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

ENFORCEMENT COMMITTEE REPORT
November 5, 2019

Allen Schaad, Licensee Member, Chair
Maria Serpa, Licensee Member, Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee Member

1. **Call to Order and Establishment of Quorum**

2. **Public Comment on Items Not on the Agenda, Matters for Future Meetings**
   Note: The committee may not discuss or take action on any matter raised during this public comment section that is not included on this agenda, except to decide whether to place the matter on the agenda of a future meeting. [Government Code sections 11125, 11125.7(a)]

3. **Approval of the July 10, 2019, Enforcement Committee Minutes**

   Attachment 1

   Attachment 1 includes a copy of the draft minutes from the July 10, 2019, Enforcement Committee Meeting.

4. **Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulation, Section 1715.65 Relating to Inventory Reconciliation Requirements for Controlled Substances**

   Attachment 2

   Relevant Law
   CCR Section 1715.65 establishes the board's requirements for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances.

   Background
   Following adoption of the regulation, in order to provide guidance to the regulated public, the board developed frequently asked questions that are published on the board's website.

   During its last meeting the committee discussed the regulation and noted that it may be appropriate to provide clarification in the regulation through amendments to the language. Some of the areas for clarification included the potential need to clarify the requirements for automated drug delivery systems used in hospitals for unit dose administration and if a definition of satellite locations would be beneficial. The committee received public comment requesting that the board clarify the term "periodic" and sought alternative solutions to maintaining signatures for individuals performing inventory counts.

For Committee Discussion

Following the meeting the committee chair worked with staff and counsel to draft possible amendments to the current regulation. As drafted the regulation language would clarify the frequency for completion of the reconciliation report for Schedule III-V medications. Further, it will allow individuals performing counts to sign and date documentation of the count as opposed to the report itself. The draft language defines the satellite location and clarifies that a physical count is not required for inventory of an ADDS in specified locations however all other reporting requirements must be completed.

Attachment 2 includes a copy of the proposed language.

5. Discussion and Consideration of Proposed Amendments to Title 16, California Code of Regulations Section 1715.6 Relating to Reporting Drugs Losses

Attachment 3

Relevant Law

Title 16, CCR section 1715.6 currently states, "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

Title 21 CFR 1301.76(b) states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft."

Background

As part of past board discussions related to the board's new inventory reconciliation regulation, the issue of drug loss reporting requirements was mentioned. It was brought to the board's attention the difference in the Code of Federal Regulations (CFR) requirements and California Code of Regulations (CCR). During the rulemaking process, it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the Drug Enforcement Administration (DEA) requirements. At that time members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act.

During its last meeting, the committee continued its discussion and contemplated in a threshold for reporting would be appropriate in lieu of the current requirement to report any loss.

For Committee Discussion

Subsequent to the meeting, the committee chair provided guidance to staff on development of draft amendments that would create threshold limits for reporting.

Attachment 3 includes a copy of the draft amendments.

6. Presentation on Routine Pharmacy Inspections

Attachment 4

Background

As part of the Enforcement Committee's discussion on April 03, 2018 regarding the board's Enforcement Program, the committee and board staff discussed issues pertaining to the

implementation of routine inspections beginning May 2018 and the proactive effect that could result from an increased number of routine inspections.

The committee's strategic goal is for a routine inspection to be completed once every four years in every facility with a PHY license.

In Fiscal Year 2018/19, board inspection staff was assigned routine inspections in addition to their normal workload to assist in achieving this goal. The purpose of routine inspections is to educate pharmacies on compliance issues and provide information on new laws and regulations that effect the practice of pharmacy.

Attachment 4 includes a copy of the Routine Inspection Presentation.

For Committee Discussion
The board has asked staff to provide information about the routine inspection program for FY 18/19. During this meeting, Board Chiefs of Enforcement Julia Ansel and Tom Lenox will provide general information on board inspections during FY 18/19.

7. Discussion and Consideration of Recently Enacted Legislation Impacting the Practice of Pharmacy

a. AB 528 (Low, Chapter 677, Statutes of 2019) Controlled Substances: CURES Database

Attachment 5

Summary: Effective January 1, 2021, expands the CURES reporting requirements to also include Schedule V drugs and would reduce the reporting period to CURES to within one business day from the date the prescription was released to the patient.

Requires reporting to the CURES system by veterinarians as soon as reasonably possible, but not more than seven days after dispensing, allows physicians that do not possess a DEA registration to enroll in the CURES system, and expands the delegate provisions for individuals working under a prescriber to retrieve data from CURES.

b. AB 690 (Aguiar-Curry, Chapter 679, Statutes of 2019) Pharmacies: Relocation: Remote Dispensing Site Pharmacy: Pharmacy Technician: Qualifications

Attachment 6

Summary: Effective immediately, this measure creates a limited exemption to the licensure transferability requirements for a pharmacy to locate because of damage caused by a declared disaster. Further the requirements for a pharmacy technician working in a remote dispensing site pharmacy are established. Specifically, to qualify to work in such a location a pharmacy technician must satisfy the following conditions:

- Possess a pharmacy technician license that is in good standing.
- Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

- Possess one of the following:
    - (A) A minimum of an associate degree in pharmacy technology.
    - (B) A minimum of a bachelor's degree in any subject.
    - (C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.
- Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

Board staff will need to establish a streamlined process for pharmacies to follow when relocation is allowed under the provisions of the bill. In addition, with the technician requirements now finalized, staff will post the application and requirements for entities seeking licensure as a remote dispensing site pharmacy.

c. AB 973 (Irwin, Chapter 184, Statutes of 2019) Pharmacies: Compounding

Attachment 7

Summary: Effective January 1, 2020, this measure explicitly states that compounding of drug preparations by a pharmacy must be done consistent with the relevant compounding chapters of the United States Pharmacopeia-National Formulary.

The new provision will augment the board's compounding regulations and BPC section 4342 which provides the board authority institute any action it deems necessary to prevent the sale of pharmaceutical preparations and drugs that do not conform with the standard and tests as to quality and strength, provided in latest edition of the USP.

d. AB 1723 (Wood, Chapter 323, Statutes of 2019) Clinics: Purchasing Drugs at Wholesale

Attachment 8

Summary: Effective January 1, 2020, this measure will conform the maximum hours of operation (increasing from 20 to 40 hours) for a primary care community or free clinic with the provisions of HSC 1206.

e. SB 159 (Wiener, Chapter 532, Statutes of 2019) HIV Preexposure and Postexposure Prophylaxis

Attachment 9

Summary: Effective July 1, 2020, this measure establishes authority for a pharmacist to furnish HIV preexposure prophylaxis and HIV postexposure prophylaxis under specified conditions.

Specifically, the conditions for HIV preexposure prophylaxis include the following:

1. Defines preexposure prophylaxis as a fixed-dose combination or tenofovia disoproxil fumerate (TDF) (300 mg) with emtricitabine (FTC) (200mg), or another drug or drug combination determined by the board to meet the clinical eligibility recommendations provided by the CDC.
2. Defines "CDC guidelines" as the "2017 Preexposrue Prophylaxis for the Prevention of HIV

Infection in the United States-2017 Update: A Clinical Practice Guideline," or any subsequent guideline.

3. Requires the board, in consultation with the Medical Board of California, to approve a training program that includes information about financial assistance programs, including the HIV prevention program described in 120972 of the Health and Safety Code. Further the board must consult with the Medical Board, Office of AIDS and other stakeholders. Pharmacists must complete this training program in advance of furnishing the product.
4. Provides that a pharmacist shall furnish at least a 30-day supply, but no more than a 60-day supply under specified conditions: Pharmacists are prohibited from furnishing more than the 6-day supply to a single patient more than once every two years unless directed by a prescriber.
5. Details the conditions that must be met for a pharmacist to furnish the product including:
    a. The patient has a documented negative HIV test within the previous seven days. If results are not available, the pharmacist must order and verify the results of the tests. If test results are positive, the pharmacist or person administering the test shall direct the patient to a primary care provider.
    b. The patient does not report any signs or symptoms of acute HIV infection.
    c. The patient is not taking any contraindicated medications.
    d. Requires consultation covering specified. Consultation may not be waived.
    e. Requires documentation of the services provided by the pharmacist in the patient's record if possible as well as maintenance of records for product furnished to each patient.
    f. Requires notification to the patient's PCP if identified and consent is provided. If not, the pharmacist must provide the patient with a list of providers to contact regarding ongoing care.
6. Requires the board to adopt emergency regulations by July 1, 2020.
    a. Regulation will be necessary to establish the additional drug or drug combinations.
    b. Regulation will be necessary to establish and/or approve a training program.

Specifically, the conditions for HIV postexposure prophylaxis include the following:

1. Defines preexposure prophylaxis either:
    a. Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily
    b. (2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.
    c. Any other drug or combination determined by the board to meet the same clinical eligibility recommendations provided by the CDC.
2. Defines "CDC guidelines" as the "Updated Guidelines for Antiretroviral Postexposure

Prophylaxis after Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV-United States, 2016" or any subsequent guideline.

3. Requires the board, in consultation with the Medical Board of California, to approve a training program that includes information about financial assistance programs, including the HIV prevention program described in 120972 of the Health and Safety Code. Further the board must consult with the Medical Board, Office of AIDS and other stakeholders. Pharmacists must complete this training program in advance of furnishing the product.
4. Provides that a pharmacist shall furnish a complete course of postexposure prophylaxis under specified conditions:
    a. The pharmacist screens the patient and determines that exposure occurred within the previous 72 hours and determines that the patient otherwise meets the clinical criteria for the product.
    b. The pharmacist provides HIV testing or determines the patient is willing to undergo such testing. A pharmacist may still furnish if a patient refuses to undergo the test but is still otherwise eligible.
    c. Requires consultation covering specified. Consultation may not be waived.
    d. Requires notification to the patient's PCP if identified and consent is provided. If not, the pharmacist must provide the patient with a list of providers to contact regarding follow-up care.
5. Requires the board to adopt emergency regulations by July 1, 2020.
    a. Regulation will be necessary to establish the additional drug or drug combinations.
    b. Regulation will be necessary to establish and/or approve a training program.

After discussion, it may be appropriate for the committee to consider if development of the regulations should be completed under the auspices of the Licensing Committee.

f. <u>SB 569 (Stone, Chapter 705, Statutes of 2019) Controlled Substances: Prescriptions: Declared Local, State, or Federal Emergency</u>

Attachment 10

Summary: Effective January 1, 2020, this measure allows a pharmacist to fill a prescription for a controlled substance that does not conform to the controlled substances security form requirements under the following conditions.

1. The prescription form indicates that the patient is affected by a declared emergency.
2. The prescription is written and dispensed within first two weeks of a notice issued by the board.
3. The pharmacist exercises appropriate professional judgement including reviewing the CURES system prior to dispensing.
4. Limits the dispensing of a Schedule II to no greater than a seven-day supply.
5. Requires confirmation that the patient is otherwise unable to access medications. Verification of residency within an evacuation area is one acceptable form of confirmation.
6. Prohibits the refill of a prescription dispensed under these provisions.

The board routinely issues a Subscriber Alert when a declared disaster declaration is made. Staff believes this alert can serve as the notice required to be issued by the board. The committee may wish to provide guidance on documentation pharmacies may wish to maintain to confirm compliance with the provisions. For example, it may be appropriate to document either on the prescription or other pharmacy records that the confirmation of the patient's residence was completed.

g. SB 655 (Roth, Chapter 213, Statutes of 2019) Pharmacy

Attachment 11

Summary: Effective January 1, 2020, this measure makes several technical and other conforming changes to Pharmacy Law.

1. Increases the number of hours of an externship for a pharmacy technician trainee to 340 hours including rotations between community and hospital pharmacy. Further increases the number of participation hours for the trainee to 140 hours at a specific location.
2. Allows a licensed reverse distributor to acquire drugs from an unlicensed source that was previously licensed.
3. Specifies that an examination score on the CPJE or NAPLEX is valid for purposes of licensure for no more than one year following replacement with another occupational analysis. Further, creates an exemption for the NAPLEX examination if the applicant holds an active license in another state or territory.
4. Modifies the advanced practice pharmacist renewal requirements to allow the board to inactivate the APH license under the following conditions:
    a. The pharmacist license becomes inactive.
    b. The APH fails to provide documentation of the completion of the required CE.
    c. The APH fails to provide documentation of completion of CE as part of an audit or investigation.
5. Effective July 1, 2021 requires application and renewal payments for government owned applicants and licensees.

8. Discussion and Consideration of Board's Enforcement Statistics

Attachment 12

Enforcement statistics for the first three months of FY 2019/20 have been provided as **Attachment 12**.

A review of workload statistics for the past year indicates a 14% decrease in the number of compliant investigations closed; 5% increase in the number of case investigations pending; a 37% decrease in the average amount of days for an investigation and a 12.5% increase in the number citations issued with an order of abatement. Additionally, administrative case outcomes have increased by 26% and the issuance of public protection sanctions has increased by 100%.

The board currently has 1,724 field investigations pending, as of October 1, 2019. Below is a breakdown providing more detail in the various investigation process:

- 107 cases under review for assignment, averaging 11 days
- 933 cases under investigation, averaging 178 days

- 297 investigations under supervisor review, averaging 86 days
- 127 investigations under second level review, averaging 53 days
- 255 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 49 days

7. Future Committee Meeting Dates

Below are the committee dates scheduled for 2020.

