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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
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Enforcement and Compounding Committee Report

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The Board will review a summary of the committee's work at its August 25, 2022, and October 4, 2022, Enforcement and Compounding Meetings as well as updates for discussion and action as necessary.

a. Discussion and Consideration of Regulation of Surgical Clinics Pursuant to Business and Professions Code section 4190

Relevant Law

Business and Professions Code (BPC) section 4190 provides that a "clinic" means a surgical clinic licensed pursuant to Health and Safety Code (HSC) section 1204(b)(1), an outpatient setting accredited by an agency as defined in HSC section 1248, or an ambulatory surgical center certified to participate in the Medicare Program as specified. This section also establishes some of the authorities vested with such a clinic licensed by the Board and provisions for drug distribution and other requirements.

BPC section 4191 specifies legal requirements that a clinic must comply with as a precursor to licensure, including the development of policies and procedures to implement laws and regulations.

BPC