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

Enforcement and Compounding Committee Report

Maria Serpa, Licensee Member, Chair
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Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

The Board will receive a summary of the committee's work at its October 27, 2020 meeting, as well as updates for discussion and action as necessary.

a. Discussion and Consideration of Recently Signed Legislation Impacting the Practice of Pharmacy

1. Assembly Bill 1710 (Woods, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines

   Description: Provides pharmacists with the authority to independently order and administer an FDA authorized or approved COVID-19 vaccine.

   Status: Chaptered September 24, 2020. Provisions take effect January 1, 2021.

   Board Position: Support.

   Comments on Implementation: Pharmacy Law provisions related to immunizations (BPC 4052.8) are well established. As such the expansion of authority for COVID19 vaccinations should be relatively straightforward. Staff recommend development of a subscriber alert focusing on AB 1710 to encourage pharmacists to complete the necessary training in advance of the January 1, 2021 effective date. Such proactive action will ensure additional pharmacists are well positioned to immediately begin vaccinations assuming approved or authorized COVID-19 vaccines are available. As part of this alert, it appears appropriate to also remind pharmacists about the reporting obligations in BPC 4052.8 and the training, CE, notification, immunization registry, and documentation requirements established in CCR 1746.

2. Assembly Bill 2077 (Ting, Chapter 274, Statutes of 2020) Hypodermic Needle and Syringes

   Description: Extends provisions for needle exchange programs

   Status: Chaptered September 29, 2020. Provisions take effect January 1, 2021.

   Board position: Support

   Comments on Implementation: Implementation should be straightforward as the legislation extends existing law. A summary of the measure will be included in the Pharmacy Law webinar for 2021 new laws and in an article included in *the Script.*

3. Assembly Bill 2113 (Low, Chapter 186, Statutes of 2020) Refugees, Asylees, and Immigrants: Licensing

   Description: Requires programs, including the Board, to expedite specified applications for licensure

   Status: Chaptered September 27, 2020. Provisions take effect January 1, 2021.

   Board position: None

   Comments on Implementation: In addition to providing education about the provisions, the application and instructions will need to be updated to provide such individuals with the necessary information to substantiate such status. Further, the Application for Pharmacy Technician Licensure will need to be updated via the regulation process as the application form itself is incorporated by reference in a regulation. In addition, staff will develop a tracking system to monitor implementation, associated workload, and determine if additional staff resources are necessary to mitigate the impact to other applicants. Staff also recommend development of an FAQ that provides applicants with guidance on what information should be provided for expedited processing. As implementation evolves, it may become necessary to promulgate regulations.

4. Assembly Bill 3330 (Calderon, Chapter 359, Statutes of 2020) Department of Consumer Affairs: Boards: Licensees: Regulatory Fees

   Description: Increases the annual CURES fee to $11/year between April 1, 2021 through March 30, 2023. Further, reduces the annual CURES fee to $9/year effective April 1, 2023.

   Status: Chaptered September 30, 2020

   Board position: None, the Board did not consider this measure.

   Comments on Implementation: Staff are working with DCA information technology staff to make necessary programming changes in advance of the April 1, 2021 effective date. In addition to inclusion in the newsletter and Pharmacy Law 2021 webinar, staff will update the renewal information and send out subscriber alert reminders. As failure to pay the higher CURES fee will result in delays in the renewal of a license, additional educational efforts are necessary to mitigate any potential negative impact.

5. Senate Bill 878 (Jones, Chapter 131, Statutes of 2020) Department of Consumer Affairs Licensing: Applications

   Description: Establishes a requirement for various programs, including the Board, to post processing times.

   Status: Chaptered September 24, 2020. Provisions take effect January 1, 2021.

   Board position: None

   Comments on Implementation: As discussed in prior Board meetings, the Board posts, as part of its quarterly Licensing Committee meeting materials, current application processing times. Beginning in January such meeting materials will be updated to also include average processing times for renewals. As this measure impacts all programs within DCA, staff will also reach out to the DCA to determine what implementation efforts will be done at the department level.

6. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)
   Description: Provides a one-year extension of the Board's sunset date
   Status: Chaptered September 29, 2020. Provisions take effect January 1, 2021.
   Board position: Support
   Comments on Implementation: Board staff are in the process of updating an additional year of licensing and enforcement data to provide the Joint Sunset Committee with updated information. In addition, staff will prepare a report detailing the Board's activities focusing on work related to COVID-19.

Attachment 1 includes a copy of each of the chaptered measures.

b. Discussion and Consideration of Compounding Animal Drugs from Bulk Drug Substances, Include Federal Law and the FDA Draft Guidance, #256

Relevant Law

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the compounding of an animal drug from bulk drug substances results in a "new animal drug" that must comply with the FD&C Act's approval, conditional approval, or indexing requirements (sections 512, 571, and 572 of the FD&C Act (21 U.S.C. §§ 360b, 360ccc, 360ccc-1)). Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirement (section 501(a)(2)(B)) of the FD&C Act (21 U.S.C. § 351(a)(2)(B)) and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)). The FDA has historically exercised enforcement discretion with regards to animal drug compounding from bulk substances under circumstances when no other medically appropriate treatment options exist.

Further, information on the FDA website provides the following:

> **Compounding Under AMDUCA**
> 21 CFR 530.13 provides specific conditions under which extralabel use from compounding of approved animal drugs or approved human drugs is permitted. The compounding must be in compliance with all relevant provisions of 21 CFR 530. The extralabel drug use regulation does not permit animal drug compounding from active pharmaceutical ingredients (bulk drugs).

Background

In November 2019, the FDA released for comment guidance for industry (GFI) #256, entitled, "Compounding Animal Drugs from Bulk Drug Substances." The FDA noted that the guidance, if finalized, would advise veterinarians on circumstances under which the FDA does not intend to take action for certain violations of the FD&C Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk substances. The comment period for this draft guidance was extended on two occasions, with the most recent comment period closing October 15, 2020.

Although still in its draft form, the draft guidance provides conditions under which the FDA will exercise enforcement discretion for violations of the FD&C's requirements for approval, directions for use and manufacturing standards, but also notes that the Agency may take action when animal drugs are compounded from bulk drug substances that (1) present particular human or animal safety concerns or (2) do not meet other manufacturing, product, quality, labeling, or packaging requirements of the FD&C Act. The FDA notes that regardless of whether the FDA intends to take action, FDA may refer a case to the appropriate state entity. The Draft Guidance also states that FDA intends "to generally defer to State licensing boards for day-to-day oversight."

The draft guidance includes conditions for compounding pursuant to patient-specific prescriptions for nonfood-producing animals, compounding without patient-specific prescriptions for nonfood-producing animals, and compounding drugs for use as antidotes for food-producing animals.

Earlier this year, the Board received information about compounding by California pharmacies using bulk substances, rather than sourced from FDA approved drugs as required by the FD&C Act. In addition, the Board received information that pharmacies may be compounding from bulk substances, instead of from commercially available products, purportedly to reduce costs.

When identifying this issue as part of an inspection, staff have been providing education on the federal law and draft guidance. In some cases, staff issued an order of correction, requesting the licensee to develop a plan to come into compliance. In such cases the order of correction indicated that the plan of compliance would be reviewed the following year.

More recently, during the July 2020 Board Meeting, CPhA requested that this matter be placed on an agenda. Subsequent to the verbal request, CPhA sent a letter again requesting that this matter be included as an agenda item for the meeting. CPhA indicates that it consulted with legal counsel stating that 21CFR 530.13(a) should not be used as a basis for compounding from bulk substances, however indicated that it was not meant to outlaw or forbid compounding from bulk drug substances as nowhere in the AMDUCA or any other does it state such a prohibition. The letter continues to state that the FDA has current Guidance for Industry (GFI) document in draft form that states conditions for compounding from bulk substances.

As indicated above, the FDA explicitly states on its website - - https://www.fda.gov/animal-veterinary/guidance-regulations/animal-medicinal-drug-use-clarification-act-1994-amduca#compounding, is clear that the extralabel drug use regulation does not permit animal drug compounding from active pharmaceutical ingredients (bulk drugs.)

In addition to information provided on its website, staff requested clarification from the FDA regarding compounding veterinary drug products, including clarification of 21 CFR 530.13(a) and its relationship with Draft Guidance for Industry GFI #256, Compounding Animal Drugs from Bulk Drug Substances. The response includes much of the same information detailed above.

<u>For Committee Discussion</u>

During the meeting members will have the opportunity to discuss the issue, educational efforts undertaken by staff, information about the provisions of Orders of Corrections, the Draft Guidance #256, as well as receive information from counsel on the current legal status of compounding of animal drugs from bulk drug substances.

Should the committee believe additional education is necessary, either a subscriber alert and/or an article in the newsletter may be appropriate. Any educational efforts should note that conditions for compounding for animals is currently in draft form.

Attachment 2 includes a copy of the Draft Guidance, FDA's response, and the letter from CPhA.

c. Discussion and Consideration of the Use of Peptides in Compounding Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Relevant Law

Section 503A of the FD&C Act describes the conditions under which a compounded drug product may qualify for an exemption from sections 501(a)(2)(B), 502(f)(1) and 505 of the FD&C Act. Those conditions include that the drug product is compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility or by a licensed physician pursuant to a valid prescription for an identified individual patient that indicates the compounded drug is necessary for the identified patient. Further, if the drug product is compounded using a bulk drug substance (active pharmaceutical ingredient) the bulk drug substance must: (1) comply with the standards of an applicable United States Pharmacopoeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, be a component of an FDA-approved drug; or (3) if such a monograph does not exist and the drug substance is not a component of an FDA-approved drug, appear on the 503A bulks list. Section 503A(b)(1)(A)(i) of the FD&C Act.

Background

Over the past several months staff has identified a number of pharmacies that are compounding using peptides. Board staff have confirmed with the FDA that many peptides are not eligible for the exemptions provided by section 503A of the FD&C as they do not satisfy the criteria for a bulk substance nor do they meet the conditions described in the "Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act."

Board staff is conducting investigation where appropriate. Further, staff is aware of pharmacies that have been issued 483 observations by the FDA.

d. Discussion and Consideration of Draft Information for Respondents Describing the Administrative Case Process

Background

During the July Board Meeting, members received a presentation on the Administrative Case Process. Following the meeting it was suggested that, to aid respondent in gaining a general understanding of the administrative case process and licensee's rights, respondents may benefit development of Frequently Asked Questions (FAQs).

For Committee Discussion and Consideration

For member consideration, **Attachment 3** includes draft FAQ's and a flowchart that could be used to provide this education.

e. Discussion and Consideration of Proposal to Develop an Alternative Enforcement Model

Relevant Law

BPC Section 4001.1 provides that protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Further, the section states that whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Article 19 (BPC sections 4300 – 4313) and other various provisions of Pharmacy Law and its regulation, defines the provisions for disciplinary proceedings and other enforcement actions, acts that constitute unprofessional conduct and other violations of law, mitigating factors, and other authorizing and notification requirements.

CCR section 1760 requires the Board, when reaching a decision on a disciplinary matter, to consider the Disciplinary Guidelines, which are incorporated by reference into this regulation.

The Administrative Procedure Act (Government Code section 1140, et seq.,) defines the administrative case process developed to ensure due process.

Background

The committee and Board have previously contemplated development of an alternative enforcement model. The goal of the alternative model is to reduce the time and cost associated with resolving a disciplinary matter. The original proposal considered by the committee and Board was based on a model used by the Physical Therapy Board, that provides an option for pre-pleading settlement of an administrative matter where the outcome of the matter is a Public Letter of Reprimand. The language for such authority is provided below:

> **BPC 2660.3.**
> In lieu of filing or prosecuting a formal accusation against a licensee, the board may, upon stipulation or agreement by the licensee, issue a public letter of reprimand after it has conducted an investigation or inspection as provided for in this chapter. The public letter of reprimand may include a requirement for specified training or education, and cost recovery for investigative costs. The board shall notify the licensee of its intention to issue the letter 30 days before the intended issuance date of the letter. The licensee shall indicate in writing at least 15 days prior to the letter's intended issuance date whether he or she agrees to the issuance of the letter. The board, at its option, may extend the time within which the licensee may respond to its notification. If the licensee does not agree to the issuance of the letter, the board shall not issue the letter and may proceed to file the accusation. The board may use a public letter of reprimand only for minor violations, as defined by the board, committed by the licensee. A public letter of reprimand issued pursuant to this section shall be disclosed by the board to an inquiring member of the public and shall be posted on the board's Internet Web site.

Subsequent to the initial drafting, additional elements were added to the proposal to include involvement by two Board members in the settlement process. Most recently, in January, the committee indicated it was interested in exploring oral conferences as part of the process. At that time, counsel advised members of possible concerns and requested time to evaluate the overall proposal as well as the addition of an oral conference as part of the alternative enforcement model.

Prior to beginning its discussion, it is recommended that the committee discuss the overall policy goal, which previously stated was to reduce resolution time and associated costs.

As the committee was advised during its July meeting, the Administrative Procedure Act establishes several safeguards to ensure due process for the respondent prior to being disciplined, including an opportunity to contest the violations through an administrative hearing. These are all rights afforded a licensee and memorialized in the Administrative Case Process Bill of Rights.

For Discussion and Consideration

As the Committee continues it discussion, provided below are various data sets that may assist members.

Overall Investigation Statistics by Outcome

Investigation Outcomes	FY 2017/18	FY 2018/19	FY 2019/20
Subject Education or No Further Action	366	405	404
Letter of Admonishment Issue	256	285	327
Citation Issued	2167	1144	1428
Referred to the Attorney General	350	264	230
Total Substantiated Investigations	3,139	2101	2,389

Overall Disciplinary Cases by Resolution Type

Disciplinary Cases – Resolution Type	FY 2017/18	FY 2018/19	FY 2019/20
Default Decision	112	105	79
Stipulated Settlement	161	165	183
Proposed Decision (Hearing)	44	49	32
Other (withdrawn)	11	31	32
Total	328	255	326

Outcomes of Mail Vote Process (Nonadopted versus adopted)

Mail Vote Outcomes by Resolution Type	FY 2017/18	FY 2018/19	FY 2019/20
Stipulated Settlement Adopted	161	165	183
Stipulated Settlement Non-adopted	3	0	1
Proposed Decision Adopted	42	49	31
Proposed Decision Non-adopted	10	10	2

Provided below is historical information on the number of disciplinary outcomes resulting from accusation matters. Consistent with the provisions of the APA, members vote on each disciplinary outcome.

Disciplinary Outcomes	FY 2017/18	FY 2018/19	FY 2019/20
Revocation	112	140	111
Voluntary Surrender	78	82	82
Suspension	0	0	0
Probation with Suspension	12	8	0
Probation	105	97	99
Probationary License Issued	5	4	10
Other (Public Reproval)	33	42	58

Case Resolution Time Frames

Based a review of data from January 1, 2020 to June 30, 2020, below is the average time for various milestone for each of the specified steps in the administrative case process:

1. Referral to AG's Office to DAG Assignment: **17 days**
2. DAG Assignment to Accusation Received: **142 days**
3. Filing of Accusation to Hearing Date: **318 days**
4. Filing of Accusation to Stipulated Settlement Reached: **381 days**
5. Hearing Date to Proposed Decision Received: **42 days**
6. Settlement or Proposed Decision Received to Mail Vote Completed: **26 days**
7. Aggregate Average from referral to closure**: 518 days**

Attachment 4 includes a copy of the proposal as discussed during the January Meeting as well as a memo from counsel on the proposal.

f. Discussion and Consideration of Proposal of Board's Policy Encouraging Pharmacies to Report to Law Enforcement Acts involving Drug Diversion by an Employee

Background

The Board routinely investigates and takes action against licensees involved with drug diversion in pharmacies. In addition to establishing requirements (e.g., the inventory reconciliation regulations) and developing trainings (including the Prescription Drug Abuse Prevention CE training), the Board has discussed other measures to prevent drug theft by pharmacy employees.

During its January 2020 Board meeting, the Board approved the following policy statement intended to encourage pharmacies to refer drug diversion cases to to local law enforcement agencies for possible prosecution in addition to of drug diversion cases, in addition to the mandatory reporting to the Board.

> *In recognition of the ongoing national opioid crisis and in addition the mandatory reporting obligations to the Board included in BPC 4104, the board encourages pharmacies and pharmacists to contact local law enforcement for guidance on matters involving narcotics diversion by its employees.*

The Board continues to receive a significant number of theft loss reports, however the number of such losses attributed to employee pilferage has been on the decline for several years.

Loss Report Information	FY 2017/18	FY 2018/19	FY 2019/20*
Total Loss Reports Received	8,436	8,966	8,462
Loss Reports – Employee Pilferage	188	141	110
Number of Thefts report to Law Enforcement	2 (0 were employee pilferage)	187 (7 were employee pilferage)	182 (10 were employee pilferage)

*Data provided as of March 15, 2020

Currently when the Board is advised of a drug loss, additional information is sought from the licensee, including information about law enforcement notification. To promote the Board's policy to encourage reporting to law enforcement agencies, the Board's policy statement will be incorporated into such communications moving forward.

g. Discussion and Consideration of Disciplinary Cases and Incorporation of the Ethics Program Requirement

Relevant Law

CCR section 1773.5 provides that, when directed by the Board, a pharmacist or intern pharmacy may be required to complete an ethics course as a condition of probation, reinstatement, or as abatement for a citation and fine. This section further defines the program components to include a minimum of 22 hours, at least 14 of which are contact hours and at least eight additional hours credited for preparation, evaluation and assessment.

Background

As part of its March 2019 meeting, the Committee consider the Board's requirements for an ethics program as established in CCR section 1773.5. At that time, staff were aware of two vendors that provided an ethics course fulfilling the requirements of the regulations. During the meeting, members were provided with a presentation from the Institute of Medical Quality (IMQ) on their ethics program. Members were advised that the course includes a full two-day program as well as follow-up program consisting of a 6-month progress report and 12-month progress report. Public comment during the meeting indicated support for the program.

Earlier this year, IMQ closed their doors; however, PBI Education provides Pharmacy Ethics and Professionalism, a 22-hour course. The cost for the program is $1875. As indicated on its website, the course learning objectives include:

- Define the concept of professionalism as it relates to pharmacists
- Identify unique risk factors that create legal, regulatory, and risk management issues for pharmacists
- Discuss the important statutes and regulations that govern the practice of pharmacy, how and why they were created, and what boards of pharmacy do to enforce them
- Identify how and why pharmacists enter the legal/regulatory system
- Define the concept of unprofessional conduct

- Identify and define violation potentials for ethical issues utilizing the Ethics Formula
- Create a personal Ethics Protection Plan to maintain professional ethics and safeguard against ethics violations
- Demonstrate the use of peer group discussions to solve ethical dilemmas

Provided below is data provided by PBI Education on California licensed pharmacists that completed the course of each of the last four calendar years:

Number of Participants	2017	2018	2019	2020
Disciplinary Matter	48	48	48	27

Despite repeated attempts, staff was unsuccessful in obtaining similar data from IMQ.

For Committee Discussion and Consideration

Recently, the Board received public comment request a future agenda item to discuss what appeared to be a decrease in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course.

Provided below is historical information on the number of disciplinary orders and orders of abatement issued that included completion of the ethics program.

Ethics Course Requirements	FY 2017/18	FY 2018/19	FY 2019/20
Disciplinary Matter	63	35	26
Citation - Mandatory OOA* Ethics Course	0	0	2
Citation – Voluntary OOA* Ethics Course	1	3	12
Total	64	38	40

OOA – Order of Abatement

h. Review and Discussion of Enforcement Statistics

Since July 1, the board received 643 complaints and has closed 635 investigations. The board has issued 48 Letters of Admonishment, 226 Citations and referred 48 cases to the Office of the Attorney General. The board has secured five interim suspension orders. Further, the board has revoked 11 licenses, accepted the disciplinary surrender of 25 licenses, denied one application, and imposed other levels of discipline against 32 licensees and/or applicants.

As of October 1, 2020, the board currently has 1345 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

- 41 cases under review for assignment, averaging 19 days
- 702 cases under investigation, averaging 179 days
- 263 investigations under supervisor review, averaging 67 days
- 170 investigations under second level review, averaging 63 days
- 169 investigations waiting final closure (typically issuance of a citation or letter of

admonishment) averaging 27 days

Attachment 5 includes the quarterly enforcement statistics.

i. <u>Future Committee Meeting Dates</u>

- January 20, 2021
- April 29, 2021
- July 15, 2021
- October 20, 2021

Attachment 1

Assembly Bill No. 1710

CHAPTER 123

An act to amend Section 4052.8 of the Business and Professions Code, relating to pharmacy.

[Approved by Governor September 24, 2020. Filed with Secretary of State September 24, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

AB 1710, Wood. Pharmacy practice: vaccines.

Existing law, the Pharmacy Law, provides for the licensing and regulation of pharmacists by the California State Board of Pharmacy in the Department of Consumer Affairs. A violation of the Pharmacy Law is a crime. Existing law authorizes a pharmacist to independently initiate and administer vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP) in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for Disease Control and Prevention (CDC) for persons 3 years of age or older.

This bill would also authorize a pharmacist to independently initiate and administer any COVID-19 vaccines approved or authorized by the federal Food and Drug Administration (FDA) under the circumstances described above. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

The people of the State of California do enact as follows:

SECTION 1. Section 4052.8 of the Business and Professions Code is amended to read:

4052.8. (a) In addition to the authority provided in paragraph (11) of subdivision (a) of Section 4052, a pharmacist may independently initiate and administer any COVID-19 vaccines approved or authorized by the federal Food and Drug Administration (FDA), or vaccines listed on the routine immunization schedules recommended by the federal Advisory Committee on Immunization Practices (ACIP), in compliance with individual ACIP vaccine recommendations, and published by the federal Centers for

Disease Control and Prevention (CDC) for persons three years of age and older.

(b) In order to initiate and administer an immunization described in subdivision (a), a pharmacist shall do all of the following:

(1) Complete an immunization training program endorsed by the CDC or the Accreditation Council for Pharmacy Education that, at a minimum, includes hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines, and shall maintain that training.

(2) Be certified in basic life support.

(3) Comply with all state and federal recordkeeping and reporting requirements, including providing documentation to the patient's primary care provider and entering information in the appropriate immunization registry designated by the immunization branch of the State Department of Public Health.

(c) A pharmacist administering immunizations pursuant to this section, or paragraph (11) of subdivision (a) of Section 4052, may also initiate and administer epinephrine or diphenhydramine by injection for the treatment of a severe allergic reaction.

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.

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Assembly Bill No. 2077

CHAPTER 274

An act to amend Section 4145.5 of, and to repeal Sections 4142 and 4326 of, the Business and Professions Code, and to amend Section 11364 of, and to repeal Section 121285 of, the Health and Safety Code, relating to healing arts.

[Approved by Governor September 29, 2020. Filed with Secretary of State September 29, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2077, Ting. Hypodermic needles and syringes.

Existing law prohibits, except as specified, the sale of a hypodermic needle or syringe at retail except upon the prescription of a physician, dentist, veterinarian, podiatrist, or naturopathic doctor.

This bill would repeal that provision.

Existing law, until January 1, 2021, authorizes a physician or pharmacist to, without a prescription or permit, furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and authorizes a person 18 years of age or older to, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist, as a public health measure, as specified.

This bill would extend this authority until January 1, 2026, and would make other conforming changes.

Existing law makes it a misdemeanor for a person to obtain a hypodermic needle or hypodermic syringe by a false or fraudulent representation or design or by a forged or fictitious name. Existing law also makes it a misdemeanor for a person who has obtained a hypodermic needle or hypodermic syringe from any person to whom a permit has been issued to use, or permit or cause, directly or indirectly, the hypodermic needle or hypodermic syringe to be used for any purpose other than that for which it was obtained.

This bill would repeal those provisions and make other conforming changes.

Existing law establishes the Disease Prevention Demonstration Project, a collaboration between pharmacies and local and state health officials for the purpose of evaluating the long-term desirability of allowing licensed pharmacists to furnish or sell nonprescription hypodermic needles or hypodermic syringes to prevent the spread of bloodborne pathogens.