- January 29-30, 2020
- May 5-6, 2020
- July 9, 2020
- July 29-30, 2020
- October 27-28, 2020

Adjournment **Upon Conclusion of Business**

Note: It is anticipated that the committee will resume its discussion on an alternate enforcement model as it continues its review of the Disciplinary Guidelines as part of its next meeting.

Attachment 1
Enforcement
Committee Minutes
July 10, 2019

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ENFORCEMENT COMMITTEE
MEETING MINUTES

DATE: July 10, 2019

LOCATION: Department of Consumer Affairs - Building Two
1747 North Market Blvd., Room 186
Sacramento, CA 95834

COMMITTEE MEMBERS PRESENT: Allen Schaad, Licensee Member, Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Albert Wong, Licensee 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
Debbie Damoth, Administration Manager

1. **Call to Order and Establishment of Quorum**
Chairperson Allen Schaad called the meeting to order at 9:01 a.m. A quorum was established.

2. **Public Comment on Items Not on the Agenda, Matters for Future Meetings**
Chairperson Schaad invited public comment.

Dr. Steven Gray suggested that Senate Bill 1442 be considered as a future agenda item. Interim Executive Officer Anne Sodergren stated that the discussion of SB 1442 is on the agenda for the July 2019 Legislation and Regulation Committee meeting. Dr. Gray responded, his request is to have SB 1442 placed specifically on the Enforcement Committee meeting agenda, in order to discuss the actual enforcement of SB 1442.

Robert Stein of KGI School of Pharmacy stated that he would provide suggested edits for the draft version of the Self-Assessment for Community Pharmacies form. Mr. Stein stated that those suggested edits would be forwarded to Ms. Sodergren for consideration.

3. **Approval of the March 14, 2019 Enforcement Committee Minutes**
Chairperson Schaad requested the review and approval of the Minutes from the March 14, 2019 Enforcement Committee meeting.

Motion: Approve the minutes, as is.
M/S: Lippe/Sanchez
Support: 4 Oppose: 0 Abstain: 0

4. **Presentation and Discussion on the Board's Citation and Fine Program**

Chairperson Schaad provided relevant law. Business and Professions Code section 4314 established the authority for the board to issue citations, which may include fines and/or orders of abatement. As included in this section, the order of abatement (OOA) may include completion of continuing education courses and specifies that any such continuing education courses shall be in addition to those required for license renewal.

Additionally, Title 16, California Code of Regulations (CCR) sections 1775-1775.4, provide the board's regulations governing its citation and fine program. More specifically, section 1775 details the types of violation for which a citation may be issued and includes the authority of the executive officer or designee to issue citations, which may contain either or both an administrative fine and an order of abatement.

Section 1775.2 establishes the factors to be considered in assessing an administrative fine. Such factors include:

1. The gravity of the violation.
2. The good or bad faith of the cited person or entity.
3. The history of previous violations.
4. Evidence that the violation was or was not willful.
5. The extent to which the cited person or entity has cooperated with the board's investigation.
6. The extent to which the cited person or entity has mitigated or attempted to mitigate any damage or injury caused by the violations.
7. Other matters as may be appropriate.
8. The number of violations found in the investigation.

Further, section 1775.3 establishes the OOA compliance requirements.

Chairperson Schaad provided background information. For several meetings the committee has discussed several aspects of the board's citation and fine program. Chairperson Schaad reminded the committee that during the May 2018 Board meeting, members suggested that staff consider using the abatement provisions, especially in cases where the violations involved medication errors. He stated that the committee continues the review of the citation and fine program.

Members received a presentation on citation and fine trends from Anne Sodergren. Data was presented covering Fiscal Years from 2014 to 2019, regarding citations issued, Orders of Abatement issued, top citation violations and citation examples in the area of medication errors and prescription disclosure errors.

Chairperson Schaad suggested that this presentation along with examples of abatements be published in The Script newsletter.

The committee heard public comments which requested clarification on the OOA issuance process and whether an OOA must always be associated with a citation. In response, SDAG Room clarified

that an OOA is issued with a citation and the OOA must be complied with in order to satisfy the citation, otherwise, disciplinary action may result. Additionally, Ms. Sodergren clarified that in some circumstances, when an OOA is completed the fine may be reduced.

Further, the committee was asked who is expected to sign an OOA. Member Lippe responded that signature may depend on who the citation is issued against.

As part of additional public comment, the committee was asked if there are specific criteria that must be met for a licensee to correct a violation by an OOA. In response, SDAG Room stated that there are no guidelines for issuance of an OOA. When the committee was asked if a licensee could request an OOA rather than a citation, Ms. Sodergren clarified that licensees do not have the option to select an OOA; an OOA is a condition of the issuance of the citation. When asked what recourse a licensee has when they feel that a violation could be better resolved with an OOA rather than just a citation, SDAG Room stated that a licensee may request an Office Conference; every citation issued is subject to modification or dismissal at the Office Conference.

5. **Post Implementation Review of Inventory Reconciliation Requirements for Controlled Substances, Including Discussion and Consideration of Title 16, California Code of Regulations Section 1715.65**

Chairperson Schaad provided background and relevant law. In April 2018, Title 16, CCR Section 1715.65 established the board's requirements for pharmacies and clinics to perform inventory reconciliation activities to detect and prevent the loss of controlled substances. Chairperson Schaad informed the committee that since that time the board has provided guidance documents including FAQs that are published on the board's website. He stated that board staff continue to receive questions regarding the regulation requirements.

Chairperson Schaad provided a sample of the types of questions in the Chair Report for review.

Chairperson Schaad stated that in addition, considering the recent enactment of the Automated Drug Delivery Systems (ADDS) provisions, it seemed appropriate to complete a post implementation review of the regulation to determine if additional guidance or changes may be necessary to meet the board's policy goal of the regulation.

Ms. Sodergren suggested that the committee may want to consider policy direction with respect to drugs in the ADDS devices as well and discuss more clear directions for devices in hospital settings and satellite locations.

As part of public comment, Mr. Martinez of CPhA requested clarification on how bulk powder substances should be reconciled on the Inventory Reconciliation Report. Chairperson Schaad advised that powdered substances should be weighed.

As part of public comment, Candace Fong of Dignity Health informed the committee that with respect to reconciliation of Schedule II Controlled Substances (CIIs), the ADDS devices located in their hospitals are already subject to internal processes, which are on a perpetual closed-loop inventory. In their opinion, to physically have to count the CIIs on a quarterly basis, given their internal controls, is repetitive and not considered a wise use of their resources. Many Dignity Health hospitals have up to 75 ADDS machines. Their understanding, when the regulations were released, was that hospitals would be required to establish policies and procedures to support an inventory

process to monitor controlled substances in the ADDS, which would remove hospitals from the physical inventory requirement. Dr. Fong also stated that when the FAQs were released and inspections commenced, there was confusion on the implementation of inventory reconciliation of ADDS in hospital settings. She stated that Dignity Health is in support of limiting the physical inventory requirement to the pharmacy's central vault area and not include the devices.

As part of public comment, Mr. Stein of KGI School of Pharmacy stated, in his own professional experience, hospitals have strict controls over dispensing devices. He stated the regulation implies that a pharmacist must conduct the inventory counting; however, if there are controls already in place that adequately ensure that an accurate inventory is conducted by nurses, even more frequently than required by the regulation, such a process should already be compliant with the law.

Chairperson Schaad recommended there should be clarification provided regarding inventory reconciliation of ADDS in satellite locations, as well as guidance on inventory requirements in hospital settings. Chairperson Schaad stated, ADDS located in hospital settings are subject to strict checks and balances, which already ensure the protection of the public and as a result, the degree of drug loss is less. Chairperson Schaad stated he would like to ensure hospitals are not put in a position to unnecessarily have to spend time completing an inventory that will have very little value.

Ms. Sodergren suggested that the committee may want to consider a policy discussion on satellite location requirements, based on their individual location. For example, the requirements of an ADDS located in a hospital may differ from the requirements of an ADDS located in a skilled nursing facility.

DCA Staff Counsel Laura Freedman suggested it may be appropriate to provide clarification about who may sign the Inventory Reconciliation Report.

As part of the public comment, a CVS Health Representative opined that the inventory reconciliation requirements are written from an antiquated perspective in that many pharmacy systems have the electronic capabilities to document every pharmacist involved in the distribution of CIIs. He stated the current requirement for a signature and date causes each pharmacist who may have performed a single count of medication to be tracked down which is not always logistically possible. He asked that board inspectors either use discretion in the enforcement of this regulation and consider the established electronic documentation already in place or the board amend the regulation to consider electronic documentation in lieu of actual signatures.

As part of the public comment, a representative from Albertson's requested that the committee clarify or define the term "periodic" regarding the periodic inventory requirement.

As part of public comment, Dr. Gray requested clarification on the retention requirement of three years for inventory reconciliation reports. Specifically, he asked if an electronic inventory record, which staff has access to in the pharmacy, meets the retention requirement. Board Member Lippe confirmed that the regulation states that the reports should be in a "readily retrievable form" which would include an electronic copy of the report. Additionally, Dr. Gray had comments on FAQs; Ms. Sodergren requested that Dr. Gray submit those comments to the board.

The committee took a break at 10:07a.m. and returned at 10:27 a.m.

Chairperson Schaad summarized that pursuant to committee discussion of Section 1715.65, board staff will work with the committee chair to discuss and develop recommendations for the following topics of concern:

- Specify requirements of ADDS in hospitals,
- Define a satellite pharmacy,
- Review FAQ pursuant to recommendations submitted during public comment,
- Discuss the use of electronic documentation of reconciliation, and
- Define periodic.

6. <u>Discussion and Consideration of Reporting Drug Losses to the Board Pursuant to Title 16, California Code of Regulations, Section 1715.6</u>

Chairperson Schaad provided background and relevant law. Title 16, CCR section 1715.6 currently states, "The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths." Title 21 CFR 1301.76(b) states, "The registrant shall notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft."

Mr. Schaad stated that as part of past board discussions related to the board's new inventory reconciliation regulation, the issue of drug loss reporting requirements was mentioned. It was brought to the board's attention the difference in the Code of Federal Regulations (CFR) requirements and California Code of Regulations (CCR). During the rulemaking process, it was suggested that the board amend its current drug loss requirement (CCR 1715.6) to mirror the DEA requirements. At that time, committee members were advised that such a change could not be implemented as the language lacked the necessary clarity required to comply with the Administrative Procedures Act.

Chairperson Schaad informed the committee the Chair Report included summary data regarding drug losses. Also, Attachment 3 provided additional information regarding the types of losses that fall within the 1-100 dosage unit range.

Chairperson Schaad recommended a correction of the Morphine data provided in Attachment 3.

Ms. Sodergren stated that there have been numerous discussions on whether there is value in receiving reports of every loss, as the law currently requires. The question arises, should the committee establish a different threshold? Ms. Sodergren suggested the committee discuss whether they agree with what the regulation currently requires. If the committee determines there is little value added to consumer protection with the notification of every pill loss, it may be appropriate for staff to work offline with the committee Chair, based on the data provided, to determine if a new reporting requirement should be considered.

In response, Chairperson Schaad stated that the current reporting requirements are confusing and reporting criteria should be more manageable. Chairperson Schaad informed that committee that he will work with board staff in the development of new reporting thresholds.

The committee heard public comment which encouraged the committee to not require the report of every schedule, every type of drug or number of dosage units lost. The board was encouraged to adopt a regulation that states that pharmacists, pharmacies, etc. shall follow the reporting requirement of the Drug Enforcement Administration (DEA) and any report that is made to the DEA also must be made to the board. He stated that there is opportunity now, by statute or by regulation, to have pharmacists, PICs and consulting pharmacists adopt their own policies and procedures using their professional judgement in conjunction with the six criteria identified by the DEA to determine what ought to be reported.

7. <u>Discussion on and Consideration of Proposal to Establish an Alternative Disciplinary Process</u>

Chairperson Schaad provided background and relevant law. In general, the Administrative Procedures Act establishes the parameters for the disciplinary process. More specifically, Government Code section 11415.60 provides the authority for an agency to formulate and issue a decision by settlement pursuant to an agreement of the parties without conducting an adjudicative proceeding.

He stated that previously the committee received a presentation by the California Pharmacists Association (CPhA), seeking to establish an alternative enforcement model. The committee expressed concerns with the proposal but directed staff to develop a possible alternative enforcement model that would meet two primary goals - - reduce cost and reduce closure times. Consistent with the direction of the committee, staff worked with the committee chair on the basic framework for an alternative model.

Chairperson Schaad invited board staff to provide a brief summary of the proposal.

Ms. Sodergren provided a review of the flowchart depicting the proposed concept of an alternative disciplinary process. Ms. Sodergren detailed that the flowchart was designed with consideration to the feedback that was shared at the last committee meeting.

Ms. Sodergren provided a description of the alternative model:

1. Investigation is completed and violations are substantiated that warrant referral to the Office of the Attorney General (AG's Office) for disciplinary charges.
2. Respondent is advised of the violations and the board's intentions to refer the matter to the AG's Office for disciplinary charges. As part of the advisement, respondent is provided the option to pursue the alternate model.
3. Matter is referred to the AG's Office.
4. Board receives respondent's notice electing to engage in the alternate model. Respondent may also provide any mitigation evidence.
5. Executive Officer (EO) and 2 board members (one public member and one licensee member) review investigation and mitigation, if any.
6. Settlement offer is developed and conveyed by AG's Office to respondent.
7. Upon agreement, the settlement along with the initial notice to respondent advising of the substantiated violations are considered by the board for action.

