prescribers by January 1, 2019. SDAG Room presented the committee with a proposed subscriber alert, which detailed proposed options for pharmacies.

As part of the public discussion, Mr. Stein questioned the use of "if applicable" in the law. SDAG Room clarified that the term "if applicable" is only used in the reporting to CURES requirement, not in the prescribing or dispensing requirement. Further, SDAG Room stated that Health & Safety Code section 11164(a) is the provision requiring that as of January 1, 2019, only a prescription with this security feature is lawful. Mr. Gray encouraged SDAG Room to amend the proposed Subscriber Alert to include the exclusion of Medi-Cal patients. In response, SDAG Room stated that the Subscriber Alert would be limited to issues at hand which was the revised prescription requirements for controlled substances. Jennifer Snyder of the California Retailers Association (CRA) and the National Association of Chain Drug Stores (NACDS), noted she has had discussions with the author's office and was informed that it was the intent of the author to allow for a broader application of the "if applicable" term and offered to work with board to find a solution.

Additional public discussion included a recommendation to delay enforcement of the bill, statutory changes and the filing for a court injunction to prevent the law from going into effect. SDAG Room confirmed that an injunction is plausible for an entity other than this state board. Danny Martinez of CPhA stated that in his experience, it is possible to have legislation enacted within just one week, given the gravity of the situation.

Ms. Herold stated that, in the past, the board has exercised enforcement discretion. Ms. Herold stated that historically the board has allowed up to a six-month transition time in order to allow time for compliance to a new regulation. DCA Counsel Laura Freedman explained that any time the Executive Officer (EO) takes an enforcement action, the EO takes into consideration all the facts that are present; in this case, included in those facts would be the availability of compliant forms. SDAG Room supported the EO's option to not make enforcement of this law a priority for the first six months of 2019.

SDAG Room clarified to the board that the DOJ does not consider itself involved in the enforcement of this requirement in regard to prescribers or dispensers. The DOJ believes its responsibility ends with approving the forms and security printers and the

collection of CURES data. The DOJ does not concern themselves with the intervening transactions.

Motion: Direct staff to release a statement clarifying that the board will not consider this an enforcement priority until July 1, 2019.

M/S: Weisser/Sanchez

Support: 5 Oppose: 0 Abstain: 0

f. AB 2138 (Chiu/Low) (Chapter 995, Statutes of 2018) Licensing Boards: Denial of Application: Revocation or Suspension of Licensure: Criminal Conviction

Chairperson Schaad informed the committee that, effective July 1, 2020, this law places restrictions on the convictions, crimes, and other acts the board may consider to deny, revoke or suspend a license. The law requires reporting on the board's website of denial summaries as well as a list of crimes that will be considered for denial and how they substantially relate to the qualifications, functions, or duties of the practice of pharmacy.

Chairperson Schaad stated that staff recommends that they begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

SDAG Room informed the committee that this law makes several changes to the types of convictions that can be used as a basis for denial and allows the board to look into the conduct that led to the convictions. Since this law becomes effective in July 2020, SDAG Room believes that any pending cases as of July 2020 will have this new law applied to it. SDAG advises that some time before July 2020 the board should make adjustments to its criteria, since pending cases which occurred before July 2020 may be subject to this law. SDAG Room clarified that only convictions within the past seven years to be the most relevant types and any conviction(s) that have been dismissed, pursuant to Penal Code section 1203.4, in which the individual has successfully completed probation, may, by petition, be dismissed. The legislature believes completion of probation is indication of sufficient rehabilitation and should no longer be a licensing consideration. SDAG Room anticipates that the DCA and the DOJ will be working on resolving issues on how to handle individuals with multiple convictions. SDAG Room stated that this legislation is consistent with the "Clean Slate" initiatives taking place nationally.

Additionally, SDAG Room stated that he recently had a courtroom appeal that predated this legislation and the courts are already taking these provisions into consideration when making decisions on cases.

DCA Counsel Freedman informed the committee that her office is actively working on general guidelines for all boards. They are working on model language and will be consulting with the DOJ.

President Law asked SDAG Room if DUI convictions would be included in this law. SDAG Room confirmed that a DUI conviction could no longer be considered for license denial if the individual who committed the DUI offense completed probation and petitioned for the conviction to be dismissed.

Member Stan Weisser asked SDAG Room if an applicant is approved for licensure may the board then immediately take disciplinary action and place the license on probation. SDAG Room stated that, in theory, the board could approve the application of an individual who has committed an offense that could no longer be considered, then take disciplinary action against that license based on that prior conviction.