This bill would repeal those provisions.

The people of the State of California do enact as follows:

SECTION 1. Section 4142 of the Business and Professions Code is repealed.

SEC. 2. Section 4145.5 of the Business and Professions Code is amended to read:

4145.5. (a) Notwithstanding any other provision of law, a pharmacist or physician may, without a prescription or a permit, furnish hypodermic needles and syringes for human use, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist or physician for human use, if the furnisher has previously been provided a prescription or other proof of a legitimate medical need requiring a hypodermic needle or syringe to administer a medicine or treatment.

(b) Notwithstanding any other provision of law, and until January 1, 2026, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, a physician or pharmacist may, without a prescription or a permit, furnish hypodermic needles and syringes for human use to a person 18 years of age or older, and a person 18 years of age or older may, without a prescription or license, obtain hypodermic needles and syringes solely for personal use from a physician or pharmacist.

(c) Notwithstanding any other provision of law, a pharmacist, veterinarian, or person licensed pursuant to Section 4141 may, without a prescription or license, furnish hypodermic needles and syringes for use on animals, and a person may, without a prescription or license, obtain hypodermic needles and syringes from a pharmacist, veterinarian, or person licensed pursuant to Section 4141 for use on animals.

(d) A pharmacy that furnishes nonprescription hypodermic needles and syringes shall store hypodermic needles and syringes in a manner that ensures that they are available only to authorized personnel, and are not accessible to other persons.

(e) In order to provide for the safe disposal of hypodermic needles and syringes, a pharmacy or hypodermic needle and syringe exchange program that furnishes nonprescription hypodermic needles and syringes shall counsel consumers on safe disposal and provide consumers with one or more of the following disposal options:

(1) It shall establish an onsite, safe, hypodermic needle and syringe collection and disposal program that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(2) It shall furnish, or make available, mail-back sharps containers authorized by the United States Postal Service that meet applicable state and federal requirements for the transport of medical sharps waste, and shall provide tracking forms to verify destruction at a certified disposal facility.

(3) It shall furnish, or make available, a sharps container that meets applicable state and federal standards for collection and disposal of medical sharps waste.

(f) Until January 1, 2026, a pharmacy that furnishes nonprescription syringes shall provide written information or verbal counseling to consumers at the time of furnishing or sale of nonprescription hypodermic needles or syringes on how to do the following:

(1) Access drug treatment.

(2) Access testing and treatment for HIV and hepatitis C.

(3) Safely dispose of sharps waste.

SEC. 3. Section 4326 of the Business and Professions Code is repealed.

SEC. 4. Section 11364 of the Health and Safety Code is amended to read:

11364. (a) It is unlawful to possess an opium pipe or any device, contrivance, instrument, or paraphernalia used for unlawfully injecting or smoking (1) a controlled substance specified in subdivision (b), (c), or (e) or paragraph (1) of subdivision (f) of Section 11054, specified in paragraph (14), (15), or (20) of subdivision (d) of Section 11054, specified in subdivision (b) or (c) of Section 11055, or specified in paragraph (2) of subdivision (d) of Section 11055, or (2) a controlled substance that is a narcotic drug classified in Schedule III, IV, or V.

(b) This section shall not apply to hypodermic needles or syringes that have been containerized for safe disposal in a container that meets state and federal standards for disposal of sharps waste.

(c) Until January 1, 2026, as a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases among persons who use syringes and hypodermic needles, and to prevent subsequent infection of sexual partners, newborn children, or other persons, this section shall not apply to the possession solely for personal use of hypodermic needles or syringes.

SEC. 5. Section 121285 of the Health and Safety Code is repealed.

O

Assembly Bill No. 2113

CHAPTER 186

An act to add Section 135.4 to the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 27, 2020. Filed with Secretary of State September 27, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

AB 2113, Low. Refugees, asylees, and special immigrant visa holders: professional licensing: initial licensure process.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs. Existing law prohibits a board within the department from denying licensure to an applicant based upon their citizenship or immigration status.

This bill, notwithstanding any other law, would require a board within the department to expedite, and authorize it to assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they are a refugee, have been granted asylum, or have a special immigrant visa, as specified. The bill would authorize a board to adopt regulations necessary to administer these provisions.

The people of the State of California do enact as follows:

SECTION 1. Section 135.4 is added to the Business and Professions Code, to read:

135.4. (a) Notwithstanding any other law, a board within the department shall expedite, and may assist, the initial licensure process for an applicant who supplies satisfactory evidence to the board that they have been admitted to the United States as a refugee under Section 1157 of Title 8 of the United States Code, have been granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to Section 1158 of Title 8 of the United States Code, or they have a special immigrant visa (SIV) that has been granted a status under Section 1244 of Public Law 110-181, under Public Law 109-163, or under Section 602(b) of Title VI of Division F of Public Law 111-8.

(b) Nothing in this section shall be construed as changing existing licensure requirements. A person applying for expedited licensure under subdivision (a) shall meet all applicable statutory and regulatory licensure requirements.

(c) A board may adopt regulations necessary to administer this section.

O

Assembly Bill No. 3330

CHAPTER 359

An act to amend Sections 2499.5 and 4970 of, and to amend, repeal, and add Sections 208, 4971, 4984.7, 4989.68, 4996.3, and 4999.120 of, the Business and Professions Code, relating to the Department of Consumer Affairs.

[Approved by Governor September 30, 2020. Filed with Secretary of State September 30, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

AB 3330, Calderon. Department of Consumer Affairs: boards: licensees: regulatory fees.

Existing law establishes the Department of Consumer Affairs, which is comprised of boards that are established for the purpose of licensing and regulating various professions and vocations, including healing arts licensees and generally authorizes a board to charge fees for the reasonable regulatory cost of administering the regulatory program for the profession or vocation. Existing law establishes the Professions and Vocations Fund in the State Treasury, which consists of specified special funds and accounts, some of which are continuously appropriated.

(1) Existing law requires a Controlled Substance Utilization Review and Evaluation System (CURES) fee of $6 to be assessed annually, at the time of license renewal, on specified active licensees to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. Existing law requires these fees to be deposited in the CURES Fund, which is subject to appropriation by the Legislature.

This bill, beginning April 1, 2021, would increase that fee to $11 and subsequently, beginning April 1, 2023, the bill would decrease that fee to $9.

(2) Existing law regulates the practice of podiatric medicine by the Podiatric Medical Board of California and prescribes various fees relating to, among others, an application, licensure, and renewal. All revenue received by the board is required to be deposited into the Podiatric Medical Board Fund, which is available to the board upon appropriation by the Legislature. Existing law, on and after January 1, 2021, decreases the biennial renewal fee from $1,100 to $900.

This bill instead would increase the biennial renewal fee from $1,100 to $1,318 on and after January 1, 2021.

(3) Existing law, the Acupuncture Licensure Act, provides for the licensure and regulation of the practice of acupuncture by the Acupuncture Board. Existing law establishes the Acupuncture Fund to carry out the provisions of the act, upon appropriation by the Legislature. Existing law

requires the board to issue a license to practice acupuncture to a person who, among other things, furnishes satisfactory evidence of completion of an approved educational and training program, as specified, satisfactory completion of a tutorial program in the practice of an acupuncturist that is approved by the board, or in the case of an applicant who has completed education and training outside the United States, documented educational training and clinical experience that meets the specified standards. Existing law requires the fees prescribed for acupuncture tutorial programs to be specified amounts. Existing law requires the board to pay the entire amount of the revenue it receives pursuant to the act to the Treasurer for deposit in the fund.

This bill would decrease the application and registration fee to supervise an acupuncture trainee from $200 to $100, and would authorize the board to increase the fee to not more than $200. The bill would increase the annual renewal fee for approval to supervise an acupuncture trainee from $50 to $200, and would authorize the board to increase the fee to not more than $500. The bill would increase the application fee for an acupuncture trainee from $25 to $1,000, and would authorize the board to increase the fee to not more than $2,500. The bill would increase the renewal fee for an acupuncture trainee from $10 to $500, and would authorize the board to increase the fee to not more than $600. The bill would revise the delinquency fee for a supervisor from 50% of the renewal fee to be 50% of the renewal fee in effect on the date of the renewal of the license, but not less than $25 nor more than $150. The bill would revise the delinquency fee for an acupuncture trainee from 50% of the renewal fee to be $100, and would authorize the board to increase the fee to not more than $200. The bill would make these provisions operative on January 1, 2021.

Existing law requires a licensee, within 30 days of licensure, to register each of the licensee's places of practice or notify the board if the licensee does not have a place of practice. Existing law requires an acupuncturist to post a wall license at their place of practice and, if the acupuncturist has more than one place of practice, to obtain and post a duplicate wall license at each place of practice.

Existing law requires a licensee to apply to the board to obtain a wall license for each place of practice and to renew each wall license biennially. Existing law requires a licensee to carry a pocket license during treatments outside of the licensee's place of practice and to make the pocket license available upon request. Existing law requires a licensee to return a former wall license to the board if the licensee obtains a new wall license for a location. Existing law revises specified fees associated with acupuncture practice, including specifying that an initial license fee shall include one wall license registration if a place of practice is specified in the application, and establishes a wall license renewal fee, a wall license replacement fee, and a pocket license replacement fee. Existing law makes the provisions described in this paragraph operative January 1, 2021.

This bill instead would revise the amounts of the fees that are operative on January 1, 2021, including requiring the application fee to be $250 and

authorizing the board to increase the application fee to not more than $350, requiring the examination and reexamination fees to be $800, requiring the initial license fee and the renewal to be $500 each, except as specified, requiring the endorsement fee to be $100, and requiring the wall license fee, the wall license renewal fee, the wall license replacement fee, and the pocket license replacement fee to be $50 each. The bill would, commencing January 1, 2021, require the application fee for foreign applicants to be $350 and authorizes the board to increase the application fee to not more than $500. The bill, commencing January 1, 2021, would require the approval fee for each provider of continuing education and the biennial renewal fee for each provider to be $500 each, and would authorize the board to increase the fees to not more than $700. The bill, commencing January 1, 2021, would require the fee for continuing education course applications to be assessed to the continuing education provider at a floor of $10 per hour of continuing education requested to offer, and a cap of $20 per hour of continuing education requested to offer, allowing up to a maximum of 50 hours to be approved per course application. The bill would specify that an approved course may be offered for a period of one year from the date of the board course approval.

(4) Existing law provides for the licensure and regulation of marriage and family therapists, licensed educational psychologists, licensed clinical social workers, and licensed professional clinical counselors by the Board of Behavioral Sciences. Existing law requires applicants for licensure and licensees under those acts to pay specified fees for licensure, license renewal, and examinations, and requires licensees who renew their license after allowing it to expire to pay delinquency fees. Existing law requires the board to establish the required fees at or below the maximum amounts specified under the act. Under existing law, the Behavioral Sciences Fund is required to be used for the purposes of carrying out and enforcing those provisions. Under existing law, all moneys in the Behavioral Sciences Fund is required to be expended, upon appropriation of the Legislature, by the board for the respective programs under its jurisdiction, as provided.

This bill would revise and recast the fees described above. The bill would establish new minimum fee amounts, and would authorize the board to adopt regulations to set the fees at a higher amount up to the prescribed maximum. The bill would require the delinquency fee to be 50% of the fee for license renewal. The bill would make these provisions operative on January 1, 2021.

The people of the State of California do enact as follows:

SECTION 1. Section 208 of the Business and Professions Code is amended to read:

208. (a) Beginning April 1, 2014, a Controlled Substance Utilization Review and Evaluation System (CURES) fee of six dollars ($6) shall be assessed annually on each of the licensees specified in subdivision (b) to

pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than six dollars ($6) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Beginning July 1, 2017, licensees issued a license that has been placed in a retired or inactive status pursuant to a statute or regulation are exempt from the CURES fee requirement in subdivision (a). This exemption shall not apply to licensees whose license has been placed in a retired or inactive status if the licensee is at any time authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Wholesalers, third-party logistics providers, nonresident wholesalers, and nonresident third-party logistics providers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(4) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(5) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the Podiatric Medical Board of California to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

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

SEC. 2. Section 208 is added to the Business and Professions Code, to read:

208. (a) Beginning April 1, 2021, a Controlled Substance Utilization Review and Evaluation System (CURES) fee of eleven dollars ($11) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than eleven dollars ($11) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Licensees issued a license that has been placed in a retired or inactive status pursuant to a statute or regulation are exempt from the CURES fee requirement in subdivision (a). This exemption shall not apply to licensees whose license has been placed in a retired or inactive status if the licensee is at any time authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Wholesalers, third-party logistics providers, nonresident wholesalers, and nonresident third-party logistics providers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(4) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(5) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the Podiatric Medical Board of California to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(e) This section shall become operative on April 1, 2021.

(f) This section shall remain in effect only until April 1, 2023, and as of that date is repealed.

SEC. 3. Section 208 is added to the Business and Professions Code, to read:

208. (a) Beginning April 1, 2023, a Controlled Substance Utilization Review and Evaluation System (CURES) fee of nine dollars ($9) shall be assessed annually on each of the licensees specified in subdivision (b) to pay the reasonable costs associated with operating and maintaining CURES for the purpose of regulating those licensees. The fee assessed pursuant to this subdivision shall be billed and collected by the regulating agency of each licensee at the time of the licensee's license renewal. If the reasonable regulatory cost of operating and maintaining CURES is less than nine dollars ($9) per licensee, the Department of Consumer Affairs may, by regulation, reduce the fee established by this section to the reasonable regulatory cost.

(b) (1) Licensees authorized pursuant to Section 11150 of the Health and Safety Code to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances or pharmacists licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2.

(2) Licensees issued a license that has been placed in a retired or inactive status pursuant to a statute or regulation are exempt from the CURES fee requirement in subdivision (a). This exemption shall not apply to licensees whose license has been placed in a retired or inactive status if the licensee is at any time authorized to prescribe, order, administer, furnish, or dispense Schedule II, Schedule III, or Schedule IV controlled substances.

(3) Wholesalers, third-party logistics providers, nonresident wholesalers, and nonresident third-party logistics providers of dangerous drugs licensed pursuant to Article 11 (commencing with Section 4160) of Chapter 9 of Division 2.

(4) Nongovernmental clinics licensed pursuant to Article 13 (commencing with Section 4180) and Article 14 (commencing with Section 4190) of Chapter 9 of Division 2.

(5) Nongovernmental pharmacies licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2.

(c) The funds collected pursuant to subdivision (a) shall be deposited in the CURES Fund, which is hereby created within the State Treasury. Moneys in the CURES Fund shall, upon appropriation by the Legislature, be available to the Department of Consumer Affairs to reimburse the Department of Justice for costs to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(d) The Department of Consumer Affairs shall contract with the Department of Justice on behalf of the Medical Board of California, the Dental Board of California, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Registered Nursing, the Physician Assistant Board, the Osteopathic Medical Board of California, the Naturopathic Medicine Committee of the Osteopathic Medical Board, the State Board of Optometry, and the Podiatric Medical Board of California

to operate and maintain CURES for the purposes of regulating the licensees specified in subdivision (b).

(e) This section shall become operative on April 1, 2023.

SEC. 4. Section 2499.5 of the Business and Professions Code is amended to read:

2499.5. The following fees apply to certificates to practice podiatric medicine. The amount of fees prescribed for doctors of podiatric medicine shall be determined by the board and shall be as described below. Fees collected pursuant to this section shall be fixed by the board in amounts not to exceed the actual costs of providing the service for which the fee is collected.

(a) Each applicant for a certificate to practice podiatric medicine shall pay an application fee of one hundred dollars ($100) at the time the application is filed. If the applicant qualifies for a certificate, they shall pay a fee of one hundred dollars ($100).

(b) Each applicant who qualifies for a certificate, as a condition precedent to its issuance, in addition to other fees required by this section, shall pay an initial license fee. The initial license fee shall be eight hundred dollars ($800). The initial license shall expire the second year after its issuance on the last day of the month of birth of the licensee. The board may reduce the initial license fee by up to 50 percent of the amount of the fee for any applicant who is enrolled in a postgraduate training program approved by the board or who has completed a postgraduate training program approved by the board within six months prior to the payment of the initial license fee.

(c) Before January 1, 2021, the biennial renewal fee shall be one thousand one hundred dollars ($1,100). Any licensee enrolled in an approved residency program shall be required to pay only 50 percent of the biennial renewal fee at the time of their first renewal.

(d) On and after January 1, 2021, the biennial renewal fee shall be one thousand three hundred and eighteen dollars ($1,318). Any licensee enrolled in an approved residency program shall be required to pay only 50 percent of the biennial renewal fee at the time of their first renewal.

(e) The delinquency fee shall be one hundred fifty dollars ($150).

(f) The duplicate wall certificate fee shall be one hundred dollars ($100).

(g) The duplicate renewal receipt fee shall be fifty dollars ($50).

(h) The endorsement fee shall be thirty dollars ($30).

(i) The letter of good standing fee or for loan deferment shall be one hundred dollars ($100).

(j) There shall be a fee of one hundred dollars ($100) for the issuance of a resident's license under Section 2475.

(k) The fee for approval of a continuing education course or program shall be two hundred fifty dollars ($250).

SEC. 5. Section 4970 of the Business and Professions Code, as added by Section 4 of Chapter 308 of the Statutes of 2019, is amended to read:

4970. The amount of fees prescribed for licensed acupuncturists shall be those set forth in this section unless a lower fee is fixed by the board in accordance with Section 4972:

(a) The application fee shall be two hundred fifty dollars ($250) and may be increased to not more than three hundred fifty dollars ($350).

(b) The application fee for foreign applicants shall be three hundred fifty dollars ($350) and may be increased to not more than five hundred dollars ($500).

(c) The examination and reexamination fees shall be eight hundred dollars ($800).

(d) The initial license fee shall be five hundred dollars ($500), except that if the license will expire less than one year after its issuance, then the initial license fee shall be an amount equal to 50 percent of the initial license fee. The initial license fee shall include one wall license registration if a place of practice is specified in the application.

(e) The renewal fee shall be five hundred dollars ($500) and may be increased to not more than seven hundred seventy-five dollars ($775) and, if a lower fee is fixed by the board, shall be an amount sufficient to support the functions of the board in the administration of this chapter. The board shall assess the renewal fee biennially.

(f) The delinquency fee shall be set in accordance with Section 163.5.

(g) The wall license fee shall be fifty dollars ($50).

(h) The wall license renewal fee shall be fifty dollars ($50).

(i) If a pocket license is lost or destroyed, the pocket license replacement fee is fifty dollars ($50).

(j) The endorsement fee is one hundred dollars ($100).

(k) If a wall license is lost or destroyed, the wall license replacement fee is fifty dollars ($50).

(*l*) The approval fee for each provider of continuing education shall be five hundred dollars ($500) and may be increased to not more than seven hundred dollars ($700).

(m) The biennial renewal approval fee for each provider of continuing education shall be five hundred dollars ($500) and may be increased to not more than seven hundred dollars ($700).

(n) (1) Fees for continuing education course applications shall be assessed to the continuing education provider at a floor of ten dollars ($10) per hour of continuing education requested to offer, and a cap of twenty dollars ($20) per hour of continuing education requested to offer, allowing up to a maximum of 50 hours to be approved per course application.

(2) Fees for course hours shall be prorated in one-half hour increments.

(3) An approved course may be offered for a period of one year from the date of board course approval.

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

SEC. 6. Section 4971 of the Business and Professions Code is amended to read:

4971. (a) The amount of fees prescribed for acupuncture tutorial programs shall be as follows:

(1) The application and registration fee to supervise an acupuncture trainee is two hundred dollars ($200).

(2) The annual renewal fee for approval to supervise an acupuncture trainee is fifty dollars ($50).

(3) The application fee for an acupuncture trainee is twenty-five dollars ($25).

(4) The annual renewal fee for an acupuncture trainee is ten dollars ($10).

(5) The delinquency fee is 50 percent of the renewal fee.

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

SEC. 7. Section 4971 is added to the Business and Professions Code, to read:

4971. (a) The amount of fees prescribed for acupuncture tutorial programs shall be as follows:

(1) The application and registration fee to supervise an acupuncture trainee shall be one hundred dollars ($100) and may be increased to not more than two hundred dollars ($200).

(2) The annual renewal fee for approval to supervise an acupuncture trainee shall be two hundred ($200) and may be increased to not more than five hundred dollars ($500).

(3) The application fee for an acupuncture trainee shall be one thousand dollars ($1,000) and may be increased to not more than two thousand five hundred dollars ($2,500).

(4) The annual renewal fee for an acupuncture trainee shall be five hundred dollars ($500) and may be increased to not more than six hundred dollars ($600).

(5) The delinquency fee for a supervisor shall be set in accordance with Section 163.5.

(6) The delinquency fee for an acupuncture trainee shall be one hundred dollars ($100) and may be increased to not more than two hundred dollars ($200).

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

SEC. 8. Section 4984.7 of the Business and Professions Code is amended to read:

4984.7. (a) The board shall assess the following fees relating to the licensure of marriage and family therapists:

(1) The application fee for an associate registration shall be seventy-five dollars ($75).

(2) The renewal fee for an associate registration shall be seventy-five dollars ($75).

(3) The fee for the application for licensure shall be one hundred dollars ($100).

(4) The fee for the clinical examination shall be one hundred dollars ($100). The fee for the California law and ethics examination shall be one hundred dollars ($100).

(A) An applicant who fails to appear for an examination, after having been scheduled to take the examination, shall forfeit the examination fee.

(B) The amount of the examination fees shall be based on the actual cost to the board of developing, purchasing, and grading each examination and the actual cost to the board of administering each examination. The examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(5) The fee for rescoring an examination shall be twenty dollars ($20).

(6) The fee for the issuance of an initial license shall be a maximum of one hundred eighty dollars ($180).

(7) The fee for license renewal shall be a maximum of one hundred eighty dollars ($180).

(8) The fee for inactive license renewal shall be a maximum of ninety dollars ($90).

(9) The renewal delinquency fee shall be a maximum of ninety dollars ($90). A person who permits their license to expire is subject to the delinquency fee.

(10) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(11) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(12) The fee for issuance of a retired license shall be forty dollars ($40).

(b) With regard to license, examination, and other fees, the board shall establish the fee amounts at or below the maximum amounts specified in this chapter.

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

SEC. 9. Section 4984.7 is added to the Business and Professions Code, to read:

4984.7. (a) The board shall assess the following fees relating to the licensure of marriage and family therapists:

(1) The application fee for an associate registration shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(2) The renewal fee for an associate registration shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(3) The fee for the application for licensure shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(4) (A) (i) The fee for the clinical examination shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(ii) The fee for the California law and ethics examination shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(B) An applicant who fails to appear for an examination, after having been scheduled to take the examination, shall forfeit the examination fee.

(C) The amount of the examination fees shall be based on the actual cost to the board of developing, purchasing, and grading each examination and the actual cost to the board of administering each examination. The examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(5) The fee for rescoring an examination shall be twenty dollars ($20).

(6) The fee for the issuance of an initial license shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(7) The fee for license renewal shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(8) The renewal delinquency fee shall be one-half of the fee for license renewal. A person who permits their license to expire is subject to the delinquency fee.

(9) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(10) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(11) The fee for issuance of a retired license shall be forty dollars ($40).

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

SEC. 10. Section 4989.68 of the Business and Professions Code is amended to read:

4989.68. (a) The board shall assess the following fees relating to the licensure of educational psychologists:

(1) The application fee for examination eligibility shall be one hundred dollars ($100).

(2) The fee for issuance of the initial license shall be a maximum amount of one hundred fifty dollars ($150).

(3) The fee for license renewal shall be a maximum amount of one hundred fifty dollars ($150).

(4) The delinquency fee shall be a maximum amount of seventy-five dollars ($75). A person who permits their license to become delinquent may have it restored only upon payment of all the fees that they would have paid if the license had not become delinquent, plus the payment of any and all delinquency fees.

(5) The written examination fee shall be one hundred dollars ($100). An applicant who fails to appear for an examination, once having been scheduled, shall forfeit any examination fees they paid.

(6) The fee for rescoring a written examination shall be twenty dollars ($20).