In addition, Ms. Sodergren presented the draft statutory proposal intended to detail the basic tenets of the proposal. She explained that in its current form, the language is a concept and not yet ready

for sponsorship. If the committee is in in agreement with the direction and concept of this as an alternative solution, this could be brought before the full board to request approval for board staff to continue the development of the statutory proposal with the committee chair.

As part of the public discussion, Danny Martinez of CPhA asked if the referral to the Office of the Attorney General be prevented or avoided in this alternative model in order to expedite the process? SDAG Room clarified that cases are routinely referred to the Office of the Attorney General to prepare the pleadings. Referrals, for these types of cases would be for purposes of pre-filing settlement; the Office of the AG has the standard templates used for stipulations, provides the reviewing the mitigation and packaging it for purposes of the board. SDAG stated that at this point, an Accusation is not being prepared.

Mr. Martinez also asked, under review of the investigation by the EO & two board members, would the committee consider increasing that panel to 3 board members, specifically 2 licensees and one public board member? Acting President Lippe responded, adding more professional than public members is in direct opposition to the concept behind having public members. He emphasized, three board members would place control in the hands of licensees, while the goal is to equal control of decisions.

In addition, Mr. Martinez asked, if a licensee chooses to use the alternative route, will the licensee have an opportunity to prove their innocence? SDAG Room clarified that the alternative route is to be used for cases where investigations have already been completed and the violations that would warrant discipline have already been substantiated. These are cases where the executive officer has already determined that the case would be referred to the Office of the AG and this is an alternative to the immediate referral for pleading. The licensee has already been provided the opportunity to provide information to dispute the violation during the investigation.

Mr. Martinez asked if it is possible for the licensee to provide evidence before the panel to prove that he/she committed no violation? Ms. Sodergren responded, if there is supplemental information to be considered that will be included as part of the mitigation. DCA Counsel Freedman stated that this process would not prohibit the EO from recommending that a pleading should not be drafted.

Mr. Martinez also asked if the licensee responds within the 60-day period, but a settlement is not agreed upon within the 60 days, may an extension be granted? SDAG Room and Ms. Sodergren confirmed that the 60-day period is for agreement to settlement; at that time the EO may forward the case to the AG's Office to prepare the pleading or grant additional time.

Mr. Martinez stated that CPhA would prepare additional comments for board for consideration while board staff finalize this proposal.

Ms. Sodergren reminded the public, at this point, staff is discussing high-level basic concepts, the proposal will need to be further refined while considering existing policy and statute. Currently neither the committee nor the board can answer some of the very detailed questions.

As part of public discussion, various members of the public contributed suggestions to be considered as the proposal is refined. Some of the suggestions included: The Executive Officer should present the information to the panel, but not be allowed to vote; a third board member

should be included in the panel who has actual pharmacy experience instead of the executive officer; the panel should consist of 3 to 5 board members. Suggested language was provided to the board for review.

A member of the public suggested that the licensed board member assigned to the panel be selected for each case according to their area of practice. SDAG Room responded that the board is designed to operate by the majority vote of public and licensee members; they are not required to bring any particular expertise to the board. Board members are required to rely on the investigation reports. He advised against creating any circumstance by which certain board members would be designated for certain types of cases and not others.

SDAG Room cautioned the board against any circumstance where public members' votes would be automatically outweighed by licensed members' votes due to the potential for liability under the North Carolina Dental Board Case.

Motion: Take the proposal to establish an alternative disciplinary model to the full board.
M/S: Lippe/Wong
Support: 4 Oppose: 0 Abstain: 0

8. <u>Discussion and Consideration of Draft Frequently Asked Questions Resulting from the Board's Ask an Inspector Program</u>

Chairperson Schaad recommended that this item be brought back to the Enforcement Committee after further review by board staff and the Chair.

Chairperson Schaad invited the public to submit written comments for review and consideration.

9. <u>Discussion and Consideration of Posting of an Individual Licensee's Address of Record on the Board's Website</u>

Chairperson Schaad provided background and relevant law. Government Code Section 6250, et seq, provides that the address of record of board licensees is public information. CCR Section 1727.1 provides that the board shall not make an intern pharmacist's address publicly available on the internet. Beginning in December 2003, the board began posting the Address of Record for board licensees on its website. At that time, it was noted that similar information is provided online by other health profession regulatory boards (physicians, dentists, therapists.) The board noted that because the addresses of record are public record by law, those licensees who wish to withhold their residence address from the public may provide a post office box, a personal mailbox number, place of employment, etc. as the address of record as long as a resident address (which is not available to the public) is also provided.

Chairperson Schaad stated, since that time the board has periodically reminded licensees in newsletters, application forms, etc. that the address of record is posted online, as well as the method by which to change the address of record.

As part of the public discussion, Dr. Steve Gray, representing California Society of Health-System Pharmacists (CSHP), stated that from a safety and protection point of view, it would be best to stop the posting of individual licensee addresses on the board's website. He asked for consideration of a process which better protects the licensees.

DCA Staff Counsel Laura Freedman stated, when a license is granted, the Public Records Act (PRA) and the Information Practice Act say the right to have a license comes with requirements established for consumer protection. By providing an address, a consumer who is trying to determine whether an individual is a qualified practitioner can go to that regulatory agency and determine whether the individual has the skills and license. The benefit of providing an address is if the licensee has a common name, it helps the consumer narrow down which licensee they are researching by knowing their location of practice.

Chairperson Schaad shared his concern, unlike most licensed professions pharmacists have access to items of value and are vulnerable to theft; by providing their address it may comprise their personal safety. DCA Counsel Freedman responded, other offices, such as the Bureau of Cannabis Control, whose licensees also have access to items of value, are required by statute to provide an address of record.

Ms. Sodergren clarified, it is her understanding that the PRA specifies the address of record of a licensee is public information. She confirmed that there are programs within DCA that are statutorily mandated to post. She stated she does not believe that Board of Pharmacy is included in that list of those mandated.

Ms. Sodergren informed the committee, it would require statutory change to the Government Code to make the address of record private. She added, the administration historically has been in support of putting the address of record on the website, therefore, in 2003 the board started to post addresses of record on the board website. Ms. Sodergren stated, board staff can look at changing the current practice and discuss with the administration to see whether it is appropriate. She informed the committee, boards comply with this law differently, compliance may be based on the functions of the computer systems they have.

Ms. Sodergren stated, the committee should decide from the policy standpoint if the policy to post the address on the website should be changed and then give staff the opportunity to come back to the committee with information as to whether the technology supports the change. If the committee decides to pursue changing the policy, she requested that the committee give staff the opportunity to talk to others that may have an opinion on this subject and determine if there is a balance that can be met.

Ms. Sodergren clarified, even if licensee addresses are removed from the website, by law, addresses are still public information, therefore, the board is still required to release that information, upon request. She also informed the committee, there is a provision in the law that states if there is a protective order issued by the court the board is not required to release information.

Chairperson Schaad recommended to move forward into revising the board policy since the website posting of addresses presents a particular danger to board licensees. Ms. Sodergren stated that she would work with the board chair on the revision.

10. Presentation on Board's Jurisdiction in Enforcement Matters Regarding Pharmacies Operating Under Common Ownership or Management

Chairperson Schaad introduced Supervising Deputy Attorney General Joshua Room who provided a presentation on the board's jurisdiction in enforcement matters regarding pharmacies operating under common ownership or management.

SDAG Room stated that there are many advantages and reasons that each site is licensed and regulated individually; it makes each site responsible for its own conduct. However, he stated, there are many instances of corporate policies, that are not set at a store level that may lead to disciplinary action where remediating that policy at an individual store level may seem either unfair or inadequate. As an example, staffing requirement decisions are not usually made at the store level for chain pharmacies, but rather at the executive or corporate HR level; therefore, when there are staffing violations due to their own staffing policy, each pharmacy within the chain would be cited. As another example, when a corporate system fails to adequately vet their employees in order to determine what their current license status is, should each pharmacy in which that individual subsequently works be cited and subject to discipline or should there be a larger sanction for the whole corporate entity since it was a failure of their human resources department. SDAG Room also provided an example from several years ago, when in response to many store level violations regarding patient consultations, the board was able to work in cooperation with some DA offices to secure larger penalties against the chains. He explained, this is not something that can be relied up on as a consistent enforcement mechanism. SDAG Room stated, these are examples of system-wide policies where individual sites sanctions may not address the issue.

SDAG Room explained, currently, unless the board wants to cite each pharmacy in violation individually, it is difficult to address these types of violations in a large-scale way. There have been instances where the board has written into an individual licensee stipulation that the chain has to make a correction; this is an indirect way of addressing an issue. SDAG Room summarized that this is a deficit in the enforcement model we currently have. It may be inadequate to sanction an individual site for a system-wide problem because it is either unfair on inadequate or may fail to encourage system-wide remediation and the sanction against an individual pharmacy may be inadequate to encourage that chain to take a larger action.

SDAG Room offered possible solutions:

- Issue a master license to the chain or corporate entity that sits above an individual pharmacy licenses. He stated that this solution may be problematic, in that it offers limited options in what sanctions could be taken against such a master license. For instance, if the board wanted to revoke or put the master license on probation it would be less meaningful unless it also has cascading effects on all or some of its sub-licensees.
- Put into law that when some threshold is met when addressing system-wide deficiencies, the owner or operator of that system is made legally accountable for those system-wide deficiencies and legally accountable for system-wide remediation. Similarly, if some form of remediation is ordered against some threshold number of pharmacies in a system-wide pharmacy system then all the pharmacies in that system would be subject to the same requirements and remediation.

SDAG Room explained that the board is experiencing consistent and more frequent issues with system wide deficiencies or with local pharmacies saying they do not have the authority to address system-wide issues identified by inspectors. It appears the board needs some ability to confront the system more directly than by way of its individual licensees.

SDAG Room explained, some ownership structures are very complicated, and most pharmacy entities have multiple layers of ownership. He presented the following challenges for the committee to consider: What level of ownership should be held accountable? If the ownership of the chain is not in CA, what are the jurisdictional issues? Where a potential site or sites is being investigated, what effect on that pending action should a potential sale of the pharmacy have? Should the sale of a pharmacy be subject to the existing disciplinary action? Should the licensee be allowed to sell the pharmacy out of a disciplinary action?

SDAG Room recommended that the committee agendize an item to discuss the possible statutory approaches to addressing multi-pharmacy owners. SDAG Room informed the committee that his recommended options would be a master license, where owners and operators are automatically responsible for occurrences in any of their stores, or remediation ordered at any of their stores must be enforced at all their stores.

Ms. Sodergren suggested that this could be a challenge identified during the Sunset Report process. By doing this the board could provide the legislature with an opportunity to look at the issue as well and come up with possible solutions through the Sunset Report process. Ms. Sodergren suggested that perhaps the committee may also want to look at the fine provisions or the ability to levy larger fines which might provide motivation to make the systemic changes necessary or allow for more control at the store level by PICs. SDAG Room added that is difficult to enforce citation and fines against non-licensed entities.

Chairperson Schaad supported the strategy to include this challenge in the Sunset Report. He stated doing so would allow the board adequate time to work through this issue, while also informing and working with the legislature.

Ms. Sodergren confirmed that that board staff will work on policy background challenges, to frame the discussion, and highlight those challenges as part of the report. Additionally, Chairperson Schaad recommended that staff work with the president and vice president to develop possible solutions to bring back to the full board.

As part to of the public discussion, Dr. Gray of CSHP asked the committee take into consideration the organizational differences of hospitals in the development of the recommendations.

Motion: Board staff will work with the president and vice president on a paper for inclusion in the Sunset Report and the recommended solutions will be developed by the Organizational Development Committee.
M/S: Lippe/Sanchez
Support: 4 Oppose: 0 Abstain: 0

The committee took a lunch break at 12:12 p.m. and returned at 12:36 p.m.

11. Discussion and Consideration of Citations as Non-Disciplinary Actions and Proposal to Amend Business and Professions Code, Section 4314 to include Provisions to that Effect

Chairperson Schaad provided relevant law and background information. He stated Business and Professions Code (BPC) section 4314 established the general statutory authority for the board to issue citations containing fines and orders of abatement for specified violations of law. He informed the committee that the board routinely advises requesting parties that citations issued by the board do not constitute discipline. Rather, a citation is an administrative action taken by the board. Regrettably, there are times when regulators from other jurisdictions may apply a different meaning to the citation.

Chairperson Schaad stated that under the letter of admonishment provisions in BPC section 4315, a provision is included in the statute that explicitly states that a letter of admonishment shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure. No similar provision exists in the board's citation statute.

Chairperson Schaad stated that It may be appropriate for the committee to consider if an amendment to BPC section 4314 is appropriate to establish similar clarification on application of a citation issued by the board.

He informed the committee that the meeting materials included the proposed language and if the committee agrees with the policy proposal, BPC section 4314 could be amended to add the following language:

> (e) The issuance of a citation pursuant to subdivision (a) shall not be construed as a disciplinary action or discipline for purposes of licensure or the reporting of discipline for licensure.

As part of the public discussion, CPhA stated their support of amending BPC section 4314. It was asked if this proposed statutory amendment would change reporting requirements under other boards or agencies within California. Ms. Freedman responded that this amendment would only mandate DCA boards to comply; other boards and agencies outside of DCA would not be subject to the provisions of the statute.