Ms. Sodergren stated that the board is faced with several implementation challenges. The board must draft regulations and educate by providing the types of convictions that could be grounds for denial. Ms. Sodergren asked the committee if they would consider amending this law to allow the Pharmacy Board a provision to take into consideration certain convictions or underlying conduct. Ms. Sodergren informed the board that in its final form, the law allows certain boards provisions to take into consideration, such as fraud convictions. Ms. Sodergren suggested that it might be beneficial to research interest in the legislature to allow for consideration of certain convictions or conduct for the board to rely upon.

As part of the public discussion, Mr. Gray noted that other healing arts boards are also pursuing legislation. Mr. Gray informed the board that there are federal regulations that require the DEA to conduct a background check for any DEA registrant who has access to controlled substances. DEA law states that individuals with a drug-related conviction may not be employed into positions with access to controlled substances. Additionally, federal law prohibits the employment of someone who fills Medicare or Medicaid prescription who are on the Federal Blacklist for having been associated with fraud-related crimes.

Motion: Direct staff to begin working with the Office of the Attorney General and DCA counsel to identify next steps including possible statutory changes that could minimize the impacts of this measure as enacted. Further, it is recommended that staff, in concert with counsel, perform a GAP analysis as the first step towards implementation.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

g. AB 2859 (Cabellero) (Chapter 240, Statutes of 2018) Pharmacy: Safe Storage Products

Chairperson Schaad informed the committee that AB 2859 requires community pharmacies that dispense Schedule II, III, or IV controlled substances (such as opioids) to display safe storage products on the premises and close to the pharmacy. Pharmacies, where a licensed pharmacist is the majority owner and manager of no more than four pharmacies, are exempt from this requirement. These provisions will remain in effect until January 1, 2023.

Chairperson Schaad stated that the language in the bill states that pharmacies are required to display safe storage products but does not specifically state that the pharmacy must offer them for sale. He asked the committee whether members wanted to discuss requiring pharmacies to stock and sell these products or simply display them for informational purposes. Member Weisser stated that he was satisfied with the approved language of the bill.

As part of the public comment, Mr. Gray requested confirmation that the board accepts the general definition of the statute that states that a pharmacy is only required to display the safe storage products, but not sell them. Member Weisser confirmed acceptance of that definition. Secondly, Mr. Gray informed the committee that the statute states that the board may choose to not assess discipline if there is a financial hardship.

DCA Counsel Freedman confirmed that the bill allows a pharmacy to display the products, but does not require a pharmacy to sell the products.

h. SB 212(Jackson) (Chapter 1004, Statutes of 2018) Solid Waste: Pharmaceutical and Sharps Waste Stewardship

Chairperson Schaad informed the committee that this law establishes a statewide program to fund drug takeback and sharps disposal programs throughout California. The provisions take effect on or before January 1, 2021. Under the provisions, the funding will be provided by covered entities, which would typically be manufacturers of drugs sold in California. CalRecycle is required to develop regulations governing this stewardship program by January 1, 2021.

Additionally, Chairperson Schaad informed the committee that under this chapter, the board is required to develop and maintain a list of all covered drugs sold in California, as defined in the measure. Further, the board is required to review each stewardship plan for compliance with applicable federal and state laws governing drug take back programs. Board staff will collaborate with CalRecycle.

Chairperson Schaad informed the committee that, as enacted, the board is required to review a list of covered and not covered products for sale in California. Should the board/committee develop reporting requirements to ensure consistency in the receipt of such data, such an approach could require regulations. The board is provided the authority to adopt regulations for administration of provisions for which it is responsible.

Ms. Sodergren identified challenges to this statute. For example, no real branders exist for basic responsibilities, such as how covered entities are to provide the information to the board; board staff would prefer an electronic standardized format. Therefore, without some type of regulation, staff could request an electronic format, but staff could not require it. Without regulations, it would be very difficult for staff to manage the receipt of information.

Ms. Sodergren informed the committee that Alameda County already has a program. Staff hopes to leverage what Alameda County is doing and use the county information to standardize submissions and develop parameters.

The committee directed staff to move forward to develop standardized submissions and parameters. Staff will provide the committee with recommendations, at a later date.

As part of the public discussion, Jennifer Snyder of the CRA and the NACDS indicated that many of the provisions of the law are problematic. She expressed concern with pharmacies that are included in the definition of covered entities. Ms. Snyder highlighted that there is a requirement that 90 days after the effective date of the bill (January 1, 2019), covered entities will have to submit to the board all of their drugs that they distribute into California and annually thereafter. Ms. Snyder stated that pharmacies in the City and County of San Francisco have successfully submitted this information on an Excel format and Ms. Snyder offered to provide that to the board as an example.

i. <u>SB 1109 (Bates) (Chapter 693, Statutes of 2018) Controlled Substances: Schedule II Drugs: Opioids</u>

Chairperson Schaad informed the committee that SB 1109 requires completion of continuing education (CE) for prescribers on the hazards of opioid use. Further, this law requires that a specified warning notice shall be prominently displayed on the label or container for an opioid dispensed to a patient for outpatient use.