(7) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(8) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(9) The fee for issuance of a retired license shall be forty dollars ($40).

(b) With regard to all license, examination, and other fees, the board shall establish fee amounts at or below the maximum amounts specified in this chapter.

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

SEC. 11. Section 4989.68 is added to the Business and Professions Code, to read:

4989.68. (a) The board shall assess the following fees relating to the licensure of educational psychologists:

(1) The application fee for licensure shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(2) The fee for issuance of the initial license shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(3) The fee for license renewal shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(4) The delinquency fee shall be one-half of the fee for license renewal. A person who permits their license to expire shall be subject to the delinquency fee.

(5) The written examination fee shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500). An applicant who fails to appear for an examination, once having been scheduled, shall forfeit any examination fees they paid.

(6) The fee for rescoring a written examination shall be twenty dollars ($20).

(7) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(8) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(9) The fee for issuance of a retired license shall be forty dollars ($40).

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

SEC. 12. Section 4996.3 of the Business and Professions Code is amended to read:

4996.3. (a) The board shall assess the following fees relating to the licensure of clinical social workers:

(1) The application fee for registration as an associate clinical social worker shall be seventy-five dollars ($75).

(2) The fee for renewal of an associate clinical social worker registration shall be seventy-five dollars ($75).

(3) The fee for application for licensure shall be one hundred dollars ($100).

(4) The fee for the board-administered clinical examination, if the board chooses to adopt this examination in regulations, shall be one hundred dollars

($100). The fee for the California law and ethics examination shall be one hundred dollars ($100).

(A) An applicant who fails to appear for an examination, after having been scheduled to take the examination, shall forfeit the examination fees.

(B) The amount of the examination fees shall be based on the actual cost to the board of developing, purchasing, and grading each examination and the actual cost to the board of administering each examination. The written examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(5) The fee for rescoring an examination shall be twenty dollars ($20).

(6) The fee for issuance of an initial license shall be a maximum of one hundred fifty-five dollars ($155).

(7) The fee for license renewal shall be a maximum of one hundred fifty-five dollars ($155).

(8) The fee for inactive license renewal shall be a maximum of seventy-seven dollars and fifty cents ($77.50).

(9) The renewal delinquency fee shall be a maximum of seventy-five dollars ($75). A person who permits their license to expire is subject to the delinquency fee.

(10) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(11) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(12) The fee for issuance of a retired license shall be forty dollars ($40).

(b) With regard to license, examination, and other fees, the board shall establish fee amounts at or below the maximum amounts specified in this chapter.

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

SEC. 13. Section 4996.3 is added to the Business and Professions Code, to read:

4996.3. (a) The board shall assess the following fees relating to the licensure of clinical social workers:

(1) The application fee for registration as an associate clinical social worker shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(2) The fee for renewal of an associate clinical social worker registration shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(3) The fee for application for licensure shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(4) (A) (i) The fee for the board-administered clinical examination, if the board chooses to adopt this examination in regulations, shall be two

hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(ii) The fee for the California law and ethics examination shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(B) An applicant who fails to appear for an examination, after having been scheduled to take the examination, shall forfeit the examination fees.

(C) The amount of the examination fees shall be based on the actual cost to the board of developing, purchasing, and grading each examination and the actual cost to the board of administering each examination. The written examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(5) The fee for rescoring an examination shall be twenty dollars ($20).

(6) The fee for issuance of an initial license shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(7) The fee for license renewal shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(8) The renewal delinquency fee shall be one-half of the fee for license renewal. A person who permits their license to expire shall be subject to the delinquency fee.

(9) The fee for issuance of a replacement registration, license, or certificate shall be twenty dollars ($20).

(10) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

(11) The fee for issuance of a retired license shall be forty dollars ($40).

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

SEC. 14. Section 4999.120 of the Business and Professions Code is amended to read:

4999.120. (a) The board shall assess fees for the application for and the issuance and renewal of licenses and for the registration of associates to cover administrative and operating expenses of the board related to this chapter. Fees assessed pursuant to this section shall not exceed the following:

(1) The fee for the application for licensure shall be up to two hundred fifty dollars ($250).

(2) The fee for the application for associate registration shall be up to one hundred fifty dollars ($150).

(3) The fee for the board-administered clinical examination, if the board chooses to adopt this examination in regulations, shall be up to two hundred fifty dollars ($250).

(4) The fee for the law and ethics examination shall be up to one hundred fifty dollars ($150).

(5) The fee for the issuance of a license shall be up to two hundred fifty dollars ($250).

(6) The fee for annual renewal of an associate registration shall be up to one hundred fifty dollars ($150).

(7) The fee for two-year renewal of licenses shall be up to two hundred fifty dollars ($250).

(8) The fee for issuance of a retired license shall be forty dollars ($40).

(9) The fee for rescoring an examination shall be twenty dollars ($20).

(10) The fee for issuance of a replacement license or registration shall be twenty dollars ($20).

(11) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

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

SEC. 15. Section 4999.120 is added to the Business and Professions Code, to read:

4999.120. (a) The board shall assess the following fees relating to the licensure of professional clinical counselors:

(1) The fee for the application for licensure shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(2) The fee for the application for associate registration shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(3) (A) (i) The fee for the board-administered clinical examination, if the board chooses to adopt this examination in regulations, shall be two hundred fifty dollars ($250). The board may adopt regulations to set the fee at a higher amount, up to a maximum of five hundred dollars ($500).

(ii) The fee for the California law and ethics examination shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(B) An applicant who fails to appear for an examination, after having been scheduled to take the examination, shall forfeit the examination fees.

(C) The amount of the examination fees shall be based on the actual cost to the board of developing, purchasing, and grading each examination and the actual cost to the board of administering each examination. The written examination fees shall be adjusted periodically by regulation to reflect the actual costs incurred by the board.

(4) The fee for the issuance of a license shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(5) The fee for annual renewal of an associate registration shall be one hundred fifty dollars ($150). The board may adopt regulations to set the fee at a higher amount, up to a maximum of three hundred dollars ($300).

(6) The fee for license renewal shall be two hundred dollars ($200). The board may adopt regulations to set the fee at a higher amount, up to a maximum of four hundred dollars ($400).

(7) The renewal delinquency fee shall be one-half of the fee for license renewal. A person who permits their license to expire shall be subject to the delinquency fee.

(8) The fee for issuance of a retired license shall be forty dollars ($40).

(9) The fee for rescoring an examination shall be twenty dollars ($20).

(10) The fee for issuance of a replacement license or registration shall be twenty dollars ($20).

(11) The fee for issuance of a certificate or letter of good standing shall be twenty-five dollars ($25).

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

O

Senate Bill No. 878

CHAPTER 131

An act to add Section 139.5 to the Business and Professions Code, relating to professions and vocations.

[Approved by Governor September 24, 2020. Filed with Secretary of State September 24, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

SB 878, Jones. Department of Consumer Affairs: license: application: processing timeframes.

Existing law provides for the licensure and regulation of various professions and vocations by boards within the Department of Consumer Affairs.

This bill, beginning July 1, 2021, would require each board within the department that issues licenses to prominently display on its internet website, on at least a quarterly basis, either the current average timeframes for processing initial and renewal license applications or the combined current average timeframe for processing both initial and renewal license applications. The bill would also require each board to prominently display on its internet website, on at least a quarterly basis, either the current average timeframes for processing each license type that the board administers or the combined current average timeframe for processing all license types that the board administers.

The people of the State of California do enact as follows:

SECTION 1. Section 139.5 is added to the Business and Professions Code, to read:

139.5. Beginning July 1, 2021, each board, as defined in Section 22, within the department that issues a license shall do both of the following on at least a quarterly basis:

(a) Prominently display on its internet website one of the following:

(1) The current average timeframes for processing initial and renewal license applications.

(2) The combined current average timeframe for processing both initial and renewal license applications.

(b) Prominently display on its internet website one of the following:

(1) The current average timeframes for processing each license type that the board administers.

(2) The combined current average timeframe for processing all license types that the board administers.

O

Senate Bill No. 1474

CHAPTER 312

An act to amend Sections 27, 101, 125.9, 130, 144, 200.1, 205, 494.5, 1000, 1913, 1917, 1917.1, 1922, 2065, 2113, 2135.5, 2460, 2531, 2531.75, 2570.19, 2602, 2607.5, 2841, 2847.1, 2847.3, 2920, 2933, 3504, 3512, 3686, 3710, 3716, 4001, 4003, 4501, 4503, 4604, 4621, 4800, 4804.5, 4990, 4990.04, 5600.4, 5810, 7000, 7000.5, 7000.6, 7011.4, 7011.5, 7011.8, 7015, 7017.3, 7028.7, 7030, 7031, 7058.7, 7071.4, 7080.5, 7085.5, 7099.2, 7123.5, 7135, 7136, 7137, 7137.5, 7138, 7139.1, 7139.2, 7141.5, 7145.5, 7159, 7170, 7303, 7512.3, 7512.14, 7512.15, 7520.3, 7525.1, 7529, 7533.5, 7538, 7538.5, 7539, 8516, 10050, 11301, 16100, and 19164 of, and to add Section 7099.9 to, the Business and Professions Code, to add Section 1670.8.5 to the Civil Code, and to amend Section 94950 of the Education Code, relating to business and professions, and making an appropriation therefor.

[Approved by Governor September 29, 2020. Filed with Secretary of State September 29, 2020.]

LEGISLATIVE COUNSEL'S DIGEST

SB 1474, Committee on Business, Professions and Economic Development. Business and professions.

(1) Existing law, the Contractors' State License Law, provides for the licensure and regulation of contractors by the Contractors' State License Board in the Department of Consumer Affairs. Existing law requires fees and penalties received pursuant to the law to be deposited in the Contractors' License Fund, a continuously appropriated fund, except that certain service fees for the deposit of money in lieu of paying a bond are required to be deposited in the Contractors' Deposit Fund.

This bill would rename the Contractors' State license Law as the Contractors State License Law, would rename the Contractors' State License Board as the Contractors State License Board, and would rename the Contractors' License Fund as the Contractors License Fund. The bill would delete the provision establishing the Contractors' Deposit Fund, and would therefore require those service fees to be deposited in the Contractors License Fund. By authorizing a new source of revenue to be deposited into a continuously appropriated fund, the bill would make an appropriation.

Existing law authorizes a licensee who is subject to a bonding provision under the law, in lieu of giving a bond, to deposit money or a cashier's check with the registrar of contractors.

This bill would prohibit the deposit from being released if the board is notified of a civil action against the deposit and, if the amount of the deposit is insufficient to pay all claims, would require the deposit to be distributed to claimants in proportion to the amount of the claims.

Existing law authorizes the registrar of contractors to grant the retroactive renewal of a license if, within 90 days from the due date, the licensee requests the retroactive renewal in a petition to the registrar, shows that the failure to renew was due to circumstances beyond their control, files an application for renewal on a form prescribed by the registrar, and pays the appropriate renewal and delinquency fees.

This bill, instead, would require the registrar to grant the retroactive renewal of a license if, within 90 days of the expiration of the license, the otherwise eligible licensee submits a completed application for renewal and pays the renewal and delinquency fees. The bill would delete the requirement that the licensee demonstrate that the delay was due to circumstances beyond the licensee's control, and would deem an application for renewal submitted for purposes of these provisions if it is delivered to the board's headquarters or postmarked within 90 days of the expiration of the license.

(2) Existing law establishes the Landscape Architects Technical Committee to assist the California Architects Board in examining candidates for a landscape architect's license. Existing law, on and after January 1, 2021, requires an applicant to furnish to the committee a full set of fingerprints for purposes of conducting criminal history record checks.

This bill would revise the date on which this requirement becomes effective to January 1, 2022.

(3) Existing law, the Chiropractic Act, enacted by an initiative measure, provides for the licensure and regulation of chiropractors in this state by the State Board of Chiropractic Examiners. Existing law requires that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature as if that act were scheduled to be repealed on January 1, 2022.

This bill would require that the powers and duties of the board, as provided, be subject to review by the appropriate policy committees of the Legislature as if that act were scheduled to be repealed on January 1, 2023.

(4) Existing law authorizes the State Board of Chiropractic Examiners and the Osteopathic Medical Board of California and any board within the Department of Consumer Affairs to issue a citation that may contain an order of abatement or an order to pay an administrative fine, and provides that a failure to pay a fine within 30 days of the date of assessment may result in disciplinary action.

This bill would also make a failure to comply with the order of abatement within 30 days of the date of the order subject to disciplinary action.

(5) Existing law provides for the licensure and regulation of registered dental hygienists by the Dental Hygiene Board of California. Existing law authorizes a registered dental hygienist to perform a procedure or provide a service within the scope of their practice under the appropriate level of supervision, as specified.

This bill would also require a registered dental hygienist to have completed the appropriate education and training required to perform the procedure or provide the service.

Existing law requires a person to have satisfactorily completed a specified examination within the preceding 2 years as a condition of licensure as a registered dental hygienist.

This bill would instead require completion of the dental hygiene examination within the preceding 3 years.

Existing law requires a person, as a condition for licensure as a registered dental hygienist in alternative practice, to successfully complete a bachelor's degree or its equivalent from an accredited college or institution of higher education, among other requirements.

This bill would specify that the equivalent of a bachelor's degree is recognized as a minimum of 120 semester credit hours or 180 quarter credit hours in postsecondary education.

(6) Existing law, the Medical Practice Act, provides for the licensure and regulation of physicians and surgeons by the Medical Board of California, and requires an applicant for a physician's and surgeon's license who has completed 36 months of approved postgraduate training in another state or Canada and who is accepted into an approved postgraduate training in another state or Canada and who is accepted into an approved postgraduate training program in California to obtain their physician's and surgeon's license within 90 days after beginning the postgraduate training program.

This bill would delete the requirement that the person be accepted into an approved postgraduate training in another state or Canada.

Existing law authorizes the Medical Board of California, in its discretion, to waive certain examination and certification requirements for licensure for a graduate of a foreign medical school who holds a certificate of registration issued by the board to practice medicine as a full-time faculty member at a medical school.

This bill would also authorize the board to accept clinical practice in an appointment as qualifying time to meet specified postgraduate training requirements for licensure for those registrants.

Existing law authorizes the Medical Board of California, upon and review and recommendation, to determine that an applicant for a physician and surgeon's certificate has satisfied the medical education and examination requirements for an applicant who holds an unlimited and unrestricted license as a physician and surgeon in another state and has held the license continuously for a minimum of 4 years, subject to satisfaction of specified requirements.

This bill would also require the applicant to meet specified postgraduate training requirements.

(7) Existing law, the Architects Practice Act, provides for the licensure and regulation of architects by the California Architects Board. Existing law requires the board to issue a retired license to an architect who meets specified requirements, and also provides for the restoration of a retired license to active status upon satisfaction of specified requirements applicable to licenses that are not renewed within 5 years of its expiration.

This bill would also authorize the restoration of a retired license to active status upon satisfaction of specified requirements applicable to licenses that are renewed within 5 years of its expiration.

(8) Existing law provides for the January 1, 2021, repeal of provisions creating the Podiatric Medical Board of California, the Board of Vocational Nursing and Psychiatric Technicians of the State of California, the Board of Psychology, the Physician Assistant Board, the California State Board of Pharmacy, the Veterinary Medical Board, the Board of Behavioral Sciences, and the State Board of Barbering and Cosmetology.

This bill would extend the operation of those provisions to January 1, 2022, and make conforming changes relating to the appointment of an executive officer, as applicable.

(9) Existing law provides for the January 1, 2022, repeal of provisions regulating naturopathic medicine and interior design and provisions creating the California Board of Occupational Therapy, the Physical Therapy Board of California, the Respiratory Care Board of California, and the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.

This bill would extend the operation of those provisions to January 1, 2023, and make conforming changes relating to the appointment of an executive officer, as applicable.

(10) Existing law, the Massage Therapy Act, until January 1, 2021, provides for the certification and regulation of massage therapists by the California Massage Therapy Council.

This bill would extend the operation of the Massage Therapy Act to January 1, 2022, and make conforming changes relating to massage therapist certification requirements.

(11) Existing law, the Private Investigator Act, provides for the licensure and regulation of private investigators by the Bureau of Security and Investigative Services. Existing law, until January 1, 2021, authorizes the bureau to issue a private investigator license to a limited liability company. A violation of the act is a crime.

This bill would extend that date to January 1, 2024. By extending the operation of these provisions, the bill would impose a state-mandated local program.

(12) Existing law, the Real Estate Law, provides for the licensure and regulation of real estate brokers by the Real Estate Commissioner, the chief officer of the Department of Real Estate within the Business, Consumer Services, and Housing Agency. The Real Estate Law subjects the powers and duties of the department, under specified provisions of law, to review by the appropriate policy committees of the Legislature, performed as if those provisions were scheduled to be repealed as of January 1, 2021.

This bill would extend that date to January 1, 2022.

(13) Existing law, the Real Estate Appraisers' Licensing and Certification Law, creates a Bureau of Real Estate Appraisers within the Department of Consumer Affairs to administer and enforce that law. The Real Estate Appraisers' Licensing and Certification Law subjects the powers and duties

of the bureau to review by the appropriate policy committees of the Legislature, performed as if that law were scheduled to be repealed as of January 1, 2021.

This bill would extend that date to January 1, 2022.

(14) Existing law regulates the formation and enforcement of contracts, including what constitutes an unlawful contract. Under existing law, a contract is unlawful if it is contrary to an express provision of law, contrary to the policy of express law, though not expressly prohibited, or otherwise contrary to good morals.

Existing law regulates licensees who are subject to the jurisdiction of a state licensing entity, including the State Bar of California, the Department of Real Estate, the Department of Consumer Affairs, or any other state agency that issues a license, certificate, or registration authorizing a person to engage in a business or profession.

This bill would prohibit a contract or proposed contract for the provision of a consumer service by a licensee regulated by a licensing board from including a provision limiting the consumer's ability to file a complaint with that board or to participate in the board's investigation into the licensee. The bill would specify that a waiver of these provisions is contrary to public policy and is void and unenforceable. The bill would provide that a violation of these provisions by a licensee constitutes unprofessional conduct subject to discipline by the licensee's regulatory board.

(15) Existing law, the California Private Postsecondary Education Act of 2009, until January 1, 2021, provides, among other things, for student protections and regulatory oversight of private postsecondary institutions in the state, enforced by the Bureau for Private Postsecondary Education within the Department of Consumer Affairs.

This bill would extend the operation of the California Private Postsecondary Education Act of 2009 to January 1, 2022.

(16) This bill would make other conforming, technical, and nonsubstantive changes.

(17) This bill would incorporate additional changes to Section 205 of the Business and Professions Code proposed by AB 896 to be operative only if this bill and AB 896 are enacted and this bill is enacted last.

(18) This bill would incorporate additional changes to Section 2113 of the Business and Professions Code proposed by AB 2273 to be operative only if this bill and AB 2273 are enacted and this bill is enacted last.

(19) This bill would incorporate additional changes to Section 7159 of the Business and Professions Code proposed by AB 2471 to be operative only if this bill and AB 2471 are enacted and this bill is enacted last.

(20) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Appropriation: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 27 of the Business and Professions Code is amended to read:

27. (a) Each entity specified in subdivisions (c), (d), and (e) shall provide on the internet information regarding the status of every license issued by that entity in accordance with the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code) and the Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code). The public information to be provided on the internet shall include information on suspensions and revocations of licenses issued by the entity and other related enforcement action, including accusations filed pursuant to the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code) taken by the entity relative to persons, businesses, or facilities subject to licensure or regulation by the entity. The information may not include personal information, including home telephone number, date of birth, or social security number. Each entity shall disclose a licensee's address of record. However, each entity shall allow a licensee to provide a post office box number or other alternate address, instead of the licensee's home address, as the address of record. This section shall not preclude an entity from also requiring a licensee, who has provided a post office box number or other alternative mailing address as the licensee's address of record, to provide a physical business address or residence address only for the entity's internal administrative use and not for disclosure as the licensee's address of record or disclosure on the internet.

(b) In providing information on the internet, each entity specified in subdivisions (c) and (d) shall comply with the Department of Consumer Affairs' guidelines for access to public records.

(c) Each of the following entities within the Department of Consumer Affairs shall comply with the requirements of this section:

(1) The Board for Professional Engineers, Land Surveyors, and Geologists shall disclose information on its registrants and licensees.

(2) The Bureau of Automotive Repair shall disclose information on its licensees, including auto repair dealers, smog stations, lamp and brake stations, smog check technicians, and smog inspection certification stations.

(3) The Bureau of Household Goods and Services shall disclose information on its licensees and registrants, including major appliance repair dealers, combination dealers (electronic and appliance), electronic repair dealers, service contract sellers, service contract administrators, and household movers.

(4) The Cemetery and Funeral Bureau shall disclose information on its licensees, including cemetery brokers, cemetery salespersons, cemetery managers, crematory managers, cemetery authorities, crematories, cremated remains disposers, embalmers, funeral establishments, and funeral directors.

(5) The Professional Fiduciaries Bureau shall disclose information on its licensees.

(6) The Contractors State License Board shall disclose information on its licensees and registrants in accordance with Chapter 9 (commencing with Section 7000) of Division 3. In addition to information related to licenses as specified in subdivision (a), the board shall also disclose information provided to the board by the Labor Commissioner pursuant to Section 98.9 of the Labor Code.

(7) The Bureau for Private Postsecondary Education shall disclose information on private postsecondary institutions under its jurisdiction, including disclosure of notices to comply issued pursuant to Section 94935 of the Education Code.

(8) The California Board of Accountancy shall disclose information on its licensees and registrants.

(9) The California Architects Board shall disclose information on its licensees, including architects and landscape architects.

(10) The State Athletic Commission shall disclose information on its licensees and registrants.

(11) The State Board of Barbering and Cosmetology shall disclose information on its licensees.

(12) The Acupuncture Board shall disclose information on its licensees.

(13) The Board of Behavioral Sciences shall disclose information on its licensees and registrants.

(14) The Dental Board of California shall disclose information on its licensees.

(15) The State Board of Optometry shall disclose information on its licensees and registrants.

(16) The Board of Psychology shall disclose information on its licensees, including psychologists, psychological assistants, and registered psychologists.

(17) The Veterinary Medical Board shall disclose information on its licensees, registrants, and permitholders.

(d) The State Board of Chiropractic Examiners shall disclose information on its licensees.

(e) The Structural Pest Control Board shall disclose information on its licensees, including applicators, field representatives, and operators in the areas of fumigation, general pest and wood destroying pests and organisms, and wood roof cleaning and treatment.

(f) The Bureau of Cannabis Control shall disclose information on its licensees.

(g) “Internet” for the purposes of this section has the meaning set forth in paragraph (6) of subdivision (f) of Section 17538.

SEC. 2. Section 101 of the Business and Professions Code is amended to read:

101. The department is comprised of the following:

(a) The Dental Board of California.

(b) The Medical Board of California.

(c) The State Board of Optometry.
(d) The California State Board of Pharmacy.
(e) The Veterinary Medical Board.
(f) The California Board of Accountancy.
(g) The California Architects Board.
(h) The State Board of Barbering and Cosmetology.
(i) The Board for Professional Engineers, Land Surveyors, and Geologists.
(j) The Contractors State License Board.
(k) The Bureau for Private Postsecondary Education.
(*l*) The Bureau of Household Goods and Services.
(m) The Board of Registered Nursing.
(n) The Board of Behavioral Sciences.
(o) The State Athletic Commission.
(p) The Cemetery and Funeral Bureau.
(q) The Bureau of Security and Investigative Services.
(r) The Court Reporters Board of California.
(s) The Board of Vocational Nursing and Psychiatric Technicians.
(t) The Landscape Architects Technical Committee.
(u) The Division of Investigation.
(v) The Bureau of Automotive Repair.
(w) The Respiratory Care Board of California.
(x) The Acupuncture Board.
(y) The Board of Psychology.
(z) The Podiatric Medical Board of California.
(aa) The Physical Therapy Board of California.
(ab) The Arbitration Review Program.
(ac) The Physician Assistant Board.
(ad) The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.
(ae) The California Board of Occupational Therapy.
(af) The Osteopathic Medical Board of California.
(ag) The Naturopathic Medicine Committee.
(ah) The Dental Hygiene Board of California.
(ai) The Professional Fiduciaries Bureau.
(aj) The State Board of Chiropractic Examiners.
(ak) The Bureau of Real Estate Appraisers.
(a*l*) The Structural Pest Control Board.
(am) The Bureau of Cannabis Control.
(an) Any other boards, offices, or officers subject to its jurisdiction by law.
(ao) This section shall become operative on July 1, 2018.