Motion: Recommend sponsoring a statutory change to amend BPC section 4314 as included in the meeting materials to the board.
M/S: Sanchez/Lippe
Support: 4 Oppose: 0 Abstain: 0

12. Discussion and Consideration of Committee's Strategic Goals

Chairperson Schaad stated that in 2016 the board finalized its current strategic plan. He recommended that the committee discuss the status of its strategic goals for the coming fiscal year as well as the remainder of the plan.

Chairperson Schaad reviewed each goal and provided a brief status.

2.1 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 during the March 2019 committee meeting a review of FY 18/19 data reported a significant decrease in the number of pending investigations over 1 year and an improvement in overall investigation times for cases that are closed.

There was no public comment received regarding Strategic Goal 2.1.

2.2 Strengthen patient consultation outcomes for Californians and increase medication safety.
Chairperson Schaad stated that inspectors continue to include in their routine inspections the pharmacy staff's compliance with consultation laws.

The committee directed staff to provide to the committee data reflecting the total number of routine inspections and of those which identified patient consultation as a violation.

There was no public comment received regarding Strategic Goal 2.2.

2.3 Collect data and report to board members about enforcement trends that are presented at case closures, so the board can better educate licensees about board priorities.
Chairperson Schaad stated that multi-year enforcement statistics are provided on an annual basis during the July board meeting. Also, in addition to posting disciplinary information online, the board's newsletter includes summaries of the violations leading to disciplinary action. Presentations are provided regarding the citation and fine program and the common violations resulting in the issuance of citations.

There was no public comment received regarding Strategic Goal 2.3.

2.4 Evaluate industry technology trends to develop future regulatory infrastructures that promote patient safety.
Chairperson Schaad stated that the board convened a technology summit on the use of automated drug delivery systems (ADDS) and evaluated the findings of a pilot project to expanding the use of ADDS. The board secured statutory changes to expand the use of ADDS in Senate Bill 1447 (Hernandez, Chapter 666, Statutes of 2018).

As part of public discussion, it was suggested that the committee takes into consideration whether new technologies protect the privacy of patient information.

2.5 Evaluate the disciplinary process and initiate process improvements for enhanced efficiency and effectiveness.
Chairperson Schaad stated that in coordination with the Office of the Attorney General, the board initiated a process to improve the efficiency of the disciplinary process. The overall goal with the cooperation of the Attorney General's Office is to process all cases through the office of the Attorney General within one year. In July 2019, the committee considered an alternative enforcement model.

There was no public comment received regarding Strategic Goal 2.5.

2.6 Collaborate with stakeholders to identify and expand resources for technicians who experience substance abuse to provide assistance in recovery.
Chairperson Schaad informed the committee that no work has been done on this strategic goal. It was decided that the committee would recommend to the board the removal of this as a strategic goal.

There was no public comment received regarding Strategic Goal 2.6.

2.7 Investigate options on the interoperability with a National Prescription Drug Monitoring Program.
Chairperson Schaad stated that Assembly Bill 1751 (Low, Chapter 478, Statutes of 2018) established the authority for 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. Ms. Sodergren informed the committee that the Department of Justice has already implemented these provisions.

2.8 Develop a process to submit complaints about inspectors anonymously and report back to the board.
Chairperson Schaad stated that the board has developed a brochure to be distributed to licensees at the time of inspection. Included in the brochure is information on filing a comment or complaint with the board's parent agency, the Department of Consumer Affairs. The brochure is currently under review with the DCA's Legal Department.

In response to public discussion, Ms. Sodergren stated that the brochure has been forwarded to the Communication and Public Education Committee for review and approval.

The committee asked staff to collect data on the number of complaints submitted in the next 6 months.

2.9 Assess the collateral consequences of post discipline and research options.
Chairperson Schaad stated that the enforcement committee has initiated a review of the board's Disciplinary Guidelines.

Chairperson Schaad reported that this is on-going, and the review of guidelines will be addressed at future committee meetings.

There was no public comment received regarding Strategic Goal 2.9.

2.10 Evaluation of the board's Citation and Fine program.
Chairperson Schaad stated that the committee has received several presentations on the citation and fine program and will continue to receive annual updates. At the policy direction of the board, staff is availing itself of the Order of Abatement authority at a much higher rate. Further, under the direction of the president and vice president, policy direction on other factors that should be considered has been integrated in at the staff level. Annual review of the program will continue to assess trends and educational opportunities.

There was no public comment received regarding Strategic Goal 2.10

2.11 Review the role and responsibility of the PIC.

Chairperson Schaad stated that Senate Bill 476 (Stone) would have created a task force to study and submit a report to the Legislature on the prevalence of management interference upon the ability of pharmacists-in-charge to do their jobs and any legislative recommendations for improvement. SB 476 was held in Committee and Under Submission on May 16, 2019. No further action has been taken on this strategic goal.

Chairperson Schaad stated that the role of the PIC will be reviewed during discussions about disciplinary guidelines and during the development of language regulating corporate entities.

As part of the public discussion, the board was reminded that SB 476 is a 2-year bill.

Motion: Recommend to the board removal of Strategic Goal 2.6.
M/S: Sanchez/Lippe
Support: 4 Oppose: 0 Abstain: 0

13. Discussion and Consideration of Board's Enforcement Statistics

Chairperson Schaad informed the committee that they have been provided a copy of enforcement statistics reflecting the last full fiscal year.

Ms. Sodergren reported that pending cases are trending down. Additionally, three-year statistics would be provided at the next board meeting.

14. Future Committee Meeting Dates

Chairperson Schaad stated that the next committee meeting date is scheduled for November 5, 2019. As the board meeting dates for next year are finalized, additional dates will be posted on the board's website.

15. Adjournment

The meeting was adjourned at 1:08 p.m.

Attachment 2

CCR 1715.65
Proposed Language

Proposal to Amend §1715.65. Inventory Reconciliation Report of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory and inventory reconciliation ~~functions~~ report to detect and prevent the loss of controlled substances. At minimum these activities must be performed at least every three months for all federal Schedule II controlled substances and on an annual basis for all other schedules.

(b) The pharmacist-in-charge of a pharmacy or consultant pharmacist for a clinic shall review all inventory and inventory reconciliation reports and sign and date the report ~~taken~~,and establish and maintain secure methods to prevent losses of controlled drugs. Written policies and procedures shall be developed for performing the inventory reconciliation reports required by this section.

(c) ~~A pharmacy or clinic shall compile~~ an inventory reconciliation report as referenced in (a) ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ shall require:

(1) A physical count, not an estimate, of all quantities of federal ~~Schedule II~~ controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section;

(2) A review of all acquisitions and dispositions of federal ~~Schedule II~~ controlled substances since the last inventory reconciliation report;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and

(5) Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

(d) A pharmacy or clinic shall report in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy or clinic is unable to identify the cause of the loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances.

(e) The inventory reconciliation report shall be dated and signed by the pharmacist-in-charge or professional director. ~~the i~~Individual(s) performing the inventory count shall sign and date the documentation of the count or the reconciliation report~~, and countersigned by the pharmacist-in-charge or professional director (if a clinic) and be~~ The reconciliation report must be readily retrievable in the pharmacy or clinic for three years and shall identify all individual(s) involved in the preparation of the report. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report as identified in subdivision (c) within 30 days of becoming pharmacist-in-charge.

Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report as required in subdivision (c).
(g) For inpatient hospital pharmacies, a separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. For purposes of this section, a pharmacy satellite location shall include all supplemental drug storage areas within the hospital under the pharmacy's control.
(h) The pharmacist-in-charge of an inpatient hospital pharmacy using an ADDS shall not be required to perform physical counts of the inventory as required in (c) (1) but shall be required to fulfill all other inventory reconciliation reporting requirements. ~~or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that~~:
~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~
~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~
~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~
~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

Attachment 3

CCR Section 1715.6

Draft Amendments

Proposal to amend 16 CCR § 1715.6 as follows:

The owner shall report to the Board within thirty (30) days of discovery of ~~any~~ the loss of the controlled substances, including their amounts and strengths under the following conditions.

(a) For tablets or capsules, any single or aggregate loss of 100 dosage units that occur in a 12-month period.
(b) For injectable medications, any single or aggregate loss of 10 dosage units that occur in a 12-month period.
(c) Any loss, regardless of the amount, attributed to employee theft.
(d) Any other substantial loss as determined by the pharmacist-in-charge.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

Attachment 4
Routine Inspections

A copy of these documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.

Attachment 5
AB 528

Assembly Bill No. 528
CHAPTER 677

Approved by Governor: October 9, 2019
Filed with Secretary of State: October 9, 2019.

SECTION 1.
It is the intent of the Legislature that state laws regarding the operation and use of prescription drug monitoring programs continue to empower health care-oriented technology solutions to the opioid crisis.

SEC. 2.
Section 209 of the Business and Professions Code is amended to read:

209.
The Department of Justice, in conjunction with the Department of Consumer Affairs and the boards and committees identified in subdivision (d) of Section 208, shall do all of the following:

(a) Identify and implement a streamlined application and approval process to provide access to the CURES Prescription Drug Monitoring Program (PDMP) database for licensed health care practitioners eligible to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances and for pharmacists. Every reasonable effort shall be made to implement a streamlined application and approval process that a licensed health care practitioner or pharmacist can complete at the time that ~~he or she is~~ *they are* applying for licensure or renewing ~~his or her~~ *their* license.

(b) Identify necessary procedures to enable licensed health care practitioners and pharmacists with access to the CURES PDMP to delegate their authority to ~~order~~ *access* reports from the CURES PDMP.

(c) Develop a procedure to enable health care practitioners who do not have a federal Drug Enforcement Administration (DEA) number to opt out of applying for access to the CURES PDMP.

SEC. 3.
Section 11164.1 of the Health and Safety Code is amended to read:

11164.1.
(a) (1) Notwithstanding any other ~~provision of~~ law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) All prescriptions for Schedule II, Schedule III, and Schedule IV controlled substances dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) Pharmacies may dispense prescriptions for Schedule III, Schedule IV, and Schedule V controlled substances from out-of-state prescribers pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 4.
Section 11164.1 is added to the Health and Safety Code, to read:

11164.1.
(a) (1) Notwithstanding any other law, a prescription for a controlled substance issued by a prescriber in another state for delivery to a patient in another state may be dispensed by a California pharmacy, if the prescription conforms with the requirements for controlled substance prescriptions in the state in which the controlled substance was prescribed.

(2) A prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance dispensed pursuant to this subdivision shall be reported by the dispensing pharmacy to the Department of Justice in the manner prescribed by subdivision (d) of Section 11165.

(b) A pharmacy may dispense a prescription for a Schedule III, Schedule IV, or Schedule V controlled substance from an out-of-state prescriber pursuant to Section 4005 of the Business and Professions Code and Section 1717 of Title 16 of the California Code of Regulations.

(c) This section shall become operative on January 1, 2021.

SEC. 5.
Section 11165 of the Health and Safety Code is amended to read:

11165.
(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, and Schedule IV controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and ~~Internet~~ *internet* access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, and Schedule IV controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The Department of Justice may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the Department of Justice, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the Department of Justice, for educational, peer review, statistical, or research purposes, if patient information, including any information that may identify the patient, is not compromised. Further, data disclosed to any individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to any third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The Department of Justice shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The Department of Justice shall, no later than July 1, 2020, adopt regulations regarding the access and use of the information within CURES. The Department of Justice shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient’s CURES patient activity report as long as no

additional CURES data are provided and keep a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, *and* respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the Department of Justice as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed, in a format specified by the Department of Justice:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, the federal controlled substance registration number, and the state medical license number of any prescriber using the federal controlled substance registration number of a government-exempt facility, if provided.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th revision (ICD-10) Code, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Date of origin of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The Department of Justice may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. All prescriber and dispenser

invitees shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The Department of Justice shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The Department of Justice may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The Department of Justice may enter into an agreement with any entity operating an interstate data sharing hub, or any agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the Department of Justice pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the Department of Justice for interstate data sharing of prescription drug monitoring program information.

(3) Any agreement entered into by the Department of Justice for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if ~~he or she~~ *the authorized user* is registered and in good standing with that state's prescription drug monitoring program.

(5) The Department of Justice shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

(i) This section shall remain in effect only until January 1, 2021, and as of that date is repealed.

SEC. 6.

Section 11165 is added to the Health and Safety Code, to read:

11165.

(a) To assist health care practitioners in their efforts to ensure appropriate prescribing, ordering, administering, furnishing, and dispensing of controlled substances, law enforcement and regulatory agencies in their efforts to control the diversion and resultant abuse of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances, and for statistical analysis, education, and research, the Department of Justice shall, contingent upon the availability of adequate funds in the CURES Fund, maintain the Controlled Substance Utilization Review and Evaluation System (CURES) for the electronic monitoring of, and internet access to information regarding, the prescribing and dispensing of Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances by all practitioners authorized to prescribe, order, administer, furnish, or dispense these controlled substances.

(b) The department may seek and use grant funds to pay the costs incurred by the operation and maintenance of CURES. The department shall annually report to the Legislature and make available to the public the amount and source of funds it receives for support of CURES.

(c) (1) The operation of CURES shall comply with all applicable federal and state privacy and security laws and regulations.