Further, Chairperson Schaad stated as enacted, this CE requirement does not apply to pharmacists who prescribe under a collaborative practice agreement. He asked the members if the board or committee should consider developing a similar requirement for pharmacists performing in such a capacity.

Both Member Weisser and President Victor Law recommended that CE requirement also be developed for pharmacists who prescribe under a collaborative practice agreement.

As part of the public discussion, Danny Martinez of CPhA stated that is his understanding that it was not the authors intent to include pharmacists in this CE requirement. Mr. Martinez questioned whether regulations could be written if the provisions were not directed to pharmacists. Mr. Martinez explained that he believes the author intended to regulate prescribers rather than pharmacists.

President Law has requested a sample of required labels.

MOTION: Board staff will develop a statutory proposal seeking a CE requirement for a pharmacist operating under a collaborative practice agreement, with the authority to work with the chair of the committee. The proposal will be brought to the board at the January 2019 meeting.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

j. SB 1254 (Stone) (Chapter 697, Statutes of 2018) Hospital Pharmacies: Medication Profiles or Lists for High-Risk Patients

Chairperson Schaad informed the committee that SB 1254 requires a pharmacist at a hospital pharmacy to obtain an accurate medication profile or list for each high-risk patient upon admission and discharge. The criteria for determining whether a patient is high-risk will be established by each hospital. Additionally, this law allows for this function to be performed by a pharmacy technician or intern pharmacist, if they have successfully completed training and proctoring by the pharmacy department or another healing arts licensee issued a license pursuant Division 2. Under the provisions, the board has the authority to adopt regulations.

Chairperson Schaad asked the committee if they wished to have staff identify hospitals that have chosen to implement medication reconciliation under the purview of the pharmacy.

Ms. Sodergren explained to the committee that data collected from hospitals could help with the development of policy moving forward.

As part of the public discussion, Mr. Gray opined that this is one of the most important bills of the year and encouraged the board to take this opportunity to take a very strong enforcement position on the implementation of this bill.

Motion: Direct board staff to collect information on how hospitals are implementing the collection of data pursuant to SB 1254.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

k. SB 1442 (Wiener) (Chapter 569, Statutes of 2018) Community Pharmacies: Staffing

Chairperson Schaad informed the committee that this law prohibits a community pharmacy from requiring a pharmacist to work alone. It requires either another employee of the pharmacy or the establishment be made available to assist the pharmacist at all times.

Chairperson Schaad identified some exceptions including:

- Hospital pharmacies and hospital outpatient services
- Government owned pharmacies
- Pharmacies owned by individuals who own up to four pharmacies in California
- Pharmacies owned and operated by a health care service plan that exclusively contracts with no more than two medical groups
- Pharmacies with a drive-through window service when only the drive-through is open and the employer does not require the pharmacist to retrieve items outside the pharmacy for sale
- Pharmacies that do not sell, furnish, or dispense controlled substances, dangerous drugs or dangerous devices at retail

As part of the public discussion, Mr. Martinez and Mr. Gray requested that the board clarify what it means to "assist the pharmacist." Ms. Snyder provided what she believes is the intent of the legislation: the intent was to identify a staff member (not a pharmacy technician) within the establishment to relieve the pharmacist for short periods of time. Mr. Gray stated that it is his understanding that the intent was to provide an actual assistant to help with administrative duties. Mr. Stein stated there may be staffing issues with separate ownerships between the pharmacy and the retailer. An example he provided is a CVS Pharmacy located inside a Target retail store.

Staff will work with counsel to research the DEA requirements and to see if a background check would be required under the Code of Federal Regulations or if the board should develop such a requirement. Staff will report back with a recommendation at the next meeting.

l. Chaptered Bills Relating to Health Care Coverage: Prescription Drugs

- AB 2863 (Nazarian) (Chapter 770, Statutes of 2018) Health Care Coverage: Prescriptions
- AB 315 (Wood) (Chapter 905, Statutes of 2018) Pharmacy Benefit Management
- SB 1021 (Wiener) (Chapter 787, Statutes of 2018) Prescription Drugs

Chairperson Schaad informed the committee that bills AB 2863, AB 315 and SB 1021 are intended to ensure that patients do not pay more for a drug if they have health insurance, than if they had paid the cash price directly.

As part of the public discussion, Ms. Snyder, requests that the board delay enforcement of provisions in AB 2863 and AB 315 that requires a pharmacy to submit a claim, but noted that submission of the claim is a problem because the systems do not allow for such a submission.

DCA Counsel Freedman recommended allowing staff and counsel more time to review each piece of legislation and their individual impacts. The committee agreed with her recommendation and asked that counsel bring any recommendations to the January Board Meeting.