SEC. 3. Section 125.9 of the Business and Professions Code is amended to read:

125.9. (a) Except with respect to persons regulated under Chapter 11 (commencing with Section 7500), any board, bureau, or commission within the department, the State Board of Chiropractic Examiners, and the Osteopathic Medical Board of California, may establish, by regulation, a

system for the issuance to a licensee of a citation which may contain an order of abatement or an order to pay an administrative fine assessed by the board, bureau, or commission where the licensee is in violation of the applicable licensing act or any regulation adopted pursuant thereto.

(b) The system shall contain the following provisions:

(1) Citations shall be in writing and shall describe with particularity the nature of the violation, including specific reference to the provision of law determined to have been violated.

(2) Whenever appropriate, the citation shall contain an order of abatement fixing a reasonable time for abatement of the violation.

(3) In no event shall the administrative fine assessed by the board, bureau, or commission exceed five thousand dollars ($5,000) for each inspection or each investigation made with respect to the violation, or five thousand dollars ($5,000) for each violation or count if the violation involves fraudulent billing submitted to an insurance company, the Medi-Cal program, or Medicare. In assessing a fine, the board, bureau, or commission shall give due consideration to the appropriateness of the amount of the fine with respect to factors such as the gravity of the violation, the good faith of the licensee, and the history of previous violations.

(4) A citation or fine assessment issued pursuant to a citation shall inform the licensee that if the licensee desires a hearing to contest the finding of a violation, that hearing shall be requested by written notice to the board, bureau, or commission within 30 days of the date of issuance of the citation or assessment. If a hearing is not requested pursuant to this section, payment of any fine shall not constitute an admission of the violation charged. Hearings shall be held pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code.

(5) Failure of a licensee to pay a fine or comply with an order of abatement, or both, within 30 days of the date of assessment or order, unless the citation is being appealed, may result in disciplinary action being taken by the board, bureau, or commission. Where a citation is not contested and a fine is not paid, the full amount of the assessed fine shall be added to the fee for renewal of the license. A license shall not be renewed without payment of the renewal fee and fine.

(c) The system may contain the following provisions:

(1) A citation may be issued without the assessment of an administrative fine.

(2) Assessment of administrative fines may be limited to only particular violations of the applicable licensing act.

(d) Notwithstanding any other provision of law, if a fine is paid to satisfy an assessment based on the finding of a violation, payment of the fine and compliance with the order of abatement, if applicable, shall be represented as satisfactory resolution of the matter for purposes of public disclosure.

(e) Administrative fines collected pursuant to this section shall be deposited in the special fund of the particular board, bureau, or commission.

SEC. 4. Section 130 of the Business and Professions Code is amended to read:

130. (a) Notwithstanding any other law, the term of office of any member of an agency designated in subdivision (b) shall be for a term of four years expiring on June 1.

(b) Subdivision (a) applies to the following boards or committees:

(1) The Medical Board of California.

(2) The Podiatric Medical Board of California.

(3) The Physical Therapy Board of California.

(4) The Board of Registered Nursing, except as provided in subdivision (c) of Section 2703.

(5) The Board of Vocational Nursing and Psychiatric Technicians.

(6) The State Board of Optometry.

(7) The California State Board of Pharmacy.

(8) The Veterinary Medical Board.

(9) The California Architects Board.

(10) The Landscape Architect Technical Committee.

(11) The Board for Professional Engineers and Land Surveyors.

(12) The Contractors State License Board.

(13) The Board of Behavioral Sciences.

(14) The Court Reporters Board of California.

(15) The State Athletic Commission.

(16) The Osteopathic Medical Board of California.

(17) The Respiratory Care Board of California.

(18) The Acupuncture Board.

(19) The Board of Psychology.

(20) The Structural Pest Control Board.

SEC. 5. Section 144 of the Business and Professions Code is amended to read:

144. (a) Notwithstanding any other law, an agency designated in subdivision (b) shall require an applicant to furnish to the agency a full set of fingerprints for purposes of conducting criminal history record checks. Any agency designated in subdivision (b) may obtain and receive, at its discretion, criminal history information from the Department of Justice and the United States Federal Bureau of Investigation.

(b) Subdivision (a) applies to the following:

(1) California Board of Accountancy.

(2) State Athletic Commission.

(3) Board of Behavioral Sciences.

(4) Court Reporters Board of California.

(5) Dental Board of California.

(6) California State Board of Pharmacy.

(7) Board of Registered Nursing.

(8) Veterinary Medical Board.

(9) Board of Vocational Nursing and Psychiatric Technicians.

(10) Respiratory Care Board of California.

(11) Physical Therapy Board of California.

(12) Physician Assistant Committee.

(13) Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board.
(14) Medical Board of California.
(15) State Board of Optometry.
(16) Acupuncture Board.
(17) Cemetery and Funeral Bureau.
(18) Bureau of Security and Investigative Services.
(19) Division of Investigation.
(20) Board of Psychology.
(21) California Board of Occupational Therapy.
(22) Structural Pest Control Board.
(23) Contractors State License Board.
(24) Naturopathic Medicine Committee.
(25) Professional Fiduciaries Bureau.
(26) Board for Professional Engineers, Land Surveyors, and Geologists.
(27) Bureau of Cannabis Control.
(28) Podiatric Medical Board of California.
(29) Osteopathic Medical Board of California.
(30) California Architects Board, beginning January 1, 2021.
(31) Landscape Architects Technical Committee, beginning January 1, 2022.

(c) For purposes of paragraph (26) of subdivision (b), the term "applicant" shall be limited to an initial applicant who has never been registered or licensed by the board or to an applicant for a new licensure or registration category.

SEC. 6. Section 200.1 of the Business and Professions Code is amended to read:

200.1. (a) Any accruals that occur on or after September 11, 1993, to any funds or accounts within the Professions and Vocations Fund that realize increased revenues to that fund or account as a result of legislation enacted on or after September 11, 1993, and that have not been transferred pursuant to Sections 13.50, 13.60, and 13.70 of the Budget Act of 1993 on the effective date of the act that enacted this section, shall be exempt from the transfers contained in Sections 13.50, 13.60, and 13.70 of the Budget Act of 1993. These funds shall include, but not be limited to, all of the following:
(1) Athletic Commission Fund.
(2) Bureau of Home Furnishings and Thermal Insulation Fund.
(3) Contractors License Fund.
(4) Private Investigator Fund.
(5) Respiratory Care Fund.
(6) Vocational Nursing and Psychiatric Technicians Fund.

(b) Subdivision (a) shall not apply to the Contingent Fund of the Medical Board of California.

SEC. 7. Section 205 of the Business and Professions Code, as amended by Section 2 of Chapter 865 of the Statutes of 2019, is amended to read:

205. (a) There is in the State Treasury the Professions and Vocations Fund. The fund shall consist of the following special funds:

(1) Accountancy Fund.
(2) California Architects Board Fund.
(3) Athletic Commission Fund.
(4) Barbering and Cosmetology Contingent Fund.
(5) Cemetery and Funeral Fund.
(6) Contractors License Fund.
(7) State Dentistry Fund.
(8) Home Furnishings and Thermal Insulation Fund.
(9) California Architects Board-Landscape Architects Fund.
(10) Contingent Fund of the Medical Board of California.
(11) Optometry Fund.
(12) Pharmacy Board Contingent Fund.
(13) Physical Therapy Fund.
(14) Private Investigator Fund.
(15) Private Security Services Fund.
(16) Professional Engineer's, Land Surveyor's, and Geologist's Fund.
(17) Consumer Affairs Fund.
(18) Behavioral Sciences Fund.
(19) Licensed Midwifery Fund.
(20) Court Reporters' Fund.
(21) Veterinary Medical Board Contingent Fund.
(22) Vocational Nursing and Psychiatric Technicians Fund.
(23) Electronic and Appliance Repair Fund.
(24) Dispensing Opticians Fund.
(25) Acupuncture Fund.
(26) Physician Assistant Fund.
(27) Board of Podiatric Medicine Fund.
(28) Psychology Fund.
(29) Respiratory Care Fund.
(30) Speech-Language Pathology and Audiology and Hearing Aid Dispensers Fund.
(31) Board of Registered Nursing Fund.
(32) Animal Health Technician Examining Committee Fund.
(33) State Dental Hygiene Fund.
(34) State Dental Assistant Fund.
(35) Structural Pest Control Fund.
(36) Structural Pest Control Eradication and Enforcement Fund.
(37) Structural Pest Control Research Fund.
(38) Household Movers Fund.

(b) For accounting and recordkeeping purposes, the Professions and Vocations Fund shall be deemed to be a single special fund, and each of the several special funds therein shall constitute and be deemed to be a separate account in the Professions and Vocations Fund. Each account or fund shall be available for expenditure only for the purposes as are now or may hereafter be provided by law.

(c) This section shall be repealed on July 1, 2022.

SEC. 8. Section 205 of the Business and Professions Code, as added by Section 3 of Chapter 865 of the Statutes of 2019, is amended to read:

205. (a) There is in the State Treasury the Professions and Vocations Fund. The fund shall consist of the following special funds:

(1) Accountancy Fund.
(2) California Architects Board Fund.
(3) Athletic Commission Fund.
(4) Barbering and Cosmetology Contingent Fund.
(5) Cemetery and Funeral Fund.
(6) Contractors License Fund.
(7) State Dentistry Fund.
(8) Home Furnishings and Thermal Insulation Fund.
(9) California Architects Board-Landscape Architects Fund.
(10) Contingent Fund of the Medical Board of California.
(11) Optometry Fund.
(12) Pharmacy Board Contingent Fund.
(13) Physical Therapy Fund.
(14) Private Investigator Fund.
(15) Private Security Services Fund.
(16) Professional Engineer's, Land Surveyor's, and Geologist's Fund.
(17) Consumer Affairs Fund.
(18) Behavioral Sciences Fund.
(19) Licensed Midwifery Fund.
(20) Court Reporters' Fund.
(21) Veterinary Medical Board Contingent Fund.
(22) Vocational Nursing and Psychiatric Technicians Fund.
(23) Electronic and Appliance Repair Fund.
(24) Dispensing Opticians Fund.
(25) Acupuncture Fund.
(26) Physician Assistant Fund.
(27) Board of Podiatric Medicine Fund.
(28) Psychology Fund.
(29) Respiratory Care Fund.
(30) Speech-Language Pathology and Audiology and Hearing Aid Dispensers Fund.
(31) Board of Registered Nursing Fund.
(32) Animal Health Technician Examining Committee Fund.
(33) State Dental Hygiene Fund.
(34) Structural Pest Control Fund.
(35) Structural Pest Control Eradication and Enforcement Fund.
(36) Structural Pest Control Research Fund.
(37) Household Movers Fund.

(b) For accounting and recordkeeping purposes, the Professions and Vocations Fund shall be deemed to be a single special fund, and each of the several special funds therein shall constitute and be deemed to be a separate account in the Professions and Vocations Fund. Each account or fund shall

be available for expenditure only for the purposes as are now or may hereafter be provided by law.

(c) This section shall become operative on July 1, 2022.

SEC. 8.5. Section 205 of the Business and Professions Code, as added by Section 3 of Chapter 865 of the Statutes of 2019, is amended to read:

205. (a) There is in the State Treasury the Professions and Vocations Fund. The fund shall consist of the following special funds:

(1) Accountancy Fund.
(2) California Architects Board Fund.
(3) Athletic Commission Fund.
(4) Barbering and Cosmetology Contingent Fund.
(5) Cemetery and Funeral Fund.
(6) Contractors License Fund.
(7) State Dentistry Fund.
(8) Home Furnishings and Thermal Insulation Fund.
(9) California Architects Board-Landscape Architects Fund.
(10) Contingent Fund of the Medical Board of California.
(11) Optometry Fund.
(12) Pharmacy Board Contingent Fund.
(13) Physical Therapy Fund.
(14) Private Investigator Fund.
(15) Private Security Services Fund.
(16) Professional Engineer's, Land Surveyor's, and Geologist's Fund.
(17) Consumer Affairs Fund.
(18) Behavioral Sciences Fund.
(19) Licensed Midwifery Fund.
(20) Court Reporters' Fund.
(21) Veterinary Medical Board Contingent Fund.
(22) Vocational Nursing and Psychiatric Technicians Fund.
(23) Electronic and Appliance Repair Fund.
(24) Acupuncture Fund.
(25) Physician Assistant Fund.
(26) Board of Podiatric Medicine Fund.
(27) Psychology Fund.
(28) Respiratory Care Fund.
(29) Speech-Language Pathology and Audiology and Hearing Aid Dispensers Fund.
(30) Board of Registered Nursing Fund.
(31) Animal Health Technician Examining Committee Fund.
(32) State Dental Hygiene Fund.
(33) Structural Pest Control Fund.
(34) Structural Pest Control Eradication and Enforcement Fund.
(35) Structural Pest Control Research Fund.
(36) Household Movers Fund.

(b) For accounting and recordkeeping purposes, the Professions and Vocations Fund shall be deemed to be a single special fund, and each of the several special funds therein shall constitute and be deemed to be a separate

account in the Professions and Vocations Fund. Each account or fund shall be available for expenditure only for the purposes as are now or may hereafter be provided by law.

(c) This section shall become operative on July 1, 2022.

SEC. 9. Section 494.5 of the Business and Professions Code is amended to read:

494.5. (a) (1) Except as provided in paragraphs (2), (3), and (4), a state governmental licensing entity shall refuse to issue, reactivate, reinstate, or renew a license and shall suspend a license if a licensee's name is included on a certified list.

(2) The Department of Motor Vehicles shall suspend a license if a licensee's name is included on a certified list. Any reference in this section to the issuance, reactivation, reinstatement, renewal, or denial of a license shall not apply to the Department of Motor Vehicles.

(3) The State Bar of California may recommend to refuse to issue, reactivate, reinstate, or renew a license and may recommend to suspend a license if a licensee's name is included on a certified list. The word "may" shall be substituted for the word "shall" relating to the issuance of a temporary license, refusal to issue, reactivate, reinstate, renew, or suspend a license in this section for licenses under the jurisdiction of the California Supreme Court.

(4) The Department of Alcoholic Beverage Control may refuse to issue, reactivate, reinstate, or renew a license, and may suspend a license, if a licensee's name is included on a certified list.

(b) For purposes of this section:

(1) "Certified list" means either the list provided by the State Board of Equalization or the list provided by the Franchise Tax Board of persons whose names appear on the lists of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code, as applicable.

(2) "License" includes a certificate, registration, or any other authorization to engage in a profession or occupation issued by a state governmental licensing entity. "License" includes a driver's license issued pursuant to Chapter 1 (commencing with Section 12500) of Division 6 of the Vehicle Code. "License" excludes a vehicle registration issued pursuant to Division 3 (commencing with Section 4000) of the Vehicle Code.

(3) "Licensee" means an individual authorized by a license to drive a motor vehicle or authorized by a license, certificate, registration, or other authorization to engage in a profession or occupation issued by a state governmental licensing entity.

(4) "State governmental licensing entity" means any entity listed in Section 101, 1000, or 19420, the office of the Attorney General, the Department of Insurance, the Department of Motor Vehicles, the State Bar of California, the Department of Real Estate, and any other state agency, board, or commission that issues a license, certificate, or registration authorizing an individual to engage in a profession or occupation, including any certificate, business or occupational license, or permit or license issued by the Department of Motor Vehicles or the Department of the California

Highway Patrol. “State governmental licensing entity” shall not include the Contractors State License Board.

(c) The State Board of Equalization and the Franchise Tax Board shall each submit its respective certified list to every state governmental licensing entity. The certified lists shall include the name, social security number or taxpayer identification number, and the last known address of the persons identified on the certified lists.

(d) Notwithstanding any other law, each state governmental licensing entity shall collect the social security number or the federal taxpayer identification number from all applicants for the purposes of matching the names of the certified lists provided by the State Board of Equalization and the Franchise Tax Board to applicants and licensees.

(e) (1) Each state governmental licensing entity shall determine whether an applicant or licensee is on the most recent certified list provided by the State Board of Equalization and the Franchise Tax Board.

(2) If an applicant or licensee is on either of the certified lists, the state governmental licensing entity shall immediately provide a preliminary notice to the applicant or licensee of the entity’s intent to suspend or withhold issuance or renewal of the license. The preliminary notice shall be delivered personally or by mail to the applicant’s or licensee’s last known mailing address on file with the state governmental licensing entity within 30 days of receipt of the certified list. Service by mail shall be completed in accordance with Section 1013 of the Code of Civil Procedure.

(A) The state governmental licensing entity shall issue a temporary license valid for a period of 90 days to any applicant whose name is on a certified list if the applicant is otherwise eligible for a license.

(B) The 90-day time period for a temporary license shall not be extended. Only one temporary license shall be issued during a regular license term and the term of the temporary license shall coincide with the first 90 days of the regular license term. A license for the full term or the remainder of the license term may be issued or renewed only upon compliance with this section.

(C) In the event that a license is suspended or an application for a license or the renewal of a license is denied pursuant to this section, any funds paid by the applicant or licensee shall not be refunded by the state governmental licensing entity.

(f) (1) A state governmental licensing entity shall refuse to issue or shall suspend a license pursuant to this section no sooner than 90 days and no later than 120 days of the mailing of the preliminary notice described in paragraph (2) of subdivision (e), unless the state governmental licensing entity has received a release pursuant to subdivision (h). The procedures in the administrative adjudication provisions of the Administrative Procedure Act (Chapter 4.5 (commencing with Section 11400) and Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) shall not apply to the denial or suspension of, or refusal to renew, a license or the issuance of a temporary license pursuant to this section.

(2) Notwithstanding any other law, if a board, bureau, or commission listed in Section 101, other than the Contractors State License Board, fails to take action in accordance with this section, the Department of Consumer Affairs shall issue a temporary license or suspend or refuse to issue, reactivate, reinstate, or renew a license, as appropriate.

(g) Notices shall be developed by each state governmental licensing entity. For an applicant or licensee on the State Board of Equalization's certified list, the notice shall include the address and telephone number of the State Board of Equalization, and shall emphasize the necessity of obtaining a release from the State Board of Equalization as a condition for the issuance, renewal, or continued valid status of a license or licenses. For an applicant or licensee on the Franchise Tax Board's certified list, the notice shall include the address and telephone number of the Franchise Tax Board, and shall emphasize the necessity of obtaining a release from the Franchise Tax Board as a condition for the issuance, renewal, or continued valid status of a license or licenses.

(1) The notice shall inform the applicant that the state governmental licensing entity shall issue a temporary license, as provided in subparagraph (A) of paragraph (2) of subdivision (e), for 90 calendar days if the applicant is otherwise eligible and that upon expiration of that time period, the license will be denied unless the state governmental licensing entity has received a release from the State Board of Equalization or the Franchise Tax Board, whichever is applicable.

(2) The notice shall inform the licensee that any license suspended under this section will remain suspended until the state governmental licensing entity receives a release along with applications and fees, if applicable, to reinstate the license.

(3) The notice shall also inform the applicant or licensee that if an application is denied or a license is suspended pursuant to this section, any moneys paid by the applicant or licensee shall not be refunded by the state governmental licensing entity. The state governmental licensing entity shall also develop a form that the applicant or licensee shall use to request a release by the State Board of Equalization or the Franchise Tax Board. A copy of this form shall be included with every notice sent pursuant to this subdivision.

(h) If the applicant or licensee wishes to challenge the submission of their name on a certified list, the applicant or licensee shall make a timely written request for release to the State Board of Equalization or the Franchise Tax Board, whichever is applicable. The State Board of Equalization or the Franchise Tax Board shall immediately send a release to the appropriate state governmental licensing entity and the applicant or licensee, if any of the following conditions are met:

(1) The applicant or licensee has complied with the tax obligation, either by payment of the unpaid taxes or entry into an installment payment agreement, as described in Section 6832 or 19008 of the Revenue and Taxation Code, to satisfy the unpaid taxes.

(2) The applicant or licensee has submitted a request for release not later than 45 days after the applicant's or licensee's receipt of a preliminary notice described in paragraph (2) of subdivision (e), but the State Board of Equalization or the Franchise Tax Board, whichever is applicable, will be unable to complete the release review and send notice of its findings to the applicant or licensee and state governmental licensing entity within 45 days after the State Board of Equalization's or the Franchise Tax Board's receipt of the applicant's or licensee's request for release. Whenever a release is granted under this paragraph, and, notwithstanding that release, the applicable license or licenses have been suspended erroneously, the state governmental licensing entity shall reinstate the applicable licenses with retroactive effect back to the date of the erroneous suspension and that suspension shall not be reflected on any license record.

(3) The applicant or licensee is unable to pay the outstanding tax obligation due to a current financial hardship. "Financial hardship" means financial hardship as determined by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, where the applicant or licensee is unable to pay any part of the outstanding liability and the applicant or licensee is unable to qualify for an installment payment arrangement as provided for by Section 6832 or Section 19008 of the Revenue and Taxation Code. In order to establish the existence of a financial hardship, the applicant or licensee shall submit any information, including information related to reasonable business and personal expenses, requested by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, for purposes of making that determination.

(i) An applicant or licensee is required to act with diligence in responding to notices from the state governmental licensing entity and the State Board of Equalization or the Franchise Tax Board with the recognition that the temporary license will lapse or the license suspension will go into effect after 90 days and that the State Board of Equalization or the Franchise Tax Board must have time to act within that period. An applicant's or licensee's delay in acting, without good cause, which directly results in the inability of the State Board of Equalization or the Franchise Tax Board, whichever is applicable, to complete a review of the applicant's or licensee's request for release shall not constitute the diligence required under this section which would justify the issuance of a release. An applicant or licensee shall have the burden of establishing that they diligently responded to notices from the state governmental licensing entity or the State Board of Equalization or the Franchise Tax Board and that any delay was not without good cause.

(j) The State Board of Equalization or the Franchise Tax Board shall create release forms for use pursuant to this section. When the applicant or licensee has complied with the tax obligation by payment of the unpaid taxes, or entry into an installment payment agreement, or establishing the existence of a current financial hardship as defined in paragraph (3) of subdivision (h), the State Board of Equalization or the Franchise Tax Board, whichever is applicable, shall mail a release form to the applicant or licensee

and provide a release to the appropriate state governmental licensing entity. Any state governmental licensing entity that has received a release from the State Board of Equalization and the Franchise Tax Board pursuant to this subdivision shall process the release within five business days of its receipt. If the State Board of Equalization or the Franchise Tax Board determines subsequent to the issuance of a release that the licensee has not complied with their installment payment agreement, the State Board of Equalization or the Franchise Tax Board, whichever is applicable, shall notify the state governmental licensing entity and the licensee in a format prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee is not in compliance and the release shall be rescinded. The State Board of Equalization and the Franchise Tax Board may, when it is economically feasible for the state governmental licensing entity to develop an automated process for complying with this subdivision, notify the state governmental licensing entity in a manner prescribed by the State Board of Equalization or the Franchise Tax Board, whichever is applicable, that the licensee has not complied with the installment payment agreement. Upon receipt of this notice, the state governmental licensing entity shall immediately notify the licensee on a form prescribed by the state governmental licensing entity that the licensee's license will be suspended on a specific date, and this date shall be no longer than 30 days from the date the form is mailed. The licensee shall be further notified that the license will remain suspended until a new release is issued in accordance with this subdivision.

(k) The State Board of Equalization and the Franchise Tax Board may enter into interagency agreements with the state governmental licensing entities necessary to implement this section.