(2) (A) CURES shall operate under existing provisions of law to safeguard the privacy and confidentiality of patients. Data obtained from CURES shall only be provided to appropriate state, local, and federal public agencies for disciplinary, civil, or criminal purposes and to other agencies or entities, as determined by the department, for the purpose of educating practitioners and others in lieu of disciplinary, civil, or criminal actions. Data may be provided to public or private entities, as approved by the department, for educational, peer review, statistical, or research purposes, if patient information, including information that may identify the patient, is not compromised. Further, data disclosed to an individual or agency as described in this subdivision shall not be disclosed, sold, or transferred to a third party, unless authorized by, or pursuant to, state and federal privacy and security laws and regulations. The department shall establish policies, procedures, and regulations regarding the use, access, evaluation, management, implementation, operation, storage, disclosure, and security of the information within CURES, consistent with this subdivision.

(B) Notwithstanding subparagraph (A), a regulatory board whose licensees do not prescribe, order, administer, furnish, or dispense controlled substances shall not be provided data obtained from CURES.

(3) The department shall, no later than January 1, 2021, adopt regulations regarding the access and use of the information within CURES. The department shall consult with all stakeholders identified by the department during the rulemaking process. The regulations shall, at a minimum, address all of the following in a manner consistent with this chapter:

(A) The process for approving, denying, and disapproving individuals or entities seeking access to information in CURES.

(B) The purposes for which a health care practitioner may access information in CURES.

(C) The conditions under which a warrant, subpoena, or court order is required for a law enforcement agency to obtain information from CURES as part of a criminal investigation.

(D) The process by which information in CURES may be provided for educational, peer review, statistical, or research purposes.

(4) In accordance with federal and state privacy laws and regulations, a health care practitioner may provide a patient with a copy of the patient's CURES patient activity report as long as no additional CURES data are provided and the health care practitioner keeps a copy of the report in the patient's medical record in compliance with subdivision (d) of Section 11165.1.

(d) For each prescription for a Schedule II, Schedule III, Schedule IV, or Schedule V controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following information to the department or contracted prescription data processing vendor as soon as reasonably possible, but not more than one working day after the date a controlled substance is released to the patient or patient's representative, in a format specified by the department:

(1) Full name, address, and, if available, telephone number of the ultimate user or research subject, or contact information as determined by the Secretary of the United States Department of Health and Human Services, and the gender, and date of birth of the ultimate user.

(2) The prescriber's category of licensure, license number, national provider identifier (NPI) number, if applicable, the federal controlled substance registration number, and the state medical license number of a prescriber using the federal controlled substance registration number of a government-exempt facility.

(3) Pharmacy prescription number, license number, NPI number, and federal controlled substance registration number.

(4) National Drug Code (NDC) number of the controlled substance dispensed.

(5) Quantity of the controlled substance dispensed.

(6) The International Statistical Classification of Diseases (ICD) Code contained in the most current ICD revision, or any revision deemed sufficient by the State Board of Pharmacy, if available.

(7) Number of refills ordered.

(8) Whether the drug was dispensed as a refill of a prescription or as a first-time request.

(9) Prescribing date of the prescription.

(10) Date of dispensing of the prescription.

(11) The serial number for the corresponding prescription form, if applicable.

(e) The department may invite stakeholders to assist, advise, and make recommendations on the establishment of rules and regulations necessary to ensure the proper administration and enforcement of the CURES database. A prescriber or dispenser invitee shall be licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, in active practice in California, and a regular user of CURES.

(f) The department shall, prior to upgrading CURES, consult with prescribers licensed by one of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, one or more of the boards or committees identified in subdivision (d) of Section 208 of the Business and Professions Code, and any other stakeholder identified by the department, for the purpose of identifying desirable capabilities and upgrades to the CURES Prescription Drug Monitoring Program (PDMP).

(g) The department may establish a process to educate authorized subscribers of the CURES PDMP on how to access and use the CURES PDMP.

(h) (1) The department may enter into an agreement with an entity operating an interstate data sharing hub, or an agency operating a prescription drug monitoring program in another state, for purposes of interstate data sharing of prescription drug monitoring program information.

(2) Data obtained from CURES may be provided to authorized users of another state's prescription drug monitoring program, as determined by the department pursuant to subdivision (c), if the entity operating the interstate data sharing hub, and the prescription drug monitoring program of that state, as applicable, have entered into an agreement with the department for interstate data sharing of prescription drug monitoring program information.

(3) An agreement entered into by the department for purposes of interstate data sharing of prescription drug monitoring program information shall ensure that all access to data obtained from CURES and the handling of data contained within CURES comply with California law, including regulations, and meet the same patient privacy, audit, and data security standards employed and required for direct access to CURES.

(4) For purposes of interstate data sharing of CURES information pursuant to this subdivision, an authorized user of another state's prescription drug monitoring program shall not be required to register with CURES, if the authorized user is registered and in good standing with that state's prescription drug monitoring program.

(5) The department shall not enter into an agreement pursuant to this subdivision until the department has issued final regulations regarding the access and use of the information within CURES as required by paragraph (3) of subdivision (c).

(i) Notwithstanding subdivision (d), a veterinarian shall report the information required by that subdivision to the department as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed.

(j) If the dispensing pharmacy, clinic, or other dispenser experiences a temporary technological or electrical failure, it shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within its control. The deadline for transmitting prescription information to the department or contracted prescription data processing vendor pursuant to subdivision (d) shall be extended until the failure is corrected. If the dispensing pharmacy, clinic, or other dispenser experiences technological limitations that are not reasonably within its control, or is impacted by a natural or manmade disaster, the deadline for transmitting prescription information to the department or contracted prescription data processing vendor shall be extended until normal operations have resumed.

(k) This section shall become operative on January 1, 2021.

SEC. 7.
Section 11165.1 of the Health and Safety Code is amended to read:

11165.1.
(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 shall, before July 1, 2016, or upon receipt of a federal Drug Enforcement Administration (DEA) registration, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that practitioner the electronic history of controlled substances dispensed to an individual under ~~his or her~~ *the practitioner's* care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, before July 1, 2016, or upon licensure, whichever occurs later, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to that pharmacist the electronic

history of controlled substances dispensed to an individual under ~~his or her~~ *the pharmacist's* care based on data contained in the CURES PDMP.

(B) An application may be denied, or a subscriber may be suspended, for reasons ~~which~~ *that* include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database.

(ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having ~~his or her~~ *their* federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or any other law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat ~~his or her patients, or~~ *a patient, or* to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of any changes to the subscriber account.

(D) Commencing no later than October 1, 2018, an approved health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) Commencing no later than October 1, 2018, an approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system can certify all of the following:

(i) The entity will not use or disclose data received from the CURES database for any purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances pursuant to Section 11150 or a

pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, or Schedule IV controlled substances, the department may initiate the referral of the history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, and 1308.14 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, and any person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from any false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for any resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic

medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(5) “User-initiated basis” means an authorized health care practitioner or pharmacist has taken an action to initiate the query to the CURES database, such as clicking a button, issuing a voice command, or taking some other action that can be attributed to a specific health care practitioner or pharmacist.

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

SEC. 8.
Section 11165.1 is added to the Health and Safety Code, to read:

11165.1.
(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 shall, upon receipt of a federal Drug Enforcement Administration (DEA) registration, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the practitioner or their delegate the electronic history of controlled substances dispensed to an individual under the practitioner’s care based on data contained in the CURES Prescription Drug Monitoring Program (PDMP).

(ii) A pharmacist shall, upon licensure, submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of a patient that is maintained by the department. Upon approval, the department shall release to the pharmacist or their delegate the electronic history of controlled substances dispensed to an individual under the pharmacist’s care based on data contained in the CURES PDMP.

(iii) A licensed physician and surgeon who does not hold a DEA registration may submit an application developed by the department to obtain approval to electronically access information regarding the controlled substance history of the patient that is maintained by the department. Upon approval, the department shall release to the physician and surgeon or their delegate the electronic history of controlled substances dispensed to a patient under their care based on data contained in the CURES PDMP.

(B) The department may deny an application or suspend a subscriber, for reasons that include, but are not limited to, the following:

(i) Materially falsifying an application to access information contained in the CURES database.

(ii) Failing to maintain effective controls for access to the patient activity report.

(iii) Having their federal DEA registration suspended or revoked.

(iv) Violating a law governing controlled substances or another law for which the possession or use of a controlled substance is an element of the crime.

(v) Accessing information for a reason other than to diagnose or treat a patient, or to document compliance with the law.

(C) An authorized subscriber shall notify the department within 30 days of a change to the subscriber account.

(D) An approved health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist pursuant to subdivision (b) of Section 209 of the Business and Professions Code may use the department's online portal or a health information technology system that meets the criteria required in subparagraph (E) to access information in the CURES database pursuant to this section. A subscriber who uses a health information technology system that meets the criteria required in subparagraph (E) to access the CURES database may submit automated queries to the CURES database that are triggered by predetermined criteria.

(E) An approved health care practitioner or pharmacist may submit queries to the CURES database through a health information technology system if the entity that operates the health information technology system certifies all of the following:

(i) The entity will not use or disclose data received from the CURES database for a purpose other than delivering the data to an approved health care practitioner or pharmacist or performing data processing activities that may be necessary to enable the delivery unless authorized by, and pursuant to, state and federal privacy and security laws and regulations.

(ii) The health information technology system will authenticate the identity of an authorized health care practitioner or pharmacist initiating queries to the CURES database and, at the time of the query to the CURES database, the health information technology system submits the following data regarding the query to CURES:

(I) The date of the query.

(II) The time of the query.

(III) The first and last name of the patient queried.

(IV) The date of birth of the patient queried.

(V) The identification of the CURES user for whom the system is making the query.

(iii) The health information technology system meets applicable patient privacy and information security requirements of state and federal law.

(iv) The entity has entered into a memorandum of understanding with the department that solely addresses the technical specifications of the health information technology system to ensure the security of the data in the CURES database and the secure transfer of data from the CURES database. The technical specifications shall be universal for all health information technology systems that establish a method of system integration to retrieve information from the CURES database. The memorandum of understanding shall not govern, or in any way impact or restrict, the use of data received from the CURES database or impose any additional burdens on covered entities in compliance with the regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996 found in Parts 160 and 164 of Title 45 of the Code of Federal Regulations.

(F) No later than October 1, 2018, the department shall develop a programming interface or other method of system integration to allow health information technology systems that meet the requirements in subparagraph (E) to retrieve information in the CURES database on behalf of an authorized health care practitioner or pharmacist.

(G) The department shall not access patient-identifiable information in an entity's health information technology system.

(H) An entity that operates a health information technology system that is requesting to establish an integration with the CURES database shall pay a reasonable fee to cover the cost of establishing and maintaining integration with the CURES database.

(I) The department may prohibit integration or terminate a health information technology system's ability to retrieve information in the CURES database if the health information technology system fails to meet the requirements of subparagraph (E), or the entity operating the health information technology system does not fulfill its obligation under subparagraph (H).

(2) A health care practitioner authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances pursuant to Section 11150 or a pharmacist shall be deemed to have complied with paragraph (1) if the licensed health care practitioner or pharmacist has been approved to access the CURES database through the process developed pursuant to subdivision (a) of Section 209 of the Business and Professions Code.

(b) A request for, or release of, a controlled substance history pursuant to this section shall be made in accordance with guidelines developed by the department.

(c) In order to prevent the inappropriate, improper, or illegal use of Schedule II, Schedule III, Schedule IV, or Schedule V controlled substances, the department may initiate the referral of the

history of controlled substances dispensed to an individual based on data contained in CURES to licensed health care practitioners, pharmacists, or both, providing care or services to the individual.

(d) The history of controlled substances dispensed to an individual based on data contained in CURES that is received by a practitioner or pharmacist from the department pursuant to this section is medical information subject to the provisions of the Confidentiality of Medical Information Act contained in Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code.

(e) Information concerning a patient's controlled substance history provided to a practitioner or pharmacist pursuant to this section shall include prescriptions for controlled substances listed in Sections 1308.12, 1308.13, 1308.14, and 1308.15 of Title 21 of the Code of Federal Regulations.

(f) A health care practitioner, pharmacist, or a person acting on behalf of a health care practitioner or pharmacist, when acting with reasonable care and in good faith, is not subject to civil or administrative liability arising from false, incomplete, inaccurate, or misattributed information submitted to, reported by, or relied upon in the CURES database or for a resulting failure of the CURES database to accurately or timely report that information.

(g) For purposes of this section, the following terms have the following meanings:

(1) "Automated basis" means using predefined criteria to trigger an automated query to the CURES database, which can be attributed to a specific health care practitioner or pharmacist.

(2) "Department" means the Department of Justice.

(3) "Entity" means an organization that operates, or provides or makes available, a health information technology system to a health care practitioner or pharmacist.

(4) "Health information technology system" means an information processing application using hardware and software for the storage, retrieval, sharing of or use of patient data for communication, decisionmaking, coordination of care, or the quality, safety, or efficiency of the practice of medicine or delivery of health care services, including, but not limited to, electronic medical record applications, health information exchange systems, or other interoperable clinical or health care information system.

(h) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

SEC. 9.
Section 11165.4 of the Health and Safety Code is amended to read:

11165.4.