4. Discussion and Consideration of Amendments to California Code of Regulations, Title 16, Section 1713, Related to Automated Drug Delivery Systems

Chairperson Schaad informed the committee that as discussed earlier in this meeting, recently enacted legislation regarding ADDS alters the condition under which a pharmacy can operate such a device. With the enactment of SB 1447 and AB 2037, the board/committee should consider amending existing regulations for ADDS that dispense medications to patients to reflect current law in this area.

Chairperson Schaad introduced a statement authored by the Ms. Sara Lake. Chairperson Schaad explained to the committee that the statement provided details on proposed regulatory changes, pursuant to the enactment of SB 1447. Chairperson Schaad also introduced a broader set of amendments developed by staff to remove duplication between the regulation and the new law as well as conflicts created by enactment of the new statute.

Chairperson Schaad provided the committee with the suggested recommendation from board staff.

Ms. Sodergren clarified that the suggested recommendation would be to amend CCR section 1713 to reflect the boards current policy with respect to ADDS because there is a conflict between the statute and previous regulations. Staff recommended conforming changes.

Motion: Recommend to the board initiation of a rulemaking to amend Title 16, California Code of Regulations section 1713 and delegate to the Executive Officer the authority to make technical or non-substantive changes consistent with the board's policy.

M/S: Weisser/Law

Support: 5 Oppose: 0 Abstain: 0

5. Discussion and Consideration of Possible Statutory Amendment to Clarify CURES Reporting Requirement Related to the Dispensing Date

Chairperson Schaad provided background to the committee. He explained that currently, all Schedule II – IV controlled substance prescriptions dispensed in California must be reported to the Prescription Drug Monitoring Program (PDMP) known as CURES.

Records of dispensing must be sent to CURES within seven days of the dispensing of the controlled substance, but there is currently no requirement to send a void/cancel message for prescriptions that were filled in the pharmacy but never picked up.

For committee consideration and discussion Chairperson Schaad explained that while the CURES reporting system is administered by the DOJ, actual submissions by pharmacies are transmitted to a third party, Atlantic Associates (AAI). AAI is tasked with data integrity, formatting checks, identifying duplicate entries, and reconciling "near matches." AAI then transmits the data for insertion into the CURES database.

Additionally, while some pharmacy systems hold a prescription's transmission to CURES until the patient actually receives the filled prescription, most systems do not. Thus, CURES reports may contain medication that, in fact, were never actually dispensed to the patient.

Chairperson Schaad welcomed Robert Stein to provide the committee with a presentation relating to this issue.

Mr. Stein presented possible solutions. First, a reverse/cancel transaction obviates the manual processes needed to remove a prescription not conveyed to a patient from CURES. Second, pharmacies with computer systems that include integrated Point of Sale or "closed loop dispensing" may not require the reverse/cancel functionality if the date of sale, physical dispensing to the patient, becomes the "trigger event" to send a prescription record to CURES; however, if the "date of dispensing" is considered to be the date of fill in the pharmacy computer system, some prescriptions may be reported to CURES later than the statutory requirement. Mr. Stein suggested a statutory amendment to Health & Safety Code section 11165 in order to clarify that the time limit to submit the transaction to CURES begins at either the date of prescription processing or the date of actual dispensing to the patient, whichever is later. Third, pharmacy system vendors should be notified that to comply with California reporting requirements, they must modify their systems to send a

void/cancel code to AAI. Fourth, Mr. Stein requested clarifying language throughout statutes and regulations that harmonizes definitions of “fill,” “dispense,” and “sale” dates.

Member Weisser suggested that the information be shared with the DOJ. Ms. Sodergren clarified that the DOJ CURES system has the capability, but the systems at the pharmacies are not capable of sending the void/cancellation to the CURES system.

Ms. Sodergren suggested that staff could publish a newsletter article or send out a subscriber alert advising pharmacies of the problem with pharmacy systems not sending the void/cancellation to the CURES system.

As part of the public discussion, Mr. Gray suggested a legislative change.

6. Discussion and Consideration of Board’s Enforcement Statistics

Chairperson Schaad informed the committee that the board received 1,156 complaints and closed 1,180 investigations. As of November 30, 2018, the board had 1,853 investigations pending.

Chairperson Schaad added that of the investigations closed, 595 complaints were closed without a substantiated violation, including 140 complaints that were determined non-jurisdictional.

In addition, the board issued 625 citations, 94 of which the board offered abatement to either reduce or eliminate the fine. The board referred 108 investigations to the Office of the Attorney General.

Chairperson Schaad concluded that the board resolved 120 administrative cases that resulted in 96 revocations or surrenders of a license, 45 licenses being placed on probation, and issued 20 public reprovals.

7. Future Committee Meeting Dates

Chairperson Schaad informed the committee that the 2019 meeting dates are March 14, 2019, July 2, 2019 and September 25, 2019.

Chairperson Schaad adjourned the meeting at 1:31 PM.