(*l*) Notwithstanding any other law, a state governmental licensing entity, with the approval of the appropriate department director or governing body, may impose a fee on a licensee whose license has been suspended pursuant to this section. The fee shall not exceed the amount necessary for the state governmental licensing entity to cover its costs in carrying out the provisions of this section. Fees imposed pursuant to this section shall be deposited in the fund in which other fees imposed by the state governmental licensing entity are deposited and shall be available to that entity upon appropriation in the annual Budget Act.

(m) The process described in subdivision (h) shall constitute the sole administrative remedy for contesting the issuance of a temporary license or the denial or suspension of a license under this section.

(n) Any state governmental licensing entity receiving an inquiry as to the licensed status of an applicant or licensee who has had a license denied or suspended under this section or who has been granted a temporary license under this section shall respond that the license was denied or suspended or the temporary license was issued only because the licensee appeared on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code. Information collected pursuant to this section by any state agency, board, or department shall be subject to the

Information Practices Act of 1977 (Chapter 1 (commencing with Section 1798) of Title 1.8 of Part 4 of Division 3 of the Civil Code). Any state governmental licensing entity that discloses on its internet website or other publication that the licensee has had a license denied or suspended under this section or has been granted a temporary license under this section shall prominently disclose, in bold and adjacent to the information regarding the status of the license, that the only reason the license was denied, suspended, or temporarily issued is because the licensee failed to pay taxes.

(o) Any rules and regulations issued pursuant to this section by any state agency, board, or department may be adopted as emergency regulations in accordance with the rulemaking provisions of the Administrative Procedure Act (Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code). The adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health, and safety, or general welfare. The regulations shall become effective immediately upon filing with the Secretary of State.

(p) The State Board of Equalization, the Franchise Tax Board, and state governmental licensing entities, as appropriate, shall adopt regulations as necessary to implement this section.

(q) (1) Neither the state governmental licensing entity, nor any officer, employee, or agent, or former officer, employee, or agent of a state governmental licensing entity, may disclose or use any information obtained from the State Board of Equalization or the Franchise Tax Board, pursuant to this section, except to inform the public of the denial, refusal to renew, or suspension of a license or the issuance of a temporary license pursuant to this section. The release or other use of information received by a state governmental licensing entity pursuant to this section, except as authorized by this section, is punishable as a misdemeanor. This subdivision may not be interpreted to prevent the State Bar of California from filing a request with the Supreme Court of California to suspend a member of the bar pursuant to this section.

(2) A suspension of, or refusal to renew, a license or issuance of a temporary license pursuant to this section does not constitute denial or discipline of a licensee for purposes of any reporting requirements to the National Practitioner Data Bank and shall not be reported to the National Practitioner Data Bank or the Healthcare Integrity and Protection Data Bank.

(3) Upon release from the certified list, the suspension or revocation of the applicant's or licensee's license shall be purged from the state governmental licensing entity's internet website or other publication within three business days. This paragraph shall not apply to the State Bar of California.

(r) If any provision of this section or the application thereof to any person or circumstance is held invalid, that invalidity shall not affect other provisions or applications of this section that can be given effect without the invalid provision or application, and to this end the provisions of this section are severable.

(s) All rights to review afforded by this section to an applicant shall also be afforded to a licensee.

(t) Unless otherwise provided in this section, the policies, practices, and procedures of a state governmental licensing entity with respect to license suspensions under this section shall be the same as those applicable with respect to suspensions pursuant to Section 17520 of the Family Code.

(u) No provision of this section shall be interpreted to allow a court to review and prevent the collection of taxes prior to the payment of those taxes in violation of the California Constitution.

(v) This section shall apply to any licensee whose name appears on a list of the 500 largest tax delinquencies pursuant to Section 7063 or 19195 of the Revenue and Taxation Code on or after July 1, 2012.

SEC. 10. Section 1000 of the Business and Professions Code is amended to read:

1000. (a) The law governing practitioners of chiropractic is found in an initiative act entitled "An act prescribing the terms upon which licenses may be issued to practitioners of chiropractic, creating the State Board of Chiropractic Examiners and declaring its powers and duties, prescribing penalties for violation hereof, and repealing all acts and parts of acts inconsistent herewith," adopted by the electors November 7, 1922.

(b) The State Board of Chiropractic Examiners is within the Department of Consumer Affairs.

(c) Notwithstanding any other law, the powers and duties of the State Board of Chiropractic Examiners, as set forth in this article and under the act creating the board, shall be subject to review by the appropriate policy committees of the Legislature. The review shall be performed as if this chapter were scheduled to be repealed as of January 1, 2023.

SEC. 11. Section 1913 of the Business and Professions Code is amended to read:

1913. Unless otherwise specified in this chapter, a registered dental hygienist may perform any procedure or provide any service within the scope of their practice in any setting under the appropriate level of supervision required by this article, if the registered dental hygienist has completed the appropriate education and training required to perform the procedure or provide the service.

SEC. 12. Section 1917 of the Business and Professions Code is amended to read:

1917. The dental hygiene board shall grant initial licensure as a registered dental hygienist to a person who satisfies all of the following requirements:

(a) Completion of an educational program for registered dental hygienists, approved by the dental hygiene board, accredited by the Commission on Dental Accreditation, and conducted by a degree-granting, postsecondary institution.

(b) Within the preceding three years, satisfactory completion of the dental hygiene examination given by the Western Regional Examining Board or any other clinical or dental hygiene examination approved by the dental hygiene board.

(c) Satisfactory completion of the National Board Dental Hygiene Examination.

(d) Satisfactory completion of the examination in California law and ethics as prescribed by the dental hygiene board.

(e) Submission of a completed application form and all fees required by the dental hygiene board.

(f) Satisfactory completion of dental hygiene board-approved instruction in gingival soft-tissue curettage, nitrous oxide-oxygen analgesia, and local anesthesia.

SEC. 13. Section 1917.1 of the Business and Professions Code is amended to read:

1917.1. (a) The dental hygiene board may grant a license as a registered dental hygienist to an applicant who has not taken a clinical examination before the dental hygiene board, if the applicant submits all of the following to the dental hygiene board:

(1) A completed application form and all fees required by the dental hygiene board.

(2) Proof of a current license as a registered dental hygienist issued by another state that is not revoked, suspended, or otherwise restricted.

(3) Proof that the applicant has been in clinical practice as a registered dental hygienist or has been a full-time faculty member in an accredited dental hygiene education program for a minimum of 750 hours per year for at least five years immediately preceding the date of application under this section. The clinical practice requirement shall be deemed met if the applicant provides proof of at least three years of clinical practice and commits to completing the remaining two years of clinical practice by filing with the dental hygiene board a copy of a pending contract to practice dental hygiene in any of the following facilities:

(A) A primary care clinic licensed under subdivision (a) of Section 1204 of the Health and Safety Code.

(B) A primary care clinic exempt from licensure pursuant to subdivision (c) of Section 1206 of the Health and Safety Code.

(C) A clinic owned or operated by a public hospital or health system.

(D) A clinic owned and operated by a hospital that maintains the primary contract with a county government to fill the county's role under Section 17000 of the Welfare and Institutions Code.

(4) Satisfactory performance on a California law and ethics examination and any examination that may be required by the dental hygiene board.

(5) Proof that the applicant has not been subject to disciplinary action by any state in which the applicant is or has been previously issued any professional or vocational license. If the applicant has been subject to disciplinary action, the dental hygiene board shall review that action to determine if it warrants refusal to issue a license to the applicant.

(6) Proof of graduation from a school of dental hygiene accredited by the Commission on Dental Accreditation.

(7) Proof of satisfactory completion of the National Board Dental Hygiene Examination and of a state clinical examination, regional clinical licensure

examination, or any other clinical dental hygiene examination approved by the dental hygiene board.

(8) Proof that the applicant has not failed the state clinical examination, the examination given by the Western Regional Examining Board, or any other clinical dental hygiene examination approved by the dental hygiene board for licensure to practice dental hygiene under this chapter more than once or once within five years prior to the date of application for a license under this section.

(9) Documentation of completion of a minimum of 25 units of continuing education earned in the two years preceding application, including completion of any continuing education requirements imposed by the dental hygiene board on registered dental hygienists licensed in this state at the time of application.

(10) Any other information as specified by the dental hygiene board to the extent that it is required of applicants for licensure by examination under this article.

(b) The dental hygiene board may periodically request verification of compliance with the requirements of paragraph (3) of subdivision (a) and may revoke the license upon a finding that the employment requirement or any other requirement of paragraph (3) of subdivision (a) has not been met.

(c) The dental hygiene board shall provide in the application packet to each out-of-state dental hygienist pursuant to this section the following information:

(1) The location of dental manpower shortage areas in the state.

(2) Any nonprofit clinics, public hospitals, and accredited dental hygiene education programs seeking to contract with licensees for dental hygiene service delivery or training purposes.

SEC. 14. Section 1922 of the Business and Professions Code is amended to read:

1922. The dental hygiene board shall license as a registered dental hygienist in alternative practice a person who demonstrates satisfactory performance on an examination in California law and ethics required by the dental hygiene board and who completes an application form and pays all application fees required by the dental hygiene board and meets either of the following requirements:

(a) Holds a current California license as a registered dental hygienist and meets the following requirements:

(1) Has been engaged in the practice of dental hygiene, as defined in Section 1908, as a registered dental hygienist in any setting, including, but not limited to, educational settings and public health settings, for a minimum of 2,000 hours during the immediately preceding 36 months.

(2) Has successfully completed a bachelor's degree or its equivalent, recognized as a minimum of 120 semester credit hours or 180 quarter credit hours in postsecondary education, from a college or institution of higher education that is accredited by a national or regional accrediting agency recognized by the United States Department of Education, and a minimum of 150 hours of additional educational requirements, as prescribed by the

dental hygiene board by regulation, that are consistent with good dental and dental hygiene practice, including, but not necessarily limited to, dental hygiene technique and theory including gerontology and medical emergencies, and business administration and practice management.

(b) Has received a letter of acceptance into the employment utilization phase of the Health Workforce Pilot Project No. 155 established by the Office of Statewide Health Planning and Development pursuant to Article 1 (commencing with Section 128125) of Chapter 3 of Part 3 of Division 107 of the Health and Safety Code.

SEC. 15. Section 2065 of the Business and Professions Code is amended to read:

2065. (a) Unless otherwise provided by law, no postgraduate trainee, intern, resident, postdoctoral fellow, or instructor may engage in the practice of medicine, or receive compensation therefor, or offer to engage in the practice of medicine unless they hold a valid, unrevoked, and unsuspended physician's and surgeon's certificate issued by the board. However, a graduate of an approved medical school may engage in the practice of medicine whenever and wherever required as a part of a postgraduate training program under the following conditions:

(1) The medical school graduate has taken and passed the board-approved medical licensing examinations required to qualify the applicant to participate in an approved postgraduate training program.

(2) If the medical school graduate graduated from a foreign medical school approved by the board pursuant to Section 2084, the Educational Commission for Foreign Medical Graduates (ECFMG) has submitted an official ECFMG Certification Status Report directly to the board confirming the graduate is ECFMG certified.

(3) The medical school graduate is enrolled in a postgraduate training program approved by the board.

(4) The board-approved postgraduate training program has submitted the required board-approved form to the board documenting the medical school graduate is enrolled in an approved postgraduate training program.

(5) The medical school graduate obtains a physician's and surgeon's postgraduate training license in accordance with Section 2064.5.

(b) A medical school graduate enrolled in an approved first-year postgraduate training program in accordance with this section may engage in the practice of medicine whenever and wherever required as a part of the training program, and may receive compensation for that practice.

(c) A graduate who has completed the first year of postgraduate training may, in an approved residency or fellowship, engage in the practice of medicine whenever and wherever required as part of that residency or fellowship, and may receive compensation for that practice. The resident or fellow shall qualify for, take, and pass the next succeeding written examination for licensure. If the resident or fellow fails to receive a license to practice medicine under this chapter within 27 months from the commencement of the residency or fellowship, except as otherwise allowed under subdivision (g) or (h), or if the board denies their application for

licensure, all privileges and exemptions under this section shall automatically cease.

(d) All approved postgraduate training the medical school graduate has successfully completed in the United States or Canada shall count toward the 39-month license exemption, except as otherwise allowed under subdivision (h).

(e) A medical school graduate from a medical school approved by the board shall have successfully completed a minimum of 36 months of approved postgraduate training, which includes successful progression through 24 months in the same program, to be eligible for a California physician's and surgeon's certificate.

(f) The program director for an approved postgraduate training program in California shall report to the board, on a form approved by the board, and provide any supporting documents as required by the board, the following actions within 30 days of the action:

(1) A postgraduate trainee is notified that they have received partial or no credit for a period of postgraduate training, and their postgraduate training period is extended.

(2) A postgraduate trainee takes a leave of absence or any break from their postgraduate training, and they are notified that their postgraduate training period is extended.

(3) A postgraduate trainee is terminated from the postgraduate training program.

(4) A postgraduate trainee resigns, dies, or otherwise leaves the postgraduate training program.

(5) A postgraduate trainee has completed a one-year contract approved by the postgraduate training program.

(g) Upon review of supporting documentation, the board, in its discretion, may grant an extension beyond 39 months to a postgraduate training licensee to successfully complete the 36 months of required approved postgraduate training.

(h) An applicant for a physician's and surgeon's license who has successfully completed 36 months of approved postgraduate training in another state or in Canada and who is accepted into an approved postgraduate training program in California shall obtain their physician's and surgeon's license within 90 days after beginning that postgraduate training program or all privileges and exemptions under this section shall automatically cease.

(i) This section shall become operative on January 1, 2020.

SEC. 16. Section 2113 of the Business and Professions Code is amended to read:

2113. (a) Any person who does not immediately qualify for a physician's and surgeon's certificate under this chapter and who is offered by the dean of an approved medical school in this state a full-time faculty position may, after application to and approval by the board, be granted a certificate of registration to engage in the practice of medicine only to the extent that the practice is incident to and a necessary part of their duties as approved by the board in connection with the faculty position. A certificate of registration

does not authorize a registrant to admit patients to a nursing or a skilled or assisted living facility unless that facility is formally affiliated with the sponsoring medical school. A clinical fellowship shall not be submitted as a faculty service appointment.

(b) Application for a certificate of registration shall be made on a form prescribed by the board and shall be accompanied by a registration fee fixed by the board in an amount necessary to recover the actual application processing costs of the program. To qualify for the certificate, an applicant shall submit all of the following:

(1) If the applicant is a graduate of a medical school other than in the United States or Canada, documentary evidence satisfactory to the board that they have been licensed to practice medicine and surgery for not less than four years in another state or country whose requirements for licensure are satisfactory to the board, or has been engaged in the practice of medicine in the United States for at least four years in approved facilities, or has completed a combination of that licensure and training.

(2) If the applicant is a graduate of a medical school in the United States or Canada, documentary evidence that the medical school is approved by the board.

(3) Written certification by the head of the department in which the applicant is to be appointed of all of the following:

(A) The applicant will be under their direction.

(B) The applicant will not be permitted to practice medicine unless incident to and a necessary part of their duties as approved by the board in subdivision (a).

(C) The applicant will be accountable to the medical school's department chair or division chief for the specialty in which the applicant will practice.

(D) The applicant will be proctored in the same manner as other new faculty members, including, as appropriate, review by the medical staff of the school's medical center.

(E) The applicant will not be appointed to a supervisory position at the level of a medical school department chair or division chief.

(4) Demonstration by the dean of the medical school that the applicant has the requisite qualifications to assume the position to which they are to be appointed and that shall include a written statement of the recruitment procedures followed by the medical school before offering the faculty position to the applicant.

(c) A certificate of registration shall be issued only for a faculty position at one approved medical school, and no person shall be issued more than one certificate of registration for the same period of time.

(d) (1) A certificate of registration is valid for one year from its date of issuance and may be renewed twice.

A request for renewal shall be submitted on a form prescribed by the board and shall be accompanied by a renewal fee fixed by the board in an amount necessary to recover the actual application processing costs of the program.

(2) The dean of the medical school may request renewal of the registration by submitting a plan at the beginning of the third year of the registrant's appointment demonstrating the registrant's continued progress toward licensure and, if the registrant is a graduate of a medical school other than in the United States or Canada, that the registrant has been issued a certificate by the Educational Commission for Foreign Medical Graduates. The board may, in its discretion, extend the registration for a two-year period to facilitate the registrant's completion of the licensure process.

(e) If the registrant is a graduate of a medical school other than in the United States or Canada, they shall meet the requirements of Section 2065 or 2135, as appropriate, in order to obtain a physician's and surgeon's certificate. Notwithstanding any other provision of law, the board may accept clinical practice in an appointment pursuant to this section as qualifying time to meet the postgraduate training requirements in Section 2065, and, in its discretion, waive the examination and the Educational Commission for Foreign Medical Graduates certification requirements specified in paragraph (3) of subdivision (a) of Section 2065 in the event the registrant applies for a physician's and surgeon's certificate. As a condition to waiving any examination or the Educational Commission for Foreign Medical Graduates certification requirement, the board in its discretion, may require an applicant to pass a clinical competency examination approved by the board. The board shall not waive any examination for an applicant who has not completed at least one year in the faculty position.

(f) Except to the extent authorized by this section, the registrant shall not engage in the practice of medicine, bill individually for medical services provided by the registrant, or receive compensation therefor, unless they are issued a physician's and surgeon's certificate.

(g) When providing clinical services, the registrant shall wear a visible name tag containing the title "visiting professor" or "visiting faculty member," as appropriate, and the institution at which the services are provided shall obtain a signed statement from each patient to whom the registrant provides services acknowledging that the patient understands that the services are provided by a person who does not hold a physician's and surgeon's certificate but who is qualified to participate in a special program as a visiting professor or faculty member.

(h) The board shall notify both the registrant and the dean of the medical school of a complaint made about the registrant. The board may terminate a registration for any act that would be grounds for discipline if done by a licensee. The board shall provide both the registrant and the dean of the medical school with written notice of the termination and the basis for that termination. The registrant may, within 30 days after the date of the notice of termination, file a written appeal to the board. The appeal shall include any documentation the registrant wishes to present to the board.

(i) This section shall become operative on January 1, 2020.

SEC. 16.5. Section 2113 of the Business and Professions Code is amended to read:

2113. (a) Any person who does not immediately qualify for a physician's and surgeon's certificate under this chapter and who is offered by the dean of an approved medical school, or dean or chief medical officer of an academic medical center, in this state a full-time faculty position may, after application to and approval by the board, be granted a certificate of registration to engage in the practice of medicine only to the extent that the practice is incident to and a necessary part of that person's duties as approved by the board in connection with the faculty position. A certificate of registration does not authorize a registrant to admit patients to a nursing or a skilled or assisted living facility unless that facility is formally affiliated with the sponsoring medical school. A clinical fellowship shall not be submitted as a faculty service appointment.

(b) Application for a certificate of registration shall be made on a form prescribed by the board and shall be accompanied by a registration fee fixed by the board in an amount necessary to recover the actual application processing costs of the program. To qualify for the certificate, an applicant shall submit all of the following:

(1) If the applicant is a graduate of a medical school other than in the United States or Canada, documentary evidence satisfactory to the board that the applicant has been licensed to practice medicine and surgery for not less than four years in another state or country whose requirements for licensure are satisfactory to the board, or has been engaged in the practice of medicine in the United States for at least four years in approved facilities, or has completed a combination of that licensure and training.

(2) If the applicant is a graduate of a medical school in the United States or Canada, documentary evidence that the medical school is approved by the board.

(3) Written certification by the head of the department in which the applicant is to be appointed of all of the following:

(A) The applicant will be under the head of the department's direction.

(B) The applicant will not be permitted to practice medicine unless incident to and a necessary part of the applicant's duties as approved by the board in subdivision (a).

(C) The applicant will be accountable to the medical school's or academic medical center's chair or division chief for the specialty in which the applicant will practice.

(D) The applicant will be proctored in the same manner as other new faculty members, including, as appropriate, review by the medical staff of the sponsoring medical school or academic medical center.

(E) The applicant will not be appointed to a supervisory position at the level of a medical school or academic medical center's department chair or division chief.

(4) Demonstration by the dean of the medical school, or dean or chief medical officer or an academic medical center, that the applicant has the requisite qualifications to assume the position to which the applicant is to be appointed and that shall include a written statement of the recruitment

procedures followed by the medical school or academic medical center before offering the faculty position to the applicant.

(c) A certificate of registration shall be issued only for a faculty position at one approved medical school, or academic medical center, and a person shall not be issued more than one certificate of registration for the same period of time.

(d) (1) A certificate of registration is valid for one year from its date of issuance and may be renewed twice.

A request for renewal shall be submitted on a form prescribed by the board and shall be accompanied by a renewal fee fixed by the board in an amount necessary to recover the actual application processing costs of the program.

(2) The dean of the medical school, or the dean or chief medical officer of an academic medical center, may request renewal of the registration by submitting a plan at the beginning of the third year of the registrant's appointment demonstrating the registrant's continued progress toward licensure and, if the registrant is a graduate of a medical school other than in the United States or Canada, that the registrant has been issued a certificate by the Educational Commission for Foreign Medical Graduates. The board may, in its discretion, extend the registration for a two-year period to facilitate the registrant's completion of the licensure process.

(e) If the registrant is a graduate of a medical school other than in the United States or Canada, the registrant shall meet the requirements of Section 2065 or 2135, as appropriate, in order to obtain a physician's and surgeon's certificate. Notwithstanding any other provision of law, the board may accept clinical practice in an appointment pursuant to this section as qualifying time to meet the postgraduate training requirements in Section 2065, and, in its discretion, waive the examination and the Educational Commission for Foreign Medical Graduates certification requirements specified in paragraph (3) of subdivision (a) of Section 2065 in the event the registrant applies for a physician's and surgeon's certificate. As a condition to waiving any examination or the Educational Commission for Foreign Medical Graduates certification requirement, the board in its discretion, may require an applicant to pass a clinical competency examination approved by the board. The board shall not waive any examination for an applicant who has not completed at least one year in the faculty position.

(f) Except to the extent authorized by this section, the registrant shall not engage in the practice of medicine, bill individually for medical services provided by the registrant, or receive compensation therefor, unless the registrant is issued a physician's and surgeon's certificate.

(g) When providing clinical services, the registrant shall wear a visible name tag containing the title "visiting professor" or "visiting faculty member," as appropriate, and the institution at which the services are provided shall obtain a signed statement from each patient to whom the registrant provides services acknowledging that the patient understands that the services are provided by a person who does not hold a physician's and

surgeon's certificate but who is qualified to participate in a special program as a visiting professor or faculty member.

(h) The board shall notify both the registrant and the dean of the medical school, or the dean or chief medical officer of an academic medical center, of a complaint made about the registrant. The board may terminate a registration for any act that would be grounds for discipline if done by a licensee. The board shall provide both the registrant and the dean of the medical school, or the dean or chief medical officer of an academic medical center, with written notice of the termination and the basis for that termination. The registrant may, within 30 days after the date of the notice of termination, file a written appeal to the board. The appeal shall include any documentation the registrant wishes to present to the board.

(i) A registrant granted a certificate of registration before January 1, 2021, to engage in the practice of medicine pursuant to this section at an academic medical center shall be deemed to be authorized at that academic medical center as though the initial application had been sponsored by the academic medical center.

(j) As used in this section, "academic medical center" has the same meaning as defined in subdivision (a) of Section 2168.

SEC. 17. Section 2135.5 of the Business and Professions Code is amended to read:

2135.5. Upon review and recommendation, the board may determine that an applicant for a physician's and surgeon's certificate has satisfied the medical education requirements of Sections 2084 and 2135 and the examination requirements of Section 2170 if the applicant meets all of the following criteria:

(a) They hold an unlimited and unrestricted license as a physician and surgeon in another state and has held that license continuously for a minimum of four years prior to the date of application.

(b) They meet the postgraduate training requirements in Section 2096 and are certified by a specialty board that is a member board of the American Board of Medical Specialties.

(c) They are not subject to denial of licensure under Division 1.5 (commencing with Section 475) or Article 12 (commencing with Section 2220).

(d) They have not been the subject of a disciplinary action by a medical licensing authority or of an adverse judgment or settlement resulting from the practice of medicine that, as determined by the board, constitutes a pattern of negligence or incompetence.