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the CURES database to review a patient's controlled substance history before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the CURES database the first time ~~he or she~~ *the health care practitioner* prescribes, orders, administers, or furnishes a controlled substance to a patient, ~~he or she~~ *the health care practitioner* shall consult the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every four months thereafter if the substance remains part of the treatment of the patient.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in ~~his or her~~ *their* role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall obtain a patient's controlled substance history from the CURES database no earlier than 24 hours, or the previous business day, before ~~he or she~~ *the health care practitioner* prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient while the patient is admitted to any of the following facilities or during an emergency transfer between any of the following facilities for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical procedure and the quantity of the controlled substance does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient currently receiving hospice care, as defined in Section 1339.40.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable five-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason ~~he or she~~ *they* did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or ~~when it~~ cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct any cause of the temporary technological or electrical failure that is reasonably within ~~his or her~~ *the health care practitioner's* control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable five-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) This section is not operative until six months after the Department of Justice certifies that the CURES database is ready for statewide use and that the department has adequate staff, which, at a minimum, shall be consistent with the appropriation authorized in Schedule (6) of Item 0820-001-0001 of the Budget Act of 2016 (Chapter 23 of the Statutes of 2016), user support, and education. The department shall notify the Secretary of State and the office of the Legislative Counsel of the date of that certification.

(f) All applicable state and federal privacy laws govern the duties required by this section.

(g) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(h) This section shall become inoperative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier, and, as of January 1, 2022, is repealed.

SEC. 10.
Section 11165.4 is added to the Health and Safety Code, to read:

11165.4.

(a) (1) (A) (i) A health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance shall consult the patient activity report or information from the patient activity report obtained from the CURES database to review a patient's controlled substance history for the past 12 months before prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient for the first time and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(ii) If a health care practitioner authorized to prescribe, order, administer, or furnish a controlled substance is not required, pursuant to an exemption described in subdivision (c), to consult the patient activity report from the CURES database the first time the health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient, the health care practitioner shall consult the patient activity report from the CURES database to review the patient's controlled substance history before subsequently prescribing a Schedule II, Schedule III, or Schedule IV controlled substance to the patient and at least once every six months thereafter if the prescriber renews the prescription and the substance remains part of the treatment of the patient.

(iii) A health care practitioner who did not directly access the CURES database to perform the required review of the controlled substance use report shall document in the patient's medical record that they reviewed the CURES database generated report within 24 hours of the controlled substance prescription that was provided to them by another authorized user of the CURES database.

(B) For purposes of this paragraph, "first time" means the initial occurrence in which a health care practitioner, in their role as a health care practitioner, intends to prescribe, order, administer, or furnish a Schedule II, Schedule III, or Schedule IV controlled substance to a patient and has not previously prescribed a controlled substance to the patient.

(2) A health care practitioner shall review a patient's controlled substance history that has been obtained from the CURES database no earlier than 24 hours, or the previous business day, before the health care practitioner prescribes, orders, administers, or furnishes a Schedule II, Schedule III, or Schedule IV controlled substance to the patient.

(b) The duty to consult the CURES database, as described in subdivision (a), does not apply to veterinarians or pharmacists.

(c) The duty to consult the CURES database, as described in subdivision (a), does not apply to a health care practitioner in any of the following circumstances:

(1) If a health care practitioner prescribes, orders, or furnishes a controlled substance to be administered to a patient in any of the following facilities or during a transfer between any of the following facilities, or for use while on facility premises:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) Another medical facility, including, but not limited to, an office of a health care practitioner and an imaging center.

(F) A correctional clinic, as described in Section 4187 of the Business and Professions Code, or a correctional pharmacy, as described in Section 4021.5 of the Business and Professions Code.

(2) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance in the emergency department of a general acute care hospital and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use.

(3) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient as part of the patient's treatment for a surgical, radiotherapeutic, therapeutic, or diagnostic procedure and the quantity of the controlled substance does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use, in any of the following facilities:

(A) A licensed clinic, as described in Chapter 1 (commencing with Section 1200) of Division 2.

(B) An outpatient setting, as described in Chapter 1.3 (commencing with Section 1248) of Division 2.

(C) A health facility, as described in Chapter 2 (commencing with Section 1250) of Division 2.

(D) A county medical facility, as described in Chapter 2.5 (commencing with Section 1440) of Division 2.

(E) A place of practice, as defined in Section 1658 of the Business and Professions Code.

(F) Another medical facility where surgical procedures are permitted to take place, including, but not limited to, the office of a health care practitioner.

(4) If a health care practitioner prescribes, orders, administers, or furnishes a controlled substance to a patient who is terminally ill, as defined in subdivision (c) of Section 11159.2.

(5) (A) If all of the following circumstances are satisfied:

(i) It is not reasonably possible for a health care practitioner to access the information in the CURES database in a timely manner.

(ii) Another health care practitioner or designee authorized to access the CURES database is not reasonably available.

(iii) The quantity of controlled substance prescribed, ordered, administered, or furnished does not exceed a nonrefillable seven-day supply of the controlled substance to be used in accordance with the directions for use and no refill of the controlled substance is allowed.

(B) A health care practitioner who does not consult the CURES database under subparagraph (A) shall document the reason they did not consult the database in the patient's medical record.

(6) If the CURES database is not operational, as determined by the department, or cannot be accessed by a health care practitioner because of a temporary technological or electrical failure. A health care practitioner shall, without undue delay, seek to correct the cause of the temporary technological or electrical failure that is reasonably within the health care practitioner's control.

(7) If the CURES database cannot be accessed because of technological limitations that are not reasonably within the control of a health care practitioner.

(8) If consultation of the CURES database would, as determined by the health care practitioner, result in a patient's inability to obtain a prescription in a timely manner and thereby adversely impact the patient's medical condition, provided that the quantity of the controlled substance does not exceed a nonrefillable seven-day supply if the controlled substance were used in accordance with the directions for use.

(d) (1) A health care practitioner who fails to consult the CURES database, as described in subdivision (a), shall be referred to the appropriate state professional licensing board solely for administrative sanctions, as deemed appropriate by that board.

(2) This section does not create a private cause of action against a health care practitioner. This section does not limit a health care practitioner's liability for the negligent failure to diagnose or treat a patient.

(e) All applicable state and federal privacy laws govern the duties required by this section.

(f) The provisions of this section are severable. If any provision of this section or its application is held invalid, that invalidity shall not affect other provisions or applications that can be given effect without the invalid provision or application.

(g) This section shall become operative on July 1, 2021, or upon the date the department promulgates regulations to implement this section and posts those regulations on its internet website, whichever date is earlier.

Attachment 6
AB 690

Assembly Bill No. 690
CHAPTER 679

Approved by Governor: October 9, 2019.
Filed with Secretary of State: October 9, 2019.

SECTION 1.
Section 4062 of the Business and Professions Code is amended to read:
4062.
(a) Notwithstanding Section 4059 or any other law, a pharmacist or a clinic licensed and acting under Section 4180 may, in good faith, furnish a dangerous drug or dangerous device in reasonable quantities without a prescription during a federal, state, or local emergency, to further the health and safety of the public. A record containing the date, name, and address of the person to whom the drug or device is furnished, and the name, strength, and quantity of the drug or device furnished shall be maintained. The pharmacist or clinic shall communicate this information to the patient's attending physician as soon as possible. Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug or dangerous device furnished without prescription pursuant to this section.

(b) During a declared federal, state, or local emergency, the board may waive application of any provisions of this chapter or the regulations adopted pursuant to it if, in the board's opinion, the waiver will aid in the protection of public health or the provision of patient care.

(c) During a declared federal, state, or local emergency, the board shall allow for the employment of a mobile pharmacy or clinic in impacted areas in order to ensure the continuity of patient care, if all of the following conditions are met:

(1) The mobile pharmacy or clinic shares common ownership with at least one currently licensed pharmacy or clinic in good standing.

(2) The mobile pharmacy or clinic retains records of dispensing, as required by subdivision (a).

(3) A licensed pharmacist, or, in the case of a clinic, a professional director, is on the premises and the mobile pharmacy is under the control and management of a pharmacist, or, in the case of a clinic, a professional director, while the drugs are being dispensed.

(4) Reasonable security measures are taken to safeguard the drug supply maintained in the mobile pharmacy or clinic.

(5) The mobile pharmacy or clinic is located within the declared emergency area or affected areas.

(6) The mobile pharmacy or clinic ceases the provision of services within 48 hours following the termination of the declared emergency.

(d) Notwithstanding any other law, the board may elect to continue to waive application of any provision of this chapter for up to 90 days following the termination of the declared emergency if, in the board's opinion, the continued waiver will aid in the protection of the public health or in the provision of patient care.

(e) (1) A pharmacy that is destroyed or severely damaged as a result of a natural disaster or due to events that led to a declared federal, state, or local emergency, may be relocated. The relocation shall not be considered a transfer of ownership or location under Section 4110, if no changes are made to the management and control, or ownership, of the pharmacy and all applicable laws and regulations are followed. Notification of the relocation shall be provided to the board immediately upon identification of the new location.

(2) For purposes of this section, "severely damaged" means damage that renders the premises unsafe or unfit for entry or occupation.

SEC. 2.
Section 4132 of the Business and Professions Code is amended to read:
4132.
(a) In addition to the requirements of Section 4202, a pharmacy technician ~~working at a remote dispensing site pharmacy shall meet the qualifications promulgated by the board. The regulations developed by the board~~ shall *satisfy each of the following requirements before* ~~only apply to pharmacy technicians~~ working at *a* remote dispensing site~~s~~ *pharmacy*.

(1) Possess a pharmacy technician license that is in good standing.

(2) Possess and maintain a certification issued by a board-approved pharmacy technician certification program.

(3) Possess one of the following:

(A) A minimum of an associate degree in pharmacy technology.

(B) A minimum of a bachelor's degree in any subject.

(C) A certificate of completion from a course of training specified by regulations adopted by the board pursuant to Section 4202.

(4) Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

(b) Notwithstanding Section 4115, a registered pharmacy technician may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at a remote dispensing

site pharmacy under the supervision of a pharmacist at a supervising pharmacy using a telepharmacy system.

(c) A pharmacy technician at a remote dispensing site pharmacy shall not do any of the following:

(1) Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law.

(2) Consult with a patient or ~~his or her~~ *their* agent regarding a prescription, either before or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart.

(3) Identify, evaluate, or interpret a prescription.

(4) Interpret the clinical data in a patient medication record system or patient chart.

(5) Consult with any prescriber, nurse, or other health care professional or authorized agent thereof.

(6) Supervise the packaging of drugs and check the packaging procedure and product upon completion.

(7) Perform any function that requires the professional judgment of a licensed pharmacist.

(8) Compound drug preparations.

(d) Notwithstanding Section 4115, a pharmacist at a supervising pharmacy may supervise up to two pharmacy technicians at each remote dispensing site pharmacy. This subdivision shall not be construed to alter a pharmacist's ability to also supervise pharmacy technicians at the supervising pharmacy.

SEC. 3.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

SEC. 4.

This act is an urgency statute necessary for the immediate preservation of the public peace, health, or safety within the meaning of Article IV of the California Constitution and shall go into immediate effect. The facts constituting the necessity are:

In order to address the public health and safety impact that recent declared federal, state, and local emergencies have had on consumers and pharmacies, especially in medically underserved areas of the state where remote dispensing site pharmacies operate, and in order to be prepared for other declared emergencies that may occur during the upcoming wildfire season which may necessitate the relocation of pharmacies, as soon as possible, it is necessary for this act to go into effect immediately.

Attachment 7
AB 973

Assembly Bill No. 973
CHAPTER 184

Approved by Governor: August 30, 2019.
Filed with Secretary of State: August 30, 2019.

SECTION 1.

Section 4126.8 is added to the Business and Professions Code, to read:

4126.8.

The compounding of drug preparations by a pharmacy for furnishing, distribution, or use in this state shall be consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance. The board may adopt regulations to impose additional standards for compounding drug preparations.

SEC. 2.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Attachment 8

AB 1723

Assembly Bill No. 1723

CHAPTER 323

Approved by Governor: September 20, 2019.

Filed with Secretary of State: September 20, 2019.

SECTION 1.

Section 4180 of the Business and Professions Code is amended to read:

4180.

(a) (1) Notwithstanding any provision of this chapter, any of the following clinics may purchase drugs at wholesale for administration or dispensing, under the direction of a physician and surgeon, to patients registered for care at the clinic:

(A) A licensed nonprofit community clinic or free clinic as defined in paragraph (1) of subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic owned or operated by a county as referred to in subdivision (b) of Section 1206 of the Health and Safety Code.

(C) A clinic operated by a federally recognized Indian tribe or tribal organization as referred to in subdivision (c) of Section 1206 of the Health and Safety Code.

(D) A clinic operated by a primary care community or free clinic, operated on separate premises from a licensed clinic, and that is open no more than ~~20~~ *the number of* hours per week as referred to in subdivision (h) of Section 1206 of the Health and Safety Code.

(E) A student health center clinic operated by a public institution of higher education as referred to in subdivision (j) of Section 1206 of the Health and Safety Code.

(F) A nonprofit multispecialty clinic as referred to in subdivision (l) of Section 1206 of the Health and Safety Code.

(2) The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed, and the records shall be available and maintained for a minimum of three years for inspection by all properly authorized personnel.

(b) No clinic shall be entitled to the benefits of this section until it has obtained a license from the board. A separate license shall be required for each clinic location. A clinic shall notify the board of any change in the clinic's address on a form furnished by the board.

(c) The board shall synchronize license renewal dates and aggregate fees for multiple clinics under common nonprofit ownership at the request of the parent organization.

Attachment 9
SB 159

Senate Bill No. 159
CHAPTER 532

Approved by Governor: October 7, 2019.
Filed with Secretary of State: October 7, 2019.

SECTION 1.
Section 4052 of the Business and Professions Code is amended to read:

4052.
(a) Notwithstanding any other law, a pharmacist may:

(1) Furnish a reasonable quantity of compounded drug product to a prescriber for office use by the prescriber.