(e) This section shall become operative on January 1, 2020.

SEC. 18. Section 2460 of the Business and Professions Code is amended to read:

2460. (a) There is created in the Department of Consumer Affairs the California Board of Podiatric Medicine. Commencing July 1, 2019, the California Board of Podiatric Medicine is renamed the Podiatric Medical Board of California. Any reference in any provision of law to the California

Board of Podiatric Medicine shall, commencing July 1, 2019, be deemed to refer to the Podiatric Medical Board of California.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the California Board of Podiatric Medicine subject to review by the appropriate policy committees of the Legislature.

(c) The amendments made by Chapter 775 of the Statutes of 2017 relating to podiatrists shall not be construed to change any rights or privileges held by podiatrists prior to the enactment of that act.

SEC. 19. Section 2531 of the Business and Professions Code is amended to read:

2531. (a) There is in the Department of Consumer Affairs the Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board in which the enforcement and administration of this chapter are vested. The Speech-Language Pathology and Audiology and Hearing Aid Dispensers Board shall consist of nine members, three of whom shall be public members.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 20. Section 2531.75 of the Business and Professions Code is amended to read:

2531.75. (a) The board may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 21. Section 2570.19 of the Business and Professions Code is amended to read:

2570.19. (a) There is hereby created a California Board of Occupational Therapy, hereafter referred to as the board. The board shall enforce and administer this chapter.

(b) The members of the board shall consist of the following:

(1) Three occupational therapists who shall have practiced occupational therapy for five years.

(2) One occupational therapy assistant who shall have assisted in the practice of occupational therapy for five years.

(3) Three public members who shall not be licentiates of the board, of any other board under this division, or of any board referred to in Section 1000 or 3600.

(c) The Governor shall appoint the three occupational therapists and one occupational therapy assistant to be members of the board. The Governor, the Senate Committee on Rules, and the Speaker of the Assembly shall each appoint a public member. Not more than one member of the board shall be

appointed from the full-time faculty of any university, college, or other educational institution.

(d) All members shall be residents of California at the time of their appointment. The occupational therapist and occupational therapy assistant members shall have been engaged in rendering occupational therapy services to the public, teaching, or research in occupational therapy for at least five years preceding their appointments.

(e) The public members may not be or have ever been occupational therapists or occupational therapy assistants or in training to become occupational therapists or occupational therapy assistants. The public members may not be related to, or have a household member who is, an occupational therapist or an occupational therapy assistant, and may not have had, within two years of the appointment, a substantial financial interest in a person regulated by the board.

(f) The Governor shall appoint two board members for a term of one year, two board members for a term of two years, and one board member for a term of three years. Appointments made thereafter shall be for four-year terms, but no person shall be appointed to serve more than two consecutive terms. Terms shall begin on the first day of the calendar year and end on the last day of the calendar year or until successors are appointed, except for the first appointed members who shall serve through the last calendar day of the year in which they are appointed, before commencing the terms prescribed by this section. Vacancies shall be filled by appointment for the unexpired term. The board shall annually elect one of its members as president.

(g) The board shall meet and hold at least one regular meeting annually in the Cities of Sacramento, Los Angeles, and San Francisco. The board may convene from time to time until its business is concluded. Special meetings of the board may be held at any time and place designated by the board.

(h) Notice of each meeting of the board shall be given in accordance with the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code).

(i) Members of the board shall receive no compensation for their services, but shall be entitled to reasonable travel and other expenses incurred in the execution of their powers and duties in accordance with Section 103.

(j) The appointing power shall have the power to remove any member of the board from office for neglect of any duty imposed by state law, for incompetency, or for unprofessional or dishonorable conduct.

(k) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

(*l*) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 22. Section 2602 of the Business and Professions Code is amended to read:

2602. (a) The Physical Therapy Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 23. Section 2607.5 of the Business and Professions Code is amended to read:

2607.5. (a) The board may employ an executive officer exempt from the provisions of the State Civil Service Act (Part 2 (commencing with Section 18500) of Division 5 of Title 2 of the Government Code) and may also employ investigators, legal counsel, physical therapist consultants, and other assistance as it may deem necessary to carry out this chapter. The board may fix the compensation to be paid for services and may incur other expenses as it may deem necessary. Investigators employed by the board shall be provided special training in investigating physical therapy practice activities.

(b) The Attorney General shall act as legal counsel for the board for any judicial and administrative proceedings and their services shall be a charge against it.

(c) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 24. Section 2841 of the Business and Professions Code is amended to read:

2841. (a) There is in the Department of Consumer Affairs a Board of Vocational Nursing and Psychiatric Technicians of the State of California, which consists of 11 members.

(b) Within the meaning of this chapter, “board,” or “the board,” refers to the Board of Vocational Nursing and Psychiatric Technicians of the State of California.

(c) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 25. Section 2847.1 of the Business and Professions Code is amended to read:

2847.1. (a) The board shall select an executive officer who shall perform duties as are delegated by the board and who shall be responsible to it for the accomplishment of those duties. The executive officer shall not be a member of the board.

(b) With the approval of the Director of Finance, the board shall fix the salary of the executive officer.

(c) The executive officer shall be entitled to traveling and other necessary expenses in the performance of their duties. The executive officer shall make a statement, certified before a duly authorized person, that the expenses have been actually incurred.

(d) Commencing January 1, 2018, the executive officer appointed by the board pursuant to subdivision (a) is abolished. Thereafter, until January 1,

2022, the executive officer shall be appointed as set forth in Section 2847.3. Commencing January 1, 2022, the executive officer shall, again, be appointed by the board as set forth in subdivision (a).

(e) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 26. Section 2847.3 of the Business and Professions Code is amended to read:

2847.3. (a) Commencing January 1, 2018, the executive officer position established pursuant to subdivision (a) of Section 2847.1 is temporarily abolished. Commencing January 1, 2018, the Governor shall appoint an executive officer who shall perform duties as are delegated by the board and who shall be responsible for the accomplishment of those duties. The executive officer shall exercise all powers, discharge all responsibilities, and administer and enforce all laws pursuant to this chapter and Chapter 10 (commencing with Section 4500) of Division 2 that are necessary to perform the duties delegated by the board.

(b) The executive officer shall serve at the pleasure of the Governor and the Governor shall fix the salary of the executive officer. The executive officer shall not be a member of the board.

(c) The executive officer shall be entitled to traveling and other necessary expenses in the performance of their duties.

(d) This section shall become operative on January 1, 2018, and shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 27. Section 2920 of the Business and Professions Code is amended to read:

2920. (a) The Board of Psychology shall enforce and administer this chapter. The board shall consist of nine members, four of whom shall be public members.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

(c) Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 28. Section 2933 of the Business and Professions Code is amended to read:

2933. (a) Except as provided by Section 159.5, the board shall employ and shall make available to the board within the limits of the funds received by the board all personnel necessary to carry out this chapter. The board may employ, exempt from the State Civil Service Act, an executive officer to the Board of Psychology. The board shall make all expenditures to carry out this chapter. The board may accept contributions to effectuate the purposes of this chapter.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 29. Section 3504 of the Business and Professions Code is amended to read:

3504. There is established a Physician Assistant Board within the jurisdiction of the Medical Board of California. The board consists of nine members. This section shall remain in effect only until January 1, 2022, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 30. Section 3512 of the Business and Professions Code is amended to read:

3512. (a) Except as provided in Sections 159.5 and 2020, the board shall employ within the limits of the Physician Assistant Fund all personnel necessary to carry out this chapter including an executive officer who shall be exempt from civil service. The Medical Board of California and board shall make all necessary expenditures to carry out this chapter from the funds established by Section 3520. The board may accept contributions to effect the purposes of this chapter.

(b) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 31. Section 3686 of the Business and Professions Code is amended to read:

3686. This chapter shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 32. Section 3710 of the Business and Professions Code is amended to read:

3710. (a) The Respiratory Care Board of California, hereafter referred to as the board, shall enforce and administer this chapter.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 33. Section 3716 of the Business and Professions Code is amended to read:

3716. (a) The board may employ an executive officer exempt from civil service and, subject to the provisions of law relating to civil service, clerical assistants and, except as provided in Section 159.5, other employees as it may deem necessary to carry out its powers and duties.

(b) This section shall remain in effect only until January 1, 2023, and as of that date is repealed.

SEC. 34. Section 4001 of the Business and Professions Code is amended to read:

4001. (a) There is in the Department of Consumer Affairs a California State Board of Pharmacy in which the administration and enforcement of this chapter is vested. The board consists of 13 members.

(b) The Governor shall appoint seven competent pharmacists who reside in different parts of the state to serve as members of the board. The Governor shall appoint four public members, and the Senate Committee on Rules and the Speaker of the Assembly shall each appoint a public member who shall

not be a licensee of the board, any other board under this division, or any board referred to in Section 1000 or 3600.

(c) At least five of the seven pharmacist appointees to the board shall be pharmacists who are actively engaged in the practice of pharmacy. Additionally, the membership of the board shall include at least one pharmacist representative from each of the following practice settings: an acute care hospital, an independent community pharmacy, a chain community pharmacy, and a long-term health care or skilled nursing facility. The pharmacist appointees shall also include a pharmacist who is a member of a labor union that represents pharmacists. For the purposes of this subdivision, a "chain community pharmacy" means a chain of 75 or more stores in California under the same ownership, and an "independent community pharmacy" means a pharmacy owned by a person or entity who owns no more than four pharmacies in California.

(d) Members of the board shall be appointed for a term of four years. No person shall serve as a member of the board for more than two consecutive terms. Each member shall hold office until the appointment and qualification of their successor or until one year shall have elapsed since the expiration of the term for which the member was appointed, whichever first occurs. Vacancies occurring shall be filled by appointment for the unexpired term.

(e) Each member of the board shall receive a per diem and expenses as provided in Section 103.

(f) This section shall remain in effect only until January 1, 2022, and as of that date is repealed. Notwithstanding any other law, the repeal of this section renders the board subject to review by the appropriate policy committees of the Legislature.

SEC. 35. Section 4003 of the Business and Professions Code is amended to read:

4003. (a) The board, with the approval of the director, may appoint a person exempt from civil service who shall be designated as an executive officer and who shall exercise the powers and perform the duties delegated by the board and vested in them by this chapter. The executive officer may or may not be a member of the board as the board may determine.

(b) The executive officer shall receive the compensation as established by the board with the approval of the Director of Finance. The executive officer shall also be entitled to travel and other expenses necessary in the performance of their duties.

(c) The executive officer shall maintain and update in a timely fashion records containing the names, titles, qualifications, and places of business of all persons subject to this chapter.

(d) The executive officer shall give receipts for all money received by them and pay it to the department, taking its receipt therefor. Besides the duties required by this chapter, the executive officer shall perform other duties pertaining to the office as may be required of them by the board.

(e) This section shall remain in effect only until January 1, 2022, and as of that date is repealed.

Attachment 2

#256

Compounding Animal Drugs from Bulk Drug Substances

Guidance for Industry

Draft Guidance

This guidance document is for comment purposes only.

Submit comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov/. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA-2018-D-4533.

For questions regarding this document, contact Eric Nelson (CVM) at 240-402-7001, or by e-mail at cvmcompliance@fda.hhs.gov.

Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at either https://www.fda.gov/animal-veterinary or https://www.regulations.gov/.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
November 2019

Table of Contents

Compounding Animal Drugs from Bulk Drug Substances

Guidance for Industry

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA or Agency) current thinking on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance describes the Food and Drug Administration's (FDA) policy regarding the compounding of animal drugs from bulk drug substances[1] by or under the direct supervision of:

- Veterinarians, or
- Pharmacists in either State-licensed pharmacies or Federal facilities (*i.e.*, facilities operated by the Federal government).[2]

Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the compounding of an animal drug from bulk drug substances results in a "new animal drug" that must comply with the FD&C Act's approval, conditional approval, or indexing requirements (sections 512, 571, and 572 of the FD&C Act (21 U.S.C. §§ 360b, 360ccc, 360ccc-1)). Further, all animal drugs are required to, among other things, be made in accordance with current good manufacturing practice (cGMP) requirements

[1] FDA regulations define "bulk drug substance" and "active pharmaceutical ingredient" as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." The terms do not include intermediates used in the synthesis of the substance. 21 CFR 207.1. "Active ingredient" is defined as "any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or other animals. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect." 21 CFR 210.3(b)(7). Any component other than an active ingredient is an "inactive ingredient." 21 CFR 210.3(b)(8). Inactive ingredients used in compounded drug products commonly include flavorings, dyes, diluents, or other excipients. In addition, for purposes of this guidance, FDA considers bulk chemicals used to make antidotes intended to treat toxicoses in animals to be bulk drug substances.

[2] Throughout this guidance, the terms "pharmacists," "pharmacies," and "veterinarians" refer to those persons or entities that are State-licensed and operate in full compliance with State laws or regulations governing their practice.

(section 501(a)(2)(B)) of the FD&C Act (21 U.S.C. § 351(a)(2)(B)) and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)). However, FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist. This guidance, a continuation of this practice, is intended to provide additional information and clarity to veterinarians and pharmacists about FDA's current thinking with respect to animal drug compounding from bulk drug substances.

At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action for violations of the FD&C Act's requirements for approval, adequate directions for use, and cGMP requirements, for these products that meet the circumstances described below. The policies described in this document aim to protect human and animal health by limiting the use of animal drugs compounded from bulk drug substances primarily to situations in which a veterinarian is acting within a valid veterinarian-client-patient relationship (VCPR) [3] and there is no medically appropriate drug that is FDA-approved, conditionally approved, or on the Index of Legally Marketed Unapproved New Animal Drugs for Minor Species (indexed) to treat the animal. These policies are also intended to address FDA's concerns with compounding animal drugs from bulk drug substances, including significant concerns with such drugs when they:

- present particular human or animal safety concerns;
- are intended for use in food-producing animals[4];
- are copies of marketed FDA-approved, conditionally approved, or indexed drugs[5]; or
- are compounded without a patient-specific prescription (*i.e.*, office stock).

This guidance does not apply to animal drugs compounded for use in investigations of new animal drugs (21 CFR part 511) or to animal drugs compounded from marketed FDA-approved animal or human drugs, which are considered extralabel uses of such drugs. Compounding animal drugs from approved drugs is lawful if the requirements for extralabel use under the FD&C Act and FDA regulations are met (sections 512(a)(4) and (5) of the FD&C Act and 21 CFR part 530).

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[3] A valid VCPR is a relationship in which, among other things, the veterinarian: (1) has assumed responsibility for making medical judgments concerning the health of the animal patient and the need for medical treatment; (2) is familiar enough with the animal patient to make a general diagnosis of the medical condition; and (3) is readily available for follow-up should an adverse reaction occur or the prescribed therapy is not effective. For a complete definition of VCPR, see Title 21 of the Code of Federal Regulations (21 CFR) section 530.3(i).

[4] Examples of food-producing animals include cattle, swine, chickens, turkeys, sheep, goats, fish (excluding ornamental and aquarium fish) and other aquatic animal species, gamebirds and wildlife raised or harvested for food, and honeybees.

[5] For purposes of this guidance, an FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug is "marketed" if the drug manufacturer is making and offering the drug for sale. In addition, an FDA-approved human drug is not "marketed" if it is on the drug shortage list in effect under section 506E of the FD&C Act.

Additionally, this guidance does not address pharmacist, pharmacy, and veterinarian responsibilities under the Controlled Substances Act (21 U.S.C. §801, et. seq.) or applicable State laws.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in FDA guidance documents means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Legal Marketing Pathways for Animal Drugs

To be legally marketed, animal drugs, with few exceptions, must be approved by FDA under section 512 of the FD&C Act, conditionally approved by FDA under section 571 of the FD&C Act, or indexed under section 572 of the FD&C Act.[6]

A drug company seeking FDA approval of an animal drug application ("applicant" or "sponsor") must submit data and information that demonstrate, among other things, that the animal drug is safe and effective (or in the case of a generic drug, that the drug is bioequivalent to an already FDA-approved drug), properly manufactured, and accurately labeled. In addition to other approval requirements, sponsors who seek FDA approval of a drug for use in food-producing animals must submit data regarding the drug's potential for creating harmful residues in the meat, milk, eggs, and other edible products from treated animals. Based on these data, FDA may approve the drug with residue tolerances; withdrawal, withholding, and/or discard times; and other conditions of use to prevent products from treated animals that contain harmful residues from entering the food supply.

In addition to pre-market review, FDA-approved animal drugs are subject to requirements once they are on the market. For instance, sponsors must submit adverse event reports, including reports of product defects, and provide information to the FDA related to safety, effectiveness, and manufacturing quality throughout the lifetime of the product. These reports allow FDA to continue to monitor the safety and effectiveness of the drug after approval.

[6] Animal drugs that are not FDA-approved, conditionally approved, or indexed are considered "unsafe" and, therefore, "adulterated" under sections 512(a)(1) and 501(a)(5) of the FD&C Act.

The conditional approval[7] and indexing[8] processes provide alternative pathways to legal marketing that address the specific challenges associated with full FDA approval for drugs intended for minor uses,[9] minor species,[10] or for certain other new animal drugs. Like the approval process under section 512, these provisions protect human and animal health by requiring FDA review of data regarding safety and effectiveness before a drug that qualifies for these pathways can be legally marketed. They also provide for FDA to monitor safety and effectiveness after the product is on the market.

B. Animal Drugs Compounded from Bulk Drug Substances

The FD&C Act does not generally distinguish between compounding animal drugs from bulk drug substances and other methods of animal drug manufacturing.[11] The FD&C Act's requirements regarding drug approval, drug manufacturing, product quality, and labeling apply to animal drugs compounded from bulk substances, just as they apply to drugs manufactured by pharmaceutical companies.

Animal drugs compounded from bulk drug substances are not FDA-approved brand-name (*i.e.*, pioneer) drugs, nor are they FDA-approved generic drugs. As a result, animal drugs compounded from bulk drug substances have not been reviewed by FDA for evidence that they are safe, effective, properly manufactured, and accurately labeled. Further, when the compounded drug is for a food-producing animal, FDA has not reviewed evidence supporting conditions of use to protect against harmful drug residues. Finally, unlike sponsors of approved animal drugs, compounders are not required to report to FDA adverse events and product defects regarding animal drugs compounded from bulk drug substances.

The law permits compounding of animal drugs when the source of the active ingredient is a finished FDA-approved drug, and not a bulk drug substance. Specifically, the extralabel use

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[7] "Conditional approval" allows the sponsor to make a drug for a minor use or minor species and certain other new animal drugs available before collecting all effectiveness data necessary for approval of a new animal drug application (NADA) under section 512 of the FD&C Act, but after proving the drug is safe in accordance with the full FDA approval standard and showing that there is a reasonable expectation of effectiveness. FDA may permit the drug sponsor to keep the conditionally approved new animal drug on the market for up to 5 years, through annual renewals, while collecting the remaining required effectiveness data.

[8] "The Index" allows drug companies to market certain unapproved drugs for minor species. The Index is limited to drugs intended for use in nonfood-producing, minor species and some early non-food life stages of food-producing minor species.

[9] The term "minor use" means the intended use of a drug in a major species for an indication that occurs infrequently only in a small number of animals, annually, or in limited geographical areas. Section 201(pp) of the FD&C Act (21 U.S.C. § 321(pp)).

[10] The term "minor species" means animals other than humans that are not major species. Section 201 (oo) of the FD&C Act. Major species are dogs, cats, horses, pigs, cattle, turkeys, and chickens. Section 201 (nn) of the FD&C Act.

[11] Sections 503A and 503B of the FD&C Act (21 U.S.C. §§ 353a, 353b), which provide certain statutory exemptions for compounded human drugs, do not apply to drugs compounded for use in animals.

provisions of the FD&C Act (section 512(a) (4) and (5)) permit the compounding of animal drugs made from FDA-approved animal or human drugs, provided the conditions for legal extralabel use described in the FD&C Act and the implementing regulations at 21 CFR part 530 are met. These regulations state that, "[n]othing in this part shall be construed as permitting compounding from bulk drugs." 21 CFR 530.13(a).

Although numerous drugs are FDA-approved, conditionally approved, or indexed for use in animals, there are many different species of animals, each with a variety of diseases and conditions for which there are no FDA-approved, conditionally approved, or indexed drugs. While there are cases in which FDA-approved animal or human drugs can be used to treat an animal under the extralabel use provisions of the FD&C Act and related regulations, FDA recognizes that there are circumstances in which no FDA-approved, conditionally approved, or indexed drug (including the extralabel use of an FDA-approved animal or human drug) can be used to treat an animal with a particular condition. In those limited circumstances, an animal drug compounded from bulk drug substances may be a medically appropriate treatment.

III. POLICY

In developing this guidance, FDA has attempted to balance its concerns about the safety, effectiveness, and quality of animal drugs compounded from bulk drug substances, which have not gone through agency premarket review, with the need for such drugs when no FDA-approved, conditionally approved, or indexed drug can be used to treat the animal. Because of the safety benefits and protections of the pre-market review process and post-market monitoring of FDA-approved, conditionally approved, and indexed drugs, veterinarians should only use drugs compounded from bulk drug substances if FDA-approved, conditionally approved, or indexed drugs are not available to treat the animal. At this time and based on our current understanding of the risks of compounding animal drugs from bulk drug substances, FDA does not intend to take enforcement action for violations of the FD&C Act's requirements for approval, adequate directions for use, and cGMP requirements, for these products that meet the circumstances described below.

These policies are intended to address FDA's concerns about the compounding of animal drugs from bulk drug substances, including significant concerns with such drugs when they:

- Present particular human or animal safety concerns. Some examples include superpotency leading to animal overdose, microbial contamination, and drug formulations that present safety risks for the treated animals or for people handling or administering the animal drug.
- Are intended for use in food-producing animals. Drugs compounded from bulk drug substances for use in food-producing animals present safety concerns because of the potential for harmful residues to be present in food from treated animals. However, FDA recognizes that in some cases of toxicosis in food-producing animals, which can be life-threatening and affect large groups of animals that are all exposed to the same known toxin in their shared environment, an antidote compounded from a bulk drug substance may be the only treatment option and may be needed immediately to prevent animal suffering or

death. As described below, this guidance describes circumstances in which, at this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action for limited compounding of certain antidotes for food-producing animals. In these cases, we expect the prescribing veterinarian, acting within a valid VCPR, to establish appropriate, scientifically supportable withdrawal, withholding, and discard times[12] to ensure that animals treated with antidotes do not contain residues of the antidotes or the toxin,[13] or alternatively, to ensure that the treated animals do not enter the food supply.

- Are copies of a marketed FDA-approved, conditionally approved, or indexed drug. Compounding copies of such drugs presents a disincentive to submit a new animal drug application, an abbreviated new animal drug application for generic animal drugs, an application for conditional approval, or a request for indexing, further reducing the availability of legally marketed animal drugs.
- Are sold as office stock (as opposed to dispensed by a pharmacy upon receipt of a prescription[14] for an identified patient[15]). The Agency is concerned that compounded office stock potentially exposes larger numbers of animals to drugs of unproven safety, effectiveness, and manufacturing quality. However, FDA recognizes that in some cases an animal drug is needed immediately, and the time needed to compound a drug in response to an individual patient prescription may result in animal suffering or death. As described below, this guidance explains circumstances under which at this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action for limited compounding of office stock.

Consistent with these concerns, FDA has developed this draft guidance to explain when the Agency, at this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, does not intend to take enforcement action for violations of the FD&C Act's requirements for approval; adequate directions for use; and cGMP requirements. When pharmacies and veterinarians compound animal drugs from bulk substances as described below, FDA intends to generally defer to their State licensing boards for day-to-day

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[12] Sources of appropriate scientific information for setting withdrawal, withholding, and discard times could include, for example, relevant scientific literature or other evidence submitted by the person nominating the bulk drug substance to the List of Bulk Drug Substances for Use in Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals, information from the Food Animal Residue Avoidance & Depletion Program (FARAD) (www.farad.org), published textbooks, and peer-reviewed published journal articles.