(2) Transmit a valid prescription to another pharmacist.

(3) Administer drugs and biological products that have been ordered by a prescriber.

(4) Perform procedures or functions in a licensed health care facility as authorized by Section 4052.1.

(5) Perform procedures or functions as part of the care provided by a health care facility, a licensed home health agency, a licensed clinic in which there is a physician oversight, a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, or a physician, as authorized by Section 4052.2.

(6) Perform procedures or functions as authorized by Section 4052.6.

(7) Manufacture, measure, fit to the patient, or sell and repair dangerous devices, or furnish instructions to the patient or the patient's representative concerning the use of those devices.

(8) Provide consultation, training, and education to patients about drug therapy, disease management, and disease prevention.

(9) Provide professional information, including clinical or pharmacological information, advice, or consultation to other health care professionals, and participate in multidisciplinary review of patient progress, including appropriate access to medical records.

(10) Furnish the medications described in subparagraph (A) in accordance with subparagraph (B):

(A) ~~(1)~~ *(i)* Emergency contraception drug therapy and self-administered hormonal contraceptives, as authorized by Section 4052.3.

~~(2)~~ *(ii)* Nicotine replacement products, as authorized by Section 4052.9.

~~(3)~~ *(iii)* Prescription medications not requiring a diagnosis that are recommended by the federal Centers for Disease Control and Prevention for individuals traveling outside of the United States.

(iv) HIV preexposure prophylaxis, as authorized by Section 4052.02.

(v) HIV postexposure prophylaxis, as authorized by Section 4052.03.

(B) The pharmacist shall notify the patient's primary care provider of any drugs or devices furnished to the patient, or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by that primary care provider. If the patient does not have a primary care provider, the pharmacist shall provide the patient with a written record of the drugs or devices furnished and advise the patient to consult a physician of the patient's choice.

(11) Administer immunizations pursuant to a protocol with a prescriber.

(12) Order and interpret tests for the purpose of monitoring and managing the efficacy and toxicity of drug therapies. A pharmacist who orders and interprets tests pursuant to this paragraph shall ensure that the ordering of those tests is done in coordination with the patient's primary care provider or diagnosing prescriber, as appropriate, including promptly transmitting written notification to the patient's diagnosing prescriber or entering the appropriate information in a patient record system shared with the prescriber, when available and as permitted by that prescriber.

(b) A pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy pursuant to this section shall personally register with the federal Drug Enforcement Administration.

(c) This section does not affect the applicable requirements of law relating to either of the following:

(1) Maintaining the confidentiality of medical records.

(2) The licensing of a health care facility.

SEC. 2.
Section 4052.02 is added to the Business and Professions Code, to read:

4052.02.

(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV preexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "preexposure prophylaxis" means a fixed-dose combination of tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), or another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "2017 Preexposure Prophylaxis for the Prevention of HIV Infection in the United States–2017 Update: A Clinical Practice Guideline," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing preexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish at least a 30-day supply, and up to a 60-day supply, of preexposure prophylaxis if all of the following conditions are met:

(1) The patient is HIV negative, as documented by a negative HIV test result obtained within the previous seven days from an HIV antigen/antibody test or antibody-only test or from a rapid, point-of-care fingerstick blood test approved by the federal Food and Drug Administration. If the patient does not provide evidence of a negative HIV test in accordance with this paragraph, the pharmacist shall order an HIV test. If the test results are not transmitted directly to the pharmacist, the pharmacist shall verify the test results to the pharmacist's satisfaction. If the patient tests positive for HIV infection, the pharmacist or person administering the test shall direct the patient to a primary care provider and provide a list of providers and clinics in the region.

(2) The patient does not report any signs or symptoms of acute HIV infection on a self-reported checklist of acute HIV infection signs and symptoms.

(3) The patient does not report taking any contraindicated medications.

(4) The pharmacist provides counseling to the patient on the ongoing use of preexposure prophylaxis, which may include education about side effects, safety during pregnancy and

breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV, renal function, hepatitis B, hepatitis C, sexually transmitted diseases, and pregnancy for individuals of child-bearing capacity. The pharmacist shall notify the patient that the patient must be seen by a primary care provider to receive subsequent prescriptions for preexposure prophylaxis and that a pharmacist may not furnish a 60-day supply of preexposure prophylaxis to a single patient more than once every two years.

(5) The pharmacist documents, to the extent possible, the services provided by the pharmacist in the patient's record in the record system maintained by the pharmacy. The pharmacist shall maintain records of preexposure prophylaxis furnished to each patient.

(6) The pharmacist does not furnish more than a 60-day supply of preexposure prophylaxis to a single patient more than once every two years, unless directed otherwise by a prescriber.

(7) The pharmacist notifies the patient's primary care provider that the pharmacist completed the requirements specified in this subdivision. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding ongoing care for preexposure prophylaxis.

(f) A pharmacist initiating or furnishing preexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 3.
Section 4052.03 is added to the Business and Professions Code, to read:

4052.03.
(a) Notwithstanding any other law, a pharmacist may initiate and furnish HIV postexposure prophylaxis in accordance with this section.

(b) For purposes of this section, "postexposure prophylaxis" means any of the following:

(1) Tenofovir disoproxil fumarate (TDF) (300 mg) with emtricitabine (FTC) (200 mg), taken once daily, in combination with either raltegravir (400 mg), taken twice daily, or dolutegravir (50 mg), taken once daily.

(2) Tenofovir disoproxil fumarate (TDF) (300 mg) and emtricitabine (FTC) (200 mg), taken once daily, in combination with darunavir (800 mg) and ritonavir (100 mg), taken once daily.

(3) Another drug or drug combination determined by the board to meet the same clinical eligibility recommendations provided in CDC guidelines.

(c) For purposes of this section, "CDC guidelines" means the "Updated Guidelines for Antiretroviral Postexposure Prophylaxis After Sexual, Injection Drug Use, or Other Nonoccupational Exposure to HIV–United States, 2016," or any subsequent guidelines, published by the federal Centers for Disease Control and Prevention.

(d) Before furnishing postexposure prophylaxis to a patient, a pharmacist shall complete a training program approved by the board, in consultation with the Medical Board of California, on the use of preexposure prophylaxis and postexposure prophylaxis. The training shall include information about financial assistance programs for preexposure prophylaxis and postexposure prophylaxis, including the HIV prevention program described in Section 120972 of the Health and Safety Code. The board shall consult with the Medical Board of California as well as relevant stakeholders, including, but not limited to, the Office of AIDS, within the State Department of Public Health, on training programs that are appropriate to meet the requirements of this subdivision.

(e) A pharmacist shall furnish a complete course of postexposure prophylaxis if all of the following conditions are met:

(1) The pharmacist screens the patient and determines the exposure occurred within the previous 72 hours and the patient otherwise meets the clinical criteria for postexposure prophylaxis consistent with CDC guidelines.

(2) The pharmacist provides HIV testing that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) or determines the patient is willing to undergo HIV testing consistent with CDC guidelines. If the patient refuses to undergo HIV testing but is otherwise eligible for postexposure prophylaxis under this section, the pharmacist may furnish postexposure prophylaxis.

(3) The pharmacist provides counseling to the patient on the use of postexposure prophylaxis consistent with CDC guidelines, which may include education about side effects, safety during pregnancy and breastfeeding, adherence to recommended dosing, and the importance of timely testing and treatment, as applicable, for HIV and sexually transmitted diseases. The pharmacist shall also inform the patient of the availability of preexposure prophylaxis for persons who are at substantial risk of acquiring HIV.

(4) The pharmacist notifies the patient's primary care provider of the postexposure prophylaxis treatment. If the patient does not have a primary care provider, or refuses consent to notify the patient's primary care provider, the pharmacist shall provide the patient a list of physicians and surgeons, clinics, or other health care service providers to contact regarding followup care for postexposure prophylaxis.

(f) A pharmacist initiating or furnishing postexposure prophylaxis shall not permit the person to whom the drug is furnished to waive the consultation required by the board.

(g) The board, by July 1, 2020, shall adopt emergency regulations to implement this section in accordance with CDC guidelines. The adoption of regulations pursuant to this subdivision shall be deemed to be an emergency and necessary for the immediate preservation of the public peace, health, safety, or general welfare. The board shall consult with the Medical Board of California in developing regulations pursuant to this subdivision.

SEC. 4.
Section 1342.74 is added to the Health and Safety Code, immediately following Section 1342.73, to read:

1342.74.
(a) (1) Notwithstanding Section 1342.71, a health care service plan shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health care service plan to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health care service plan shall not prohibit, or permit a delegated pharmacy benefit manager to prohibit, a pharmacy provider from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) A health care service plan shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

(d) This section does not require a health care service plan to cover preexposure prophylaxis or postexposure prophylaxis by a pharmacist at an out-of-network pharmacy, unless the health care service plan has an out-of-network pharmacy benefit.

SEC. 5.
Section 10123.1933 is added to the Insurance Code, immediately following Section 10123.1932, to read:

10123.1933.

(a) (1) Notwithstanding Section 10123.201, a health insurer shall not subject antiretroviral drugs that are medically necessary for the prevention of AIDS/HIV, including preexposure prophylaxis or postexposure prophylaxis, to prior authorization or step therapy, except as provided in paragraph (2).

(2) If the United States Food and Drug Administration has approved one or more therapeutic equivalents of a drug, device, or product for the prevention of AIDS/HIV, this section does not require a health insurer to cover all of the therapeutically equivalent versions without prior authorization or step therapy, if at least one therapeutically equivalent version is covered without prior authorization or step therapy.

(b) Notwithstanding any other law, a health insurer shall not prohibit, or permit a contracted pharmacy benefit manager to prohibit, a pharmacist from dispensing preexposure prophylaxis or postexposure prophylaxis.

(c) Notwithstanding subdivision (b), a health insurer shall not cover preexposure prophylaxis that has been furnished by a pharmacist, as authorized in Section 4052.02 of the Business and Professions Code, in excess of a 60-day supply to a single patient once every two years, unless the pharmacist has been directed otherwise by a prescriber.

SEC. 6.
Section 14132.968 of the Welfare and Institutions Code is amended to read:

14132.968.
(a) (1) Pharmacist services are a benefit under the Medi-Cal program, subject to approval by the federal Centers for Medicare and Medicaid Services.

(2) The department shall establish a fee schedule for the list of pharmacist services.

(3) The rate of reimbursement for pharmacist services shall be at 85 percent of the fee schedule for physician services under the Medi-Cal program.

(b) (1) The following services are covered pharmacist services that may be provided to a Medi-Cal beneficiary:

(A) Furnishing travel ~~medications~~ *medications,* as authorized in clause (3) of subparagraph (A) of paragraph (10) of subdivision (a) of Section 4052 of the Business and Professions Code.

(B) Furnishing naloxone ~~hydrochloride~~ *hydrochloride,* as authorized in Section 4052.01 of the Business and Professions Code.

(C) Furnishing self-administered hormonal contraception, as authorized in *subdivision (a) of* Section 4052.3 of the Business and Professions Code.

(D) Initiating and administering ~~immunizations~~ *immunizations,* as authorized in Section 4052.8 of the Business and Professions Code.

(E) Providing tobacco cessation counseling and furnishing nicotine replacement ~~therapy~~ *therapy,* as authorized in Section 4052.9 of the Business and Professions Code.

(F) Initiating and furnishing preexposure prophylaxis, as authorized in Section 4052.02 of the Business and Professions Code, limited to no more than a 60-day supply of preexposure prophylaxis to a single patient once every two years.

(G) Initiating and furnishing postexposure prophylaxis, as authorized in Section 4052.03 of the Business and Professions Code.

(2) Covered pharmacist services shall be subject to department protocols and utilization controls.

(c) A pharmacist shall be enrolled as an ordering, referring, and prescribing provider under the Medi-Cal program prior to rendering a pharmacist service that is submitted by a Medi-Cal pharmacy provider for reimbursement pursuant to this section.

(d) (1) The director shall seek any necessary federal approvals to implement this section. This section shall not be implemented until the necessary federal approvals are obtained and shall be implemented only to the extent that federal financial participation is available.

(2) This section ~~does not restrict or prohibit~~ *neither restricts nor prohibits* any services currently provided by pharmacists as authorized by law, including, but not limited to, this chapter, or the Medicaid state plan.

(e) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the department may implement, interpret, or make specific this section, and any applicable federal waivers and state plan amendments, by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions, without taking regulatory action. By July 1, 2021, the department shall adopt regulations in accordance with the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. Commencing July 1, 2017, the department shall provide a status report to the Legislature on a semiannual basis, in compliance with Section 9795 of the Government Code, until regulations have been adopted.

SEC. 7.

No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the

Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

Attachment 10

SB 569

Senate Bill No. 569
CHAPTER 705

Approved by Governor: October 9, 2019.
Filed with Secretary of State: October 9, 2019.

SECTION 1.
Section 11159.3 is added to the Health and Safety Code, to read:

11159.3.
(a) Notwithstanding any other law, during a declared local, state, or federal emergency, if the California State Board of Pharmacy issues a notice that the board is waiving the application of the provisions of, or regulations adopted pursuant to, the Pharmacy Law, as specified in subdivision (b) of Section 4062 of the Business and Professions Code, a pharmacist may fill a prescription for a controlled substance for use by a patient who cannot access medications as a result of the declared local, state, or federal emergency, regardless of whether the prescription form meets the requirements of Section 11162.1, if the prescription meets the following requirements:

(1) Contains the information specified in subdivision (a) of Section 11164.