[13] Food containing residues of the antidote or the toxin the antidote is intended to treat may be considered adulterated under section 402(a) of the FD&C Act (21 U.S.C. § 342(a)).

[14] For purposes of this guidance, a prescription includes the species of the animal patient, and identifying information about the animal patient (*e.g.*, patient name or identification number, room or cage number, *etc.*), and otherwise complies with applicable State law.

[15] For purposes of this guidance, a patient may be a single animal or a group of animals in a specific, identified location (e.g., cats in isolation ward X, dogs in kennel Y, or horses in stable Z).

oversight. Nonetheless, the Agency may take action when animal drugs compounded from bulk drug substances (1) present particular human or animal safety concerns or, (2) do not meet other manufacturing, product quality, labeling, or packaging requirements of the FD&C Act (*e.g.*, if the product is made under insanitary conditions or the labeling is false or misleading). Regardless of whether FDA intends to take action, FDA may refer a case to the appropriate state entity.

A. Compounding Pursuant to Patient-Specific Prescriptions for Nonfood-Producing Animals

At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances for any nonfood-producing animal for violations of the new animal drug approval requirements in sections 512 and 501(a)(5) of the FD&C Act, the adequate directions for use requirements in section 502(f)(1) of the FD&C Act, and the cGMP requirements in section 501(a)(2)(B) of the FD&C Act, provided:

1. The drug is compounded by or under the direct supervision of a veterinarian or a pharmacist in a State-licensed pharmacy or Federal facility;
2. The drug is compounded in accordance with the current United States Pharmacopeia and National Formulary (USP-NF) Chapters <795> "Pharmaceutical Compounding – Nonsterile Preparations" or <797> "Pharmaceutical Compounding-Sterile Preparations" and complies with the standards of all applicable USP-NF monographs (*e.g.*, a monograph for a bulk drug substance or a monograph for a compounded finished product);
3. The drug is dispensed by–
    (a) the pharmacy, after receipt of a prescription for a specific patient from the veterinarian acting within a valid VCPR, directly to the prescribing veterinarian or to the patient's owner or caretaker and is not dispensed or transferred to a third party (*e.g.*, distributor, retailer, veterinarian who did not write the prescription); or,
    (b) the veterinarian to the owner or caretaker of a patient in his or her practice, or to another veterinarian in his or her practice located in the same physical location;
4. The compounded drug is not a copy of a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug. For purposes of this guidance, a drug compounded from bulk drug substance is a copy if it has
    (a) the same active ingredient as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug, and
    (b) can be given by the same route of administration as the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug, and

(c) is in the same, similar, or easily substitutable strength[16] as the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug,

provided that there is not a difference between the compounded drug and the FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the identified patient, and the medical rationale is documented in the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record. For example, the patient requires a 1.0% solution and the FDA-approved solution is 0.1%;

5. If the compounded drug contains the same active moiety[17] as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug but as a different salt, ester, or other noncovalent derivative, there is a difference between the compounded drug and the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the identified patient, and the medical rationale is documented in the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record;

6. If the compounded animal drug has any of the same active ingredient moiety(ies) as one or more marketed FDA-approved, conditionally approved, or indexed animal drugs or FDA-approved human drugs, the compounder has determined and documented the reason(s) why the FDA-approved, conditionally approved, or indexed animal drug(s) or FDA-approved human drug(s) cannot be used as the source of the active ingredient(s).[18] One reason may be that the chemical properties of the FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug prevent its practical and effective use in compounding. For example, it may not be possible to compound an ophthalmic solution from an approved topical cream;

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[16] An easily substitutable strength is one where the same or similar dosage can be achieved by administration of fractional or multiple doses of a drug product.

[17] Active moiety means the molecule or ion, excluding those appended portions of the molecule that cause the drug to be an ester, salt (including a salt with hydrogen or coordination bonds), or other noncovalent derivative (such as a complex, chelate, or clathrate) of the molecule responsible for the physiological or pharmacological action of the drug substance. 21 CFR 314.3. For example, for the active ingredients erythromycin stearate, erythromycin ethylsuccinate, and erythromycin lactobionate, the active moiety is erythromycin.

[18] While the FD&C Act prohibits the extralabel use of conditionally approved and indexed animal drugs, under this guidance, at this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action when conditionally approved and indexed animal drugs are used as the source of the starting material for compounded animal drugs.

7. Upon becoming aware of any adverse event[19] or product defect[20] associated with an animal drug compounded from a bulk drug substance, the pharmacy or veterinarian that compounded the drug reports the event on Form FDA 1932a, which is available online, within 15 days; and
8. The labeling of the compounded drug includes the following, in addition to any other information required by State law:
    - name of drug;
    - strength of drug;
    - identifying information about the patient including the species of the patient, the name of the patient, identifier for the individual animal (*e.g.*, horse in stall X), or identification of a group of animals (*e.g.*, dogs in shelter kennel X);
    - the name, address, and contact information for the compounding pharmacy or veterinarian and name of prescribing veterinarian;
    - a beyond use date;
    - the statement, "Report adverse events to FDA using online Form FDA 1932a";
    - the statement, "This is a compounded drug"; and
    - the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

B. Compounding Without Patient-Specific Prescriptions ("Office Stock") for Nonfood-Producing Animals

At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action against the compounding of animal drugs from bulk drug substances as office stock for nonfood-producing animals for violations of the new animal drug approval requirements in sections 512 and 501(a)(5) of the FD&C Act, the adequate directions for use requirements in section 502(f)(1) of the FD&C Act, and the cGMP requirements in section 501(a)(2)(B) of the FD&C Act, provided:

1. The drug is compounded by or under the direct supervision of a veterinarian or a pharmacist in a State-licensed pharmacy or a Federal facility;
2. The drug is intended for use in a nonfood-producing species and is compounded from a bulk drug substance listed on FDA's "List of Bulk Drug Substances for Compounding

[19] Adverse events include those occurring in animals, reports of lack of effectiveness, or adverse events occurring in humans from product exposure.

[20] A product defect includes product quality issues in the drug product, product components, or product labeling. Examples of product defects include sterility failures, endotoxin failures, media fill failures, suspected cross contaminations, and incorrect potency.

Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals" (https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals-or-antidotes) described in the appendix to this guidance;

3. The drug is compounded in accordance with the current United States Pharmacopeia and National Formulary (USP-NF) Chapters <795> "Pharmaceutical Compounding – Nonsterile Preparations" or <797> "Pharmaceutical Compounding-Sterile Preparations" and complies with the standards of all applicable USP-NF monograph (*e.g.*, a monograph for a bulk drug substance or a monograph for a compounded finished product);
4. Except for a veterinarian dispensing the drug to the owner or caretaker of his or her animal patient or to another veterinarian in the same practice located in the same physical location, the drug is not dispensed or transferred by the pharmacy, pharmacist, or veterinarian to a third party (*e.g.*, distributor, retailer, or veterinarian in another practice);
5. Upon becoming aware of any adverse event or product defect associated with an animal drug compounded from a bulk drug substance, the pharmacy or veterinarian that compounded the drug reports the event on Form FDA 1932a, which is available online, within 15 days; and
6. The labeling of the compounded drug includes the following:
    - name of drug;
    - strength of drug;
    - the species of the patient(s) and indication(s) for which the drug will be used;
    - the name, address, and contact information for the compounding pharmacy or compounding veterinarian;
    - the name, address, and contact information for the veterinarian ordering the office stock;
    - a beyond use date;
    - the statement, "Report adverse events to FDA using online Form FDA 1932a";
    - the statement, "This is a compounded drug";
    - the statement, "Not for use in food-producing animals"; and
    - the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

C. Compounding Drugs for Use as Antidotes for Food-Producing Animals

At this time and based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action against the compounding of drugs from bulk drug substances intended for use as antidotes for treating

toxicoses in food-producing animals for violations of the new animal drug approval requirements in sections 512 and 501(a)(5) of the FD&C Act, the adequate directions for use requirements in section 502(f)(1) of the FD&C Act, and the current good manufacturing practices requirements in section 501(a)(2)(B) of the FD&C Act, provided:

1. The drug is compounded by or under the direct supervision of a veterinarian or a pharmacist in a State-licensed pharmacy or a Federal facility;
2. The drug is compounded from a bulk drug substance on the "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals" (https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals-or-antidotes);
3. The veterinarian establishes and documents a scientifically based withdrawal time that ensures residues of the antidote and the underlying toxin are not present in the animal at the time of slaughter or the veterinarian ensures the animal does not enter the food supply;
4. Upon becoming aware of any adverse event or product defect associated with a drug compounded from a bulk drug substance, the pharmacy or veterinarian that compounded the drug reports the event on Form FDA 1932a, which is available online, within 15 days; and
5. The labeling of the antidote includes all the following:
    - name of drug;
    - strength of drug;
    - the species of the patient(s) and indications for which the drug will be used;
    - the name, address, and contact information for the compounding pharmacy or compounding veterinarian;
    - the name, address, and contact information for the veterinarian ordering the antidote;
    - a beyond use date;
    - veterinarian-determined withdrawal time;
    - the statement, "Report adverse events to FDA using online Form FDA 1932a";
    - the statement, "This is a compounded drug"; and
    - the statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian."

APPENDIX

Request for Nominations to the List of Bulk Drug Substances for Compounding:

1. **Office Stock Drugs for Use in Nonfood-Producing Animals**

2. **Antidotes for Food-Producing Animals**

In a Federal Register notice published November 19, 2019, FDA established a public docket (FDA-2018-N-4626) so that interested parties could nominate bulk drug substances to a list of bulk drug substances for compounding office stock drugs for use in nonfood-producing animals or antidotes for food-producing animals (the List) and comment on nominated and evaluated bulk drug substances. This appendix provides information from the notice regarding the submission of nominations.

When Will FDA Include a Bulk Drug Substance on the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals?

FDA intends to include a bulk drug substance on the List (https://www.fda.gov/animal-veterinary/animal-drug-compounding/list-bulk-drug-substances-compounding-office-stock-drugs-use-nonfood-producing-animals-or-antidotes) when:

1. There is no marketed FDA-approved, conditionally approved, or indexed animal drug that can be used as labeled to treat the condition;
2. There is no marketed FDA-approved animal or human drug that could be used in an extralabel manner under section 512(a)(4) or (a)(5) of the FD&C Act and 21 CFR part 530 to treat the condition;
3. The drug cannot be compounded from a marketed FDA-approved animal or human drug consistent with 21 CFR part 530;
4. Immediate treatment with the compounded drug is necessary to avoid animal suffering or death; and
5. FDA has not identified a significant safety concern specific to use of the bulk drug substance in animals.

For bulk drug substances used to compound drugs intended for use as antidotes in food-producing animals, in addition to 1-5 above:

6. There is sufficient scientific information for the veterinarian to determine appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

How do I submit a nomination for the List?

You may submit nominations and comments to the docket through https://www.regulations.gov. The information to support nominations can be uploaded as attachments to your comment. The Docket No. is FDA-2018-N-4626.

You may submit written submissions to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All submissions must include the Docket No. FDA-2018-N-4626 for "List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals."

What information should I submit with the nomination?

You may nominate specific bulk drug substances for inclusion on the List. Each bulk drug substance should be submitted to the docket as its own, separate nomination. Submissions to the docket containing more than one bulk drug substance will not be considered an adequate nomination and will not be reviewed. In addition, nominations will only be evaluated if they are for specific active ingredients that meet the definition of a bulk drug substance. Nominated substances that do not meet this definition will not be evaluated for inclusion on the List.

For FDA to evaluate a bulk drug substance for inclusion on the List, you should submit the following information about the bulk drug substance and the compounded animal drug in the nomination:

1. **Confirmation That the Nominated Substance is a Bulk Drug Substance:**

   A statement that the nominated substance meets the definition of bulk drug substance.

2. **Description of the Nominated Bulk Drug Substance:**

   (a) chemical name(s);

   (b) common name(s);

   (c) chemical grade (*e.g.*, USP-NF, ACS, etc.);

   (d) description of the strength, stability, purity; and

   (e) how the nominated bulk drug substance is supplied (*e.g.*, powder, liquid).

3. **Description of the Animal Drugs That Will be Compounded with the Nominated Bulk Drug Substance:**

   (a) dosage form(s) into which the nominated bulk drug substance will be compounded (*e.g.*, capsule, tablet, suspension),

   (b) strength(s) of the compounded drug(s), and

(c) intended route(s) of administration of the compounded drug(s).

4. Information Requested for FDA to Evaluate Nominated Bulk Drug Substances for Inclusion on the List:

(a) The species and condition(s) that the drug to be compounded with the nominated bulk drug substance is intended to treat;

(b) A bibliography of scientific literature containing safety and effectiveness data for the drug compounded using the nominated bulk drug substance;

(c) A list of animal drugs, if any, that are FDA-approved, conditionally approved, or indexed for the condition(s) in the species that the drug compounded with the nominated bulk drug substance is intended to address;

(d) If there are marketed FDA-approved, conditionally approved, or indexed drugs that address the same condition(s) in the same species, an explanation, supported by relevant scientific literature or other evidence, of why a compounded drug is necessary (*e.g.*, why the FDA-approved drug is not suitable for a particular animal population);

(e) Confirmation, using supporting evidence, that there are no marketed FDA-approved animal or human drugs that could be prescribed in an extralabel manner under section 512(a)(4) and (a)(5) of the FD&C Act and 21 CFR part 530 to treat the condition(s) in the species that the drug compounded with the nominated bulk drug substance is intended to address;

(f) If the nominated bulk drug substance is an active ingredient in a marketed FDA-approved animal or human drug, an explanation, supported by appropriate scientific data or information, of why the animal drug cannot be compounded from the marketed FDA-approved animal or human drug under 21 CFR 530.13(b);

(g) An explanation, supported by relevant scientific literature or other evidence, of why the animal drug to be compounded with the nominated bulk drug substance must be available to the veterinarian for immediate treatment to avoid animal suffering or death. Nominations should include specific information documenting that animal suffering or death will result if treatment is delayed until a compounded animal drug can be obtained pursuant to a prescription for an individually identified animal; and

(h) A description of any human user or animal safety concerns associated with use of the nominated bulk drug substance or finished compounded drug for the condition(s) in the species that the compounded drug is intended to address. If there are concerns, an explanation, supported by scientific literature or other evidence, of why the concerns should not preclude inclusion of that nominated bulk drug substance on the List.

(i) For compounded drugs intended for use as antidotes to treat toxicoses in food-producing animals, relevant scientific literature or other evidence that demonstrates that the prescribing veterinarian has a basis for determining appropriate withdrawal, withholding, or discard time(s) for meat, milk, eggs, or any food which might be derived from the treated animal(s).

From: Adams, Michelle <Michelle.Adams@fda.hhs.gov>
Sent: Tuesday, October 20, 2020 8:06 AM

[EXTERNAL]: Michelle.Adams@fda.hhs.gov

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Hi Christine,

On behalf of FDA's Intergovernmental Affairs (IGA) team, thank you for your recent inquiry pertaining to FDA law and regulations regarding compounding veterinary drug products. In particular, you would like FDA to clarify the intention of 21 CFR 530.13(a) and its relationship with draft Guidance for Industry (GFI) #256, *Compounding Animal Drugs from Bulk Drug Substances*.

As described further below, the short answer is that the only compounding of animal drugs that is legal under the Federal Food, Drug, and Cosmetic (FD&C) Act is compounding from approved, finished dosage form drugs. Among other things, the Animal Medicinal Drug Use Clarification Act (AMDUCA) amended the FD&C Act to permit extralabel use by veterinarians using "compounded" products from approved, finished dosage form of drugs under conditions described in FDA regulations at 21 CFR Part 530 ("Extralabel Drugs Use in Animals"). The distribution of animal drugs compounded from bulk drug substances (BDS), by contrast, violates the FD&C Act and is not permitted under the extralabel use provisions of 21 CFR Part 530.

The regulation at 21 CFR 530.13(a) is not what explicitly prohibits compounding from BDS. The FD&C Act does not distinguish between compounding animal drugs from BDS and any other method of making or processing animal drugs. Consequently, compounded animal drugs must comply with the FD&C Act's approval and CGMP requirements, but this is not feasible for compounded drugs. The only exception to these requirements is that FDA considers compounding animal drugs using approved, finished drugs (rather than BDS) as the source of the active ingredients as a form of extralabel use, which is lawful under Section 512 of the FD&C Act and FDA regulations at 21 CFR Part 530.

The FDA's 2019 draft guidance on animal drug compounding, GFI #256, if finalized as written, would identify FDA's enforcement priorities regarding compounded animal drugs and would describe the circumstances under which we do not intend to take action in situations involving compounding animal drugs from BDS. FDA recognizes that a drug compounded from BDS may be the only treatment option for an animal because there may not be an FDA-approved product that can be used on-label or extralabel to treat the variety of illnesses and conditions that can occur in the many different species of animals treated by veterinarians. Therefore, FDA has issued a draft guidance for industry to address such circumstances, draft GFI #256, *Compounding Animal Drugs from Bulk Drug Substances*.

As noted above, if finalized, the guidance would identify FDA's enforcement priorities regarding compounded animal drugs and would describe the circumstances under which we do not intend to take action against compounding animal drugs from BDS. The draft guidance would not make compounding animal drugs from BDS legal under federal law, but instead describes how FDA would use its enforcement discretion to strike a balance between FDA's current understanding about the risks of animal drugs compounded from BDS and the need for those drugs when no FDA-approved drug can be used to treat the animal. The policies described in the guidance, if finalized, would focus FDA's enforcement resources on compounding from BDS that presents the greatest human and animal health concerns, while providing for access to animal drugs compounded from BDS when such drugs are the only appropriate treatment option.

As described in the draft guidance, FDA's enforcement priorities in regard to animal drugs compounded from BDS include drugs that

- Present particular human or animal safety concerns;
- Are copies of marketed FDA-approved, conditionally approved, or indexed drugs;
- Are compounded without a patient-specific prescription (*i.e.*, office stock); or
- Are intended for use in food-producing animals

Consistent with these priorities, the draft also describes FDA's general intentions to exercise its enforcement discretion and generally not take action against drugs compounded from BDS that

- Are dispensed under a prescription written by the treating veterinarian for an identified, specific nonfood-producing animal patient or specific group of patients, as long as the drug is not a copy of an approved, conditionally approved, or indexed product and the compounder has determined it cannot be made from an approved, conditionally approved, or indexed product; or
- Are ordered by a veterinarian as office stock and are made from BDS on a list developed by FDA of compounded drugs for nonfood-producing animal patients that veterinarians need on hand for immediate, emergency treatment of patients; or
- Are for food-producing animals and are made from BDS on a list developed by FDA of BDS used to prepare antidotes for treatment of poisoning or toxicosis.

As described in the draft guidance, to promote the quality of drugs compounded from BDS, they should meet the standards for compounding in the U.S. Pharmacopeia (USP), or applicable state requirements that exceed the USP standards.

Thank you again for your interest in this matter. We would be happy to talk with you on this issue if you have any additional questions. Please do not hesitate to contact our Intergovernmental Affairs team at IGA@fda.hhs.gov.

Regards,
Michelle

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Intergovernmental Affairs (IGA)
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
Tel: 240.672.6569
Michelle.Adams@fda.hhs.gov

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california **pharmacists** association

August 26, 2020

Maria Serpa, Pharm D
Chair, Enforcement and Compounding Committee
California Board of Pharmacy
2720 Gateway Oaks Dr, Ste. 100
Sacramento, CA 95833

Dear Dr. Serpa,

The California Pharmacists Association (CPhA), is respectfully requesting that you add an item to the agenda at the October 27, 2020 meeting regarding the issue of preparing compounded drugs for animals from bulk active pharmaceutical ingredients (APIs) in relation to 21 CFR 530.13(a).

CPhA is in receipt of "orders of correction" issued to a number of our members from Board inspectors stating that licensees are to "update the practice", "please state how pharmacy will comply with this law", "please find a path for compliance" and "PIC educated on 21 CFR 530.13(a)." While CPhA is appreciative that the Board is following through on its commitment to educate licensees, as opposed to being punitive, CPhA is concerned that Board inspectors are misinterpreting the stated federal regulation.

21 CFR 530.13(a) states in full that *"This part applies to compounding of a product from approved animal or human drugs by a veterinarian or a pharmacist on the order of a veterinarian within the practice of veterinary medicine. Nothing in this part shall be construed as permitting compounding from bulk drugs."*

This section is part of a larger set of regulations dealing with the Animal Medicinal Drug Use Clarification Act (AMDUCA) of 1994. Specifically, 530.13 deals with "extralabel use from compounding of approved animal or human drugs." The last sentence, per the various orders of correction from Board inspectors, seem to be the nexus of the confusion. Through the orders of correction, the Board inspectors seem to be indicating that this regulation prevents a compounding pharmacist's ability to compound veterinary drugs from bulk drug substances.

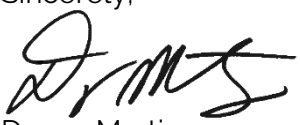
CPhA has consulted with legal counsel and we believe this regulation is saying is that this particular regulation, 21 CFR 530.13(a), should not be used as a basis for compounding from bulk drug substances. However, this is not meant to outlaw or forbid compounding from bulk drug substances, as nowhere in AMDUCA or any other regulation at the state or federal level does it state such a prohibition. In fact, the FDA has a current Guidance for Industry (GFI) document in draft form that states conditions for compounding from bulk drug substances. This GFI (CVM GFI #256) is accepting comments from the public and from stakeholders through October 15, 2020.

CPhA is concerned that because orders of correction have been issued to our members, the Board is telling pharmacists they have done something wrong or illegal and corrective action is required of them. As the Board is aware, failure to take remedial action on these orders will result in disciplinary action from the Board.

CPhA would appreciate the opportunity to discuss this issue at the October 27 Enforcement and Compounding meeting to get clarification from the Board on what is expected from licensees in relation to veterinary compounding from bulk drug substances.

Should you have any questions about our request, please don't hesitate to contact me at dmartinez@cpha.com or at (916) 779-4519. Thank you.

Sincerely,



Danny Martinez
Director, Regulatory Affairs and Policy Development
California Pharamcists Association

Attachment 3

I just received an Accusation in the mail. What is this?

An accusation is a pleading that details violations of Pharmacy Law or other violations substantially related to the practice of pharmacy that are alleged to have been committed by the licensee(s).

Why am I receiving an Accusation?

As part of the Board's consumer protection mandate, board staff conduct investigations into violations of Pharmacy Law and other related provisions. If violations are confirmed, the Board has several different options. When violations are serious and substantial, the Board will refer the matter to the Office of the Attorney General. The assigned Deputy Attorney General will review the investigation, and if deemed appropriate, prepare an accusation.

Do I need to hire an attorney?

You are not required to hire an attorney to resolve the matter, but you may choose to do so.

Will the Board have an attorney?

Yes, the Board is represented by the Office of the Attorney General. The name and contact information of the attorney representing the Board is included on the accusation. You are welcome to contact the assigned Deputy Attorney General if you have questions about the process.

What are my rights?

Under the administrative procedures act, you have the right to due process. Due process is required to ensure that you, as a respondent, are afforded a fair process including the opportunity to contest the violations as well as provide the Board with proof of mitigation and rehabilitation since the violations occurred.

What if I disagree with the information included in the Accusation?

Included with accusation are other important documents, one of which is called a Notice of Defense. If you would like to contest the accusation or would like to be considered for a stipulated settlement, you must complete and return the Notice of Defense.

What happens after I return the completed Notice of Defense

The Deputy Attorney General representing the Board will contact you or your attorney to discuss possible dates to hold a hearing on the matter or ask you if you are interested in settling the matter through a stipulated agreement.

Do I have the right to have access to the Board's investigation and other relevant items?

Yes, under the administrative procedures act, all parties are required to provide relevant documents, as well as witness lists, on request. If you would like to make such a request, you can do so by contacting the assigned Deputy Attorney General.

What is a stipulated settlement?

A stipulated settlement is an agreement between the Board and Respondent(s)on the outcome of the accusation. This agreement is then sent to the Board Members, who serve as the final decision maker in the matter. The Board's Disciplinary Guidelines provide information about the types of violations and general categories of penalties association with applicable violations. Board staff, through its assigned Deputy Attorney General will convey settlement terms consistent with these Guidelines.