(2) Indicates that the patient is affected by a declared emergency with the words "11159.3 exemption" or a similar statement.

(3) Is written and dispensed within the first two weeks of the notice issued by the board.

(b) A pharmacist filling a prescription pursuant to this section shall do all of the following:

(1) Exercise appropriate professional judgment, including reviewing the patient's activity report from the CURES Prescription Drug Monitoring Program before dispensing the medication.

(2) If the prescription is for a Schedule II controlled substance, dispense no greater than the amount needed for a seven-day supply.

(3) Require the patient to first demonstrate, to the satisfaction of the pharmacist, their inability to access medications. This demonstration may include, but is not limited to, verification of residency within an evacuation area.

(c) A pharmacist shall not refill a prescription that has been dispensed pursuant to this section.

Attachment 11
SB 655

Senate Bill No. 655
CHAPTER 213

Approved by Governor: August 30, 2019.
Filed with Secretary of State: August 30, 2019.

SECTION 1.
Section 4115.5 of the Business and Professions Code is amended to read:

4115.5.
(a) Notwithstanding any other ~~provision of~~ law, a pharmacy technician trainee may be placed in a pharmacy to complete an externship for the purpose of obtaining practical training required to become licensed as a pharmacy technician.

(b) (1) A pharmacy technician trainee participating in an externship as described in subdivision (a) may perform the duties described in subdivision (a) of Section 4115 only under the direct supervision and control of a pharmacist.

(2) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall be directly responsible for the conduct of the trainee.

(3) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall verify any prescription prepared by the trainee under supervision of the pharmacist by initialing the prescription label before the medication is disbursed to a patient or by engaging in other verification procedures that are specifically approved by board regulations.

(4) A pharmacist may only supervise one pharmacy technician trainee at any given time.

(5) A pharmacist supervising a pharmacy technician trainee participating in an externship as described in subdivision (a) shall certify attendance for the pharmacy technician trainee and certify that the pharmacy technician trainee has met the educational objectives established by a California public postsecondary education institution or the private postsecondary vocational institution in which the trainee is enrolled, as established by the institution.

(c) (1) Except as described in paragraph (2), an externship in which a pharmacy technician trainee is participating as described in subdivision (a) shall be for a period of no *fewer than 120 hours and no* more than ~~120~~ *140* hours.

(2) When an externship in which a pharmacy technician trainee is participating as described in subdivision (a) involves rotation between a community and hospital pharmacy for the purpose of training the student in distinct practice settings, the externship may be for a period of up to ~~320 hours. No more than 120 of the 320 hours may be completed in a community pharmacy setting or in a single department in a hospital pharmacy.~~ *340 hours.*

(d) An externship in which a pharmacy technician trainee may participate as described in subdivision (a) shall be for a period of no more than six consecutive months in a community

pharmacy and for a total of no more than 12 months if the externship involves rotation between a community and hospital pharmacy. The externship shall be completed while the trainee is enrolled in a course of instruction at the institution.

(e) A pharmacy technician trainee participating in an externship as described in subdivision (a) shall wear identification that indicates ~~his or her trainee status.~~ *the pharmacy technician trainee's status as a trainee.*

SEC. 2.
Section 4163 of the Business and Professions Code is amended to read:

4163.
(a) A manufacturer, wholesaler, repackager, or pharmacy ~~may~~ *shall* not furnish a dangerous drug or dangerous device to an unauthorized person.

(b) ~~Dangerous~~ *Except as provided in subdivision (c), dangerous* drugs or dangerous devices shall be acquired from a person authorized by law to possess or furnish dangerous drugs or dangerous devices. If the person acquiring the dangerous drugs or dangerous devices is a wholesaler, the obligation of the wholesaler shall be limited to obtaining confirmation of licensure of those sources from whom it has not previously acquired dangerous drugs or dangerous devices.

(c) Upon approval of the board, a reverse distributor licensed as a wholesaler may acquire a dangerous drug or dangerous device from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drug or dangerous device.

SEC. 3.
Section 4200 of the Business and Professions Code is amended to read:

4200.
(a) The board may license as a pharmacist an applicant who meets all the following requirements:

(1) Is at least 18 years of age.

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

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

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

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

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

(6) Has passed ~~the North American Pharmacist Licensure Examination and the~~ *a version of the* California Practice Standards and Jurisprudence Examination for Pharmacists ~~on or after January 1, 2004.~~ *that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure and the applicant meets either of the following requirements:*

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

(B) Has passed the North American Pharmacist Licensure Examination that, at the time of application for licensure, was based on an occupational analysis that is either current or that was replaced by another occupational analysis no more than one year before the application for licensure.

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

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

SEC. 4.
Section 4211 is added to the Business and Professions Code, to read:

4211.
(a) An applicant for renewal of an advanced practice pharmacist recognition shall maintain a current and active pharmacist license, and shall submit all of the following as part of the renewal:

(1) Application and payment of the renewal fees.

(2) (A) Proof satisfactory to the board that the licensee has completed 10 hours of continuing education pursuant to Section 4233.

(B) The 10 hours shall be in addition to the continuing education requirements necessary for a pharmacist license renewal pursuant to Section 4231.

(C) An advanced practice pharmacist shall retain documentation of completion of continuing education for four years.

(b) Notwithstanding subdivision (a), the board shall not require completion of continuing education for the first renewal cycle of an advanced practice pharmacist recognition.

(c) The board may issue an inactive advanced practice pharmacist recognition under any of the following conditions:

(1) The pharmacist's license becomes inactive.

(2) The advanced practice pharmacist fails to provide documentation of the completion of the required continuing education.

(3) As part of an investigation or audit conducted by the board, the advanced practice pharmacist fails to provide documentation substantiating the completion of continuing education.

(d) The board shall reactivate an inactive advanced practice pharmacist recognition only if the advanced practice pharmacist pays the required renewal fees pursuant to Section 4210, submits satisfactory proof to the board of completion of the continuing education requirements under Section 4233, and meets all renewal requirements in this section.

SEC. 5.
Section 4400 of the Business and Professions Code is amended to read:

4400.
The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a nongovernmental pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary nongovernmental pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a nongovernmental pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a nongovernmental wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for ~~the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information,~~ *processing an application to change information on a premises license record* shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a nongovernmental clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a nongovernmental sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the

application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250). The fee for the annual renewal of the license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

(ab) This section shall become inoperative on July 1, 2021, and, as of January 1, 2022, is repealed.

SEC. 6.

Section 4400 is added to the Business and Professions Code, to read:

4400.

The amount of fees and penalties prescribed by this chapter, except as otherwise provided, is that fixed by the board according to the following schedule:

(a) The fee for a pharmacy license shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The fee for the issuance of a temporary pharmacy permit shall be two hundred fifty dollars ($250) and may be increased to three hundred twenty-five dollars ($325).

(b) The fee for a pharmacy license annual renewal shall be six hundred sixty-five dollars ($665) and may be increased to nine hundred thirty dollars ($930).

(c) The fee for the pharmacist application and examination shall be two hundred sixty dollars ($260) and may be increased to two hundred eighty-five dollars ($285).

(d) The fee for regrading an examination shall be ninety dollars ($90) and may be increased to one hundred fifteen dollars ($115). If an error in grading is found and the applicant passes the examination, the regrading fee shall be refunded.

(e) The fee for a pharmacist license shall be one hundred ninety-five dollars ($195) and may be increased to two hundred fifteen dollars ($215). The fee for a pharmacist biennial renewal shall be three hundred sixty dollars ($360) and may be increased to five hundred five dollars ($505).

(f) The fee for a wholesaler or third-party logistics provider license and annual renewal shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(g) The fee for a hypodermic license shall be one hundred seventy dollars ($170) and may be increased to two hundred forty dollars ($240). The fee for a hypodermic license renewal shall be two hundred dollars ($200) and may be increased to two hundred eighty dollars ($280).

(h) (1) The fee for application, investigation, and issuance of a license as a designated representative pursuant to Section 4053, as a designated representative-3PL pursuant to Section 4053.1, or as a designated representative-reverse distributor pursuant to Section 4053.2 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative, designated representative-3PL, or designated representative-reverse distributor shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(i) (1) The fee for the application, investigation, and issuance of a license as a designated representative for a veterinary food-animal drug retailer pursuant to Section 4053 shall be one hundred fifty dollars ($150) and may be increased to two hundred ten dollars ($210).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be two hundred fifteen dollars ($215) and may be increased to three hundred dollars ($300).

(j) (1) The application fee for a nonresident wholesaler or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(2) For nonresident wholesalers or third-party logistics providers that have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820). The application fee for any additional location after licensure of the first 20 locations shall be three hundred dollars ($300) and may be decreased to no less than two hundred twenty-five dollars ($225). A temporary license fee shall be seven hundred fifteen dollars ($715) and may be decreased to no less than five hundred fifty dollars ($550).

(3) The annual renewal fee for a nonresident wholesaler license or third-party logistics provider license issued pursuant to Section 4161 shall be seven hundred eighty dollars ($780) and may be increased to eight hundred twenty dollars ($820).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars ($40) per course hour.

(l) The fee for an intern pharmacist license shall be one hundred sixty-five dollars ($165) and may be increased to two hundred thirty dollars ($230). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars ($25) and may be increased to thirty dollars ($30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(o) The fee for processing an application to change information on a premises license record shall be one hundred dollars ($100) and may be increased to one hundred thirty dollars ($130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the Pharmacy Board Contingent Fund equal to approximately one year's operating expenditures.

(q) The fee for any applicant for a clinic license shall be five hundred twenty dollars ($520) for each license and may be increased to five hundred seventy dollars ($570). The annual fee for

renewal of the license shall be three hundred twenty-five dollars ($325) for each license and may be increased to three hundred sixty dollars ($360).

(r) The fee for the issuance of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195). The fee for renewal of a pharmacy technician license shall be one hundred forty dollars ($140) and may be increased to one hundred ninety-five dollars ($195).

(s) The fee for a veterinary food-animal drug retailer license shall be four hundred thirty-five dollars ($435) and may be increased to six hundred ten dollars ($610). The annual renewal fee for a veterinary food-animal drug retailer license shall be three hundred thirty dollars ($330) and may be increased to four hundred sixty dollars ($460).

(t) The fee for issuance of a retired license pursuant to Section 4200.5 shall be thirty-five dollars ($35) and may be increased to forty-five dollars ($45).

(u) The fee for issuance of a sterile compounding pharmacy license or a hospital satellite compounding pharmacy shall be one thousand six hundred forty-five dollars ($1,645) and may be increased to two thousand three hundred five dollars ($2,305). The fee for a temporary license shall be five hundred fifty dollars ($550) and may be increased to seven hundred fifteen dollars ($715). The annual renewal fee of the license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to one thousand eight hundred fifty-five dollars ($1,855).

(v) The fee for the issuance of a nonresident sterile compounding pharmacy license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to three thousand three hundred thirty-five dollars ($3,335). The annual renewal of the license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to three thousand one hundred eighty dollars ($3,180). In addition to paying that application fee, the nonresident sterile compounding pharmacy shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4127.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(w) The fee for the issuance of an outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. The fee for the renewal of an outsourcing facility license shall be one thousand three hundred twenty-five dollars ($1,325) and may be increased to up to one thousand eight hundred fifty-five dollars ($1,855) by the board. The fee for a temporary outsourcing facility license shall be seven hundred fifteen dollars ($715).

(x) The fee for the issuance of a nonresident outsourcing facility license shall be two thousand three hundred eighty dollars ($2,380) and may be increased to up to three thousand three

hundred thirty-five dollars ($3,335) by the board. The fee for the renewal of a nonresident outsourcing facility license shall be two thousand two hundred seventy dollars ($2,270) and may be increased to up to three thousand one hundred eighty dollars ($3,180) by the board. In addition to paying that application fee, the nonresident outsourcing facility shall deposit, when submitting the application, a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing the inspection required by Section 4129.2. If the required deposit is not submitted with the application, the application shall be deemed to be incomplete. If the actual cost of the inspection exceeds the amount deposited, the board shall provide to the applicant a written invoice for the remaining amount and shall not take action on the application until the full amount has been paid to the board. If the amount deposited exceeds the amount of actual and necessary costs incurred, the board shall remit the difference to the applicant.

(y) The fee for the issuance of a centralized hospital packaging license shall be eight hundred twenty dollars ($820) and may be increased to one thousand one hundred fifty dollars ($1,150). The annual renewal of the license shall be eight hundred five dollars ($805) and may be increased to one thousand one hundred twenty-five dollars ($1,125).

(z) The fee for the issuance of a license to a correctional clinic pursuant to Article 13.5 (commencing with Section 4187) that is not owned by the state shall be five hundred twenty dollars ($520) and may be increased to five hundred seventy dollars ($570). The annual renewal fee for that correctional clinic license shall be three hundred twenty-five dollars ($325) and may be increased to three hundred sixty dollars ($360).

(aa) Beginning on and after July 1, 2019, the fee for an ADDS license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250). The fee for the annual renewal of the license shall be two hundred dollars ($200) and may be increased to two hundred fifty dollars ($250).

(ab) This section shall become operative on July 1, 2021.

Attachment 12
Enforcement Statistics

A copy of these documents will be made available for public inspection at the meeting and are available upon request. Requests may be emailed to debbie.damoth@dca.ca.gov.