Is the information I can provide that will help settle the case?

The Board's Disciplinary Guidelines detail out the types of mitigation that is helpful in determining the appropriate outcome. Examples of mitigation include performance appraisals from your employer, treatment provide reports, letters from licensees speaking to your character or rehabilitation. Review the Disciplinary Guidelines for additional information.

If the matter does not settle, what should I expect during a hearing?

An administrative law judge will preside over the hearing and can assist you with procedural questions, but will not provide any legal advice. You have the right to be represented by an attorney at the hearing, however one will not be provided for you. In general, you will have an opportunity to present your case, including submission of documents and other physical evidence, as well oral testimony from you and any other witnesses, under oath. The Deputy Attorney General will present the case on behalf of the Board. Following the hearing the judge will issue a proposed decision. The proposed decision will be sent to Board Members, who will serve as the final decision maker in the matter.

When will I know the outcome of the hearing?

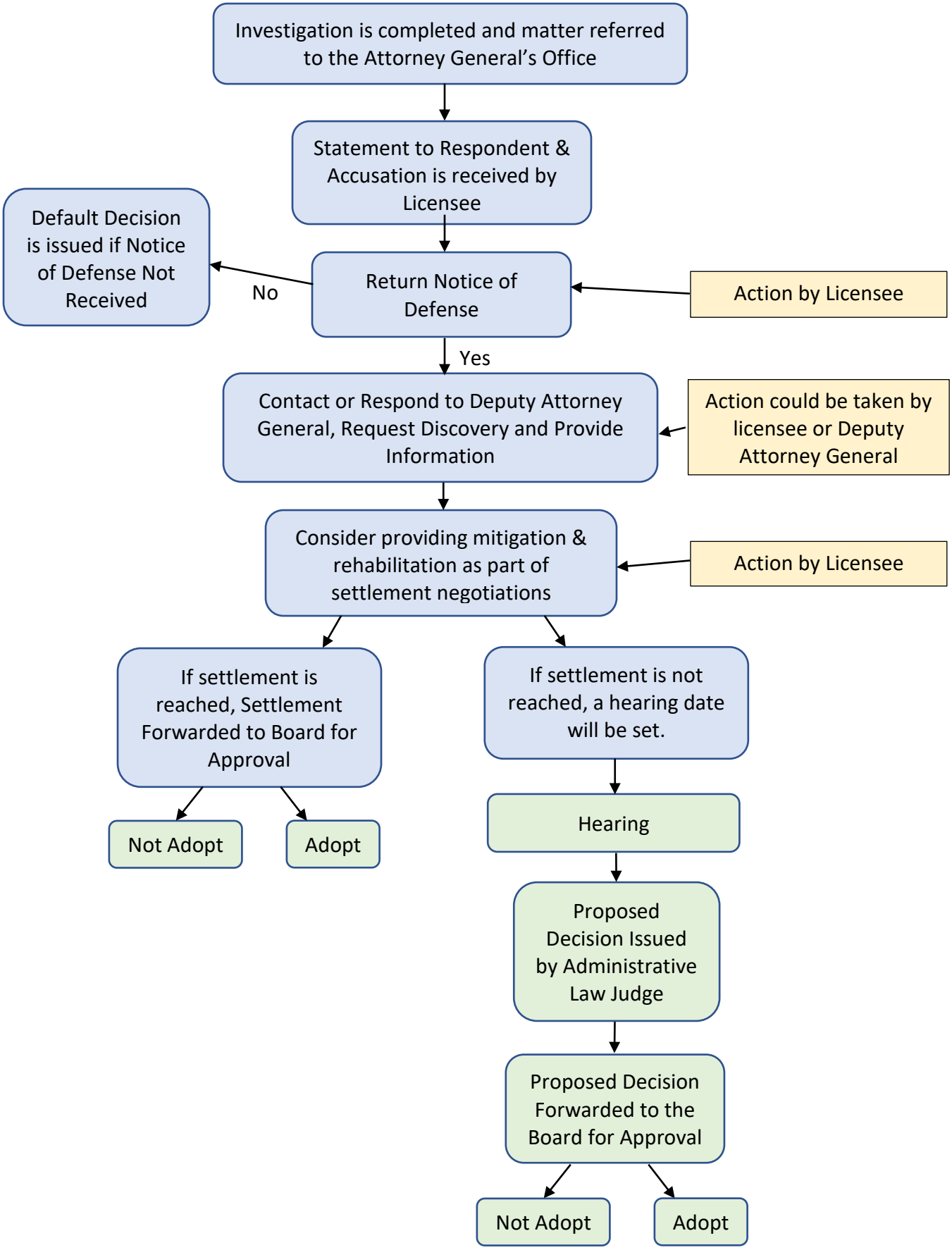
Typically, you will be advised of the outcome of the case after the Board Members complete their review and action on the matter, generally somewhere around 60-120 days after the hearing.

What happens if I don't return the Notice of Defense?

If you don't return the Notice of Defense, a default decision will be issued that will revoke your license.

The above information is intended to provide you with a general understanding of the administrative case process. It is not intended to you with a full and comprehensive understanding nor should it be interpreted to be legal advice.

ADMINISTRATIVE CASE PROCESS



Attachment 4

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MEMORANDUM

DATE	October 20, 2020
TO	Maria Serpa, Chair of Enforcement and Compounding Committee via Anne Sodergren, Executive Officer California State Board of Pharmacy
FROM	Eileen Smiley, Attorney III
SUBJECT	Alternative Enforcement Model

The purpose of this memorandum is to discuss and analyze the proposed alternative enforcement model that is under consideration by the Board. The purpose of this proposal is to attempt to settle some cases before an operative pleading is filed to achieve time and costs savings to the Board and licensees or applicants.

Latest Proposal

The latest proposal is to add section 4300.2 to the Business and Professions Code (BPC). All section references in this memorandum refer to the proposed section 4300.2 of the BPC. The current proposal encompasses two board members (one professional member and one public member) participating in settlement negotiations after completion of an investigation but prior to the filing of an operable pleading. To participate in the process, the licensee must agree to waive the administrative adjudication provisions of the Administrative Procedure Act (Act). The licensee then may submit mitigation and rehabilitation evidence as specified in the board's Disciplinary Guidelines. The proposed model establishes time deadlines to complete a Stipulated Settlement and Disciplinary Order based on the findings of the investigation. If the parties cannot agree to the terms of the Stipulated Settlement and Disciplinary Order within the time periods set out in paragraph 5 of the proposal, the staff may proceed with filing the appropriate disciplinary pleading.

Sections 2 and 3 of the Proposal

Currently, after completion of the investigation, enforcement staff provides the licensee with its findings of violation(s) including some of the evidence found and provides the licensee with 14 days to provide additional information as part of the investigative process. Upon receipt of any additional information provided by the licensee, the enforcement staff evaluates the findings. Supervising and

executive staff review the matter and determine whether to refer the matter to the Office of the Attorney General. This part of the investigative process will not change.

Under proposed section 4300.2(3), the licensee would have 15 days after being advised that a matter will be referred to the Office of the Attorney General to indicate in writing their desire to participate in this process and waive the provisions of the Administrative Procedure Act (Act). Proposed section 4300.2(3) should be amended to reflect that the 15-day election period begins after a licensee is informed that a referral will be made to the Office of the Attorney General. Respondents may waive their rights under the Act, but such a waiver must be an informed waiver and signed by the licensee. Generally, the Accusation or Statement of Issues sets out the alleged conduct in greater detail and stipulated settlements generally refer to the operative pleading for the details to ensure a licensee is making an informed waiver of the rights under the Act. The staff might have to create a new document that provides more detail than the notice of violation(s) typically given to licensees during the investigative process. This new document will serve as the disclosure document that a potential respondent would receive to constitute an informed waiver of the rights afforded by the Act. Also, although an Accusation may not have to be drafted, the Stipulated Judgment will have to incorporate in some fashion the causes of action resulting in the stipulated settlement presumably by the Attorney General's office, which will entail some of the same attorney costs to draft as an Accusation. If time and cost savings are of primary importance, then this process may not realize complete cost savings, especially if settlement is not reached through this alternative enforcement process as the Board would be incurring additional enforcement-related costs.

Section 4 of the Proposal

Paragraph 4 of proposed section 4300.2(4) provides that licensees should submit evidence of rehabilitation and mitigation to facilitate settlement. Implicit in this statement is that the licensee must admit, for purposes of this process, the violations alleged. If a licensee wants to challenge factual matters or the application of the law to the facts determined during the investigation then the case should go through the process under the Act. The waiver signed by the licensee should explicitly state that for purposes of this process, the licensee is admitting the allegations as found during the investigation. The waiver should also explicitly state that any admission to the findings cannot be used against the licensee in later proceedings if the parties fail to agree on a Stipulated Judgment and Disciplinary Order (Settlement).

The proposal does not specify how mitigation and rehabilitation evidence will be submitted - solely through a paper process or some type of hearing. From an evidentiary standpoint and monitoring purposes, a paper process is preferable to show new policies or changes implemented as a result of the violations found. Because a committee of the Board would be involved, if there is a hearing component such hearing must be conducted in public during a public meeting, although deliberation on the matter would occur in closed session. Also, inclusion of a hearing component raises issues such as who will conduct the hearing, what evidentiary rules would apply and whether statements or

evidence considered by the Committee are admissible if the parties cannot reach agreement on a Settlement. As the hearing is conducted in public, arguably a judge would be required to swear in witnesses and preside over the hearing. Further, a public record of the hearing would be made. Typically, under the Act, matters between attorneys through the settlement process are not public. That could change with a hearing component. As a practical matter, if the hearing conducted via the alternative enforcement model does not result in a Settlement, or the Board subsequently non-adopts a stipulated settlement, under the proposal, the matter will transition to the APA process. Legal issues could arise at this point. Specifically, the public record created through the alternative enforcement model exists. Typically, an administrative law judge presiding over a disciplinary matter is not privy to settlement negotiations or other relevant information to ensure impartiality. A hearing component also would raise practical issues of the evidentiary and probative value of statements made by Committee members that may not reflect the Board's overall opinion on the matter and whether evidence introduced at a first hearing that may not be relevant to an adjudication under the Act. Evidence from the first hearing could unduly complicate the record at the later disciplinary proceeding and on appeal if a writ is filed appealing the administrative decision.

In addition to the issues raised above, it appears that inclusion of a hearing also runs contrary to the stated policy goals of the alternative model - - to reduce costs and the time of resolving certain matters. If the parties cannot agree on a Settlement, inclusion of a hearing component would impose additional costs on the board and potentially to the licensee in permissible cost recovery from having two hearings on the same matter. It could also delay ultimate determination of the matter.

Time Delays

Because one purpose of the proposal is to reduce the delay in resolving some matters, there should be hard deadlines for the licensee to submit mitigation and rehabilitation evidence (Section 2) which is currently silent. Section 5 provides that the Stipulated Judgment and Disciplinary Order must be agreed to within 60 days of the licensee's signed waiver but gives the committee the power to extend this time period. This power should be used sparingly or it could result in significant time delays if the parties do not agree to a Settlement.

Recusal Issues-Participating Board Members

Paragraph 7 of proposed section 4300.2 provides that if a Settlement is reached that the participating board members in the process would be recused from voting on the approval of the final Stipulated Settlement and Disciplinary Order. However, the proposed section is silent about the recusal of the participating board members from participating in voting on a later disciplinary proceeding if the parties do not agree to a Settlement. The participating board members in the settlement process should be recused from both voting on any agreed Settlement and in a later proceeding if the parties fail to agree to a Settlement because of their participation in the settlement process. As a practical

matter, this could raise quorum issues if other board members in a case must recuse themselves for other reasons.

Conclusion

Although, counsel does not see any legal prohibitions in including an alternate method of resolving uncontested matters in an expeditious manner prior to filing an Accusation or Statement of Issues if the appropriate statutory changes are made, as outlined above, there are some legal issues and practical considerations issues that must be considered before implementing such a proposal that includes board members as well as a hearing component.

Proposal to Add Section 4300.2

Notwithstanding the provisions of Government Code section 11415.60(b), the Board may offer, and a licensee may accept, a stipulated agreement to license discipline without and in advance of the filing of an accusation or other agency pleading, under the following conditions:

1. Enforcement staff or investigators for the board conducted an inspection or investigation as provided for in this chapter and substantiated violations of law.
2. Enforcement staff at the board provides the licensee with findings of the violations in writing, and a notice of possible eligibility for a pre-filing settlement.
3. The licensee, within 15 days of being provided with the findings of the violations, notified the board in writing of the licensee's willingness to waive the administrative adjudication provisions of the Administrative Procedure Act, including notice and hearing requirements, and to consider a pre-filing settlement as an alternative to action taken on the basis of a pleading. The board may, for good cause, extend the deadline for the licensee to respond in writing beyond 15 days.
4. In order to be eligible for consideration for a pre-filing settlement, the licensee must submit mitigation and rehabilitation information as specified in the board's Disciplinary Guidelines. A committee consisting of the Executive Officer and two members of the Board, one (1) public member and one (1) licensee member, will consider the mitigation and rehabilitation information and may, in their sole discretion, extend a pre-filing settlement offer to the licensee. Any settlement offer shall be based on the violations substantiated by the investigation, and shall be consistent with the board's Disciplinary Guidelines. Nothing in this section should be construed to limit or prohibit any and all good faith settlement negotiations.
5. The proposed settlement agreement in the form of a Stipulated Settlement and Disciplinary Order, and incorporating the findings of the violations, must be agreed to in writing within sixty (60) calendar days of the date of the licensee's waiver. The committee may agree to extend this time period at their exclusive discretion. Any such extension must be in writing, and shall be granted only for good cause or when good faith settlement discussions are ongoing.
6. If the parties have failed to come to agreement within the time limits set forth in paragraph 5, the board shall proceed to file the appropriate disciplinary pleading.
7. The Stipulated Settlement and Disciplinary Order is contingent upon approval by the board itself, except that the members of the committee shall recuse themselves and not participate or vote on the Stipulated Settlement and Disciplinary Order.
8. If the Stipulated Settlement and Disciplinary Order is adopted by the board itself, it shall be a public document in accordance with Business and Professions Code section 27 and the California Public Records Act.
9. If the board itself fails to adopt the Stipulated Settlement and Disciplinary Order, the Stipulated Settlement and Disciplinary Order shall be of no force or effect, and the board itself shall not be disqualified from further action by having offered or considered the Stipulated Settlement and Disciplinary Order.
10. If the board itself fails to adopt the Stipulated Settlement and Disciplinary Order, the board will file the appropriate disciplinary pleading. Nothing in this section should be construed to limit the ability of the parties to negotiate and enter into a Stipulated Settlement and Disciplinary Order after the disciplinary pleading has been filed.

Attachment 5

Enforcement Workload Statistics FY 2020/21 *(Corrected)*

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	592	0	0	0	592
Closed	561	0	0	0	561
Pending	1,649	0	0	0	1,649
Average Days for Investigation	227	0	0	0	57

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	820	0	0	0	820
Drug Diversion / Fraud	175	0	0	0	175
Prescription Drug Abuse	62	0	0	0	62
Compounding	67	0	0	0	67
Outsourcing	24	0	0	0	24
Probation / PRP	28	0	0	0	28
Enforcement	187	0	0	0	187
Criminal Conviction	286	0	0	0	286

Application Investigations *(Corrected)*	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	51	0	0	0	51
Closed					
Approved	47	0	0	0	47
Denied	8	0	0	0	8
Total Closed (includes withdrawn)	***74***	***0***	***0***	***0***	***74***
Pending	89	0	0	0	89

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	124	0	0	0	124
Non-Jurisdictional	69	0	0	0	69
No Violation	70	0	0	0	70
No Further Action	47	0	0	0	47
Other - Non-Substantiated	6	0	0	0	6
Subject Educated	34	0	0	0	34

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	48	0	0	0	48
Citations Issued	226	0	0	0	226
Proof of Abatement Requested	53	0	0	0	53
Appeals Received	17	0	0	0	17
Dismissed	0	0	0	0	0
Total Fines Collected	***$204,815***	***$0***	***$0***	***$0***	***$204,815***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	48	0	0	0	48
Pleadings Filed	56	0	0	0	56
Pending					Quarter Ending
Pre-Accusation	117	0	0	0	117
Post-Accusation	205	0	0	0	205
Total Pending	**327**	**0**	**0**	**0**	**327**
Total Closed	50	0	0	0	50

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	0	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	9	0	0	0	9
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***0***	***0***	***0***	***11***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	12	0	0	0	12
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	5	0	0	0	5
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	4	0	0	0	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***22***	***0***	***0***	***0***	***22***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	10	0	0	0	10
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	2	0	0	0	2
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	13	0	0	0	13
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***25***	***0***	***0***	***0***	***25***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	5	0	0	0	5
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	1	0	0	0	1
Wholesaler	1	0	0	0	1
Pharmacy	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	2	0	0	0	2
Total	***10***	***0***	***0***	***0***	***10***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***0***	***0***	***0***	***1***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$448,360***	***$0***	***$0***	***$0***	***$448,360***
Cost Recovery Collected	***$380,388***	***$0***	***$0***	***$0***	***$380,388***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	0	0	0	5
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	0	0	0	0	0
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	236	0	0	0	236
Intern Pharmacist	13	0	0	0	13
Pharmacy Technician	29	0	0	0	29
Designated Representative	2	0	0	0	2
Wholesaler	3	0	0	0	3
Pharmacy	73	0	0	0	73
Sterile Compounding	2	0	0	0	2
Total	***358***	***0***	***0***	***0***	***358***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	2	0	0	0	2
Probation Site Inspections	121	0	0	0	121
Probation Terminated / Completed	7	0	0	0	7
Referred to AG for Non-Compliance	0	0	0	0	0

As of 9/30/2020

California State Board of Pharmacy
SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

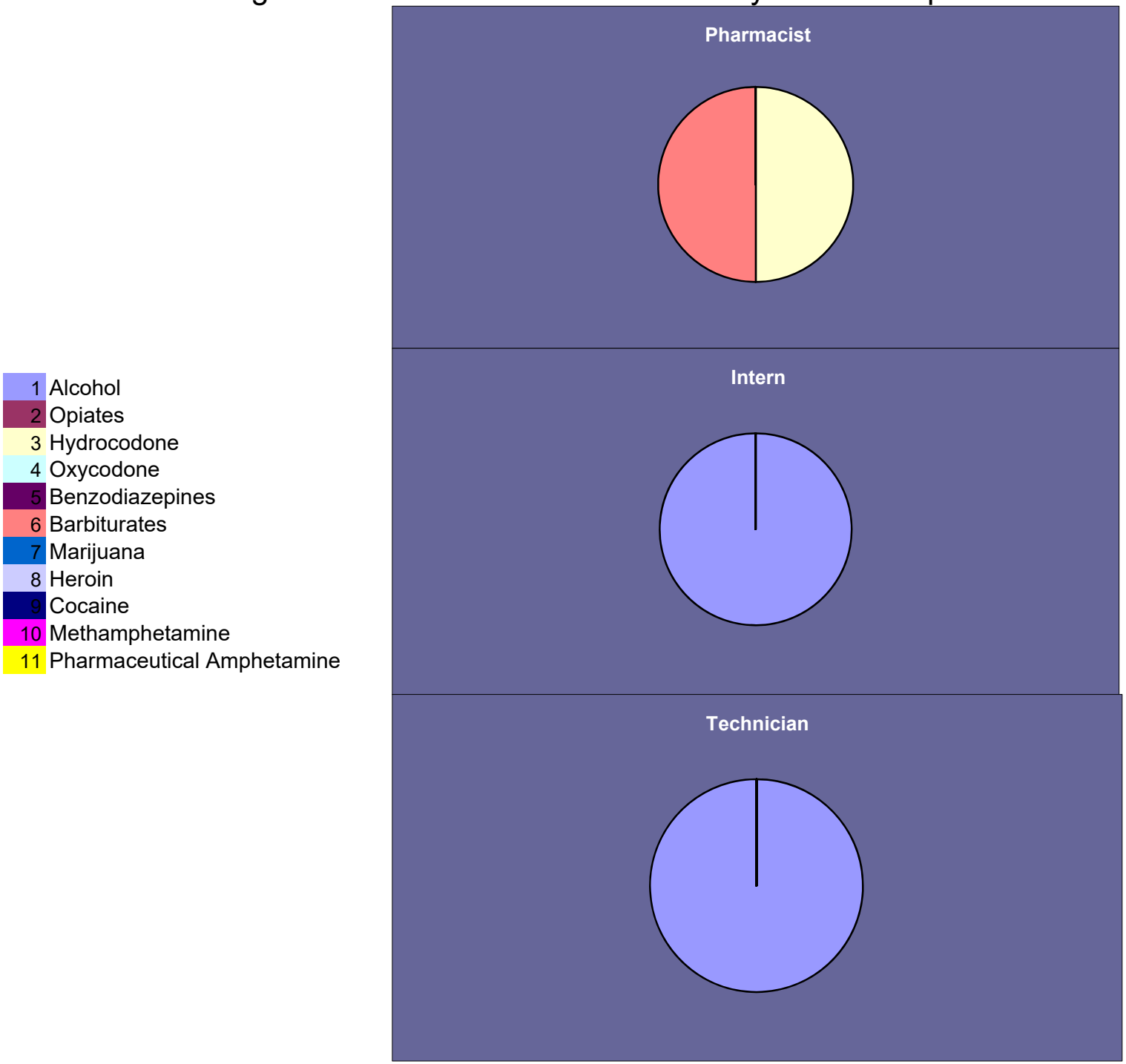
Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	2				2
PRP Under Investigation					
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes					
New Probationers					
Pharmacists	3				3
Intern Pharmacists	1				1
Pharmacy Technicians	2				2
Total New Probationers	6				6
PRP Participants and Recovery Agreements					
Total PRP Participants					N/A
Recovery Agreements Reviewed					
Probationers and Inspections					
Total Probationers	80				N/A
Inspections Completed	53				53
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)					
Drug Tests					
Drug Test Ordered (PRP and Probationers)	744				744
Drug Tests Conducted (PRP and Probationers)	721				721
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	1				1
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3				3
Termination from PRP	1				1
Probationers Referred for Discipline					
Closure					
Successful Completion (PRP and Probationers)	1				1
Termination (Probation)					
Voluntary Surrender (Probation)	4				4
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	23				23
Other (PRP)	2				2
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders.

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol					
Ambien					
Opiates	1				1
Hydrocodone					
Oxycodone					
Morphine	1				1
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	2				2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Drug Of Choice - Data entered from July 2020 to September 2020



Printed on 10/19/2020

Board of Pharmacy

Citation and Fine Statistics FY20/21

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	60	0	0	0	60
Pharmacist no Fine	38	0	0	0	38
Pharmacy with Fine	42	0	0	0	42
Pharmacy no Fine	47	0	0	0	47
Pharmacist-in-Charge with Fine*	29	0	0	0	29
Pharmacist-in-Charge no Fine	31	0	0	0	31
Pharmacy Technician with Fine	17	0	0	0	17
Pharmacy Technician no Fine	1	0	0	0	1
Wholesalers	3	0	0	0	3
Designated Representative	2	0	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	6	0	0	0	6
Miscellaneous**	12	0	0	0	12
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	0	0	0	0	0

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	31%	1716 - Variation from prescription	28%	1716 - Variation from prescription	24%
1761(a)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Schedule II,	17%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	16%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	15%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	10%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	15%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	9%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	7%	1761(a)/11164(a) - No pharmacist shall compound or dispense	9%	1761(a)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Schedule II,	9%
1761(a)(b)/11164(a)/11152 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Sche	7%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	9%
11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	7%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept	6%	1304.11(b) - Inventory requirements-Initial inventory date	9%
11164(a)/1761(a) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	7%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	6%	1751.8(d)(1) - Beyond Use Dating for Sterile Compounded Drug Products; The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug prep	6%
1764/56.10 - Unauthorized disclosure of prescription and medical information	5%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	6%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%
1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	5%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	4%	1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission…	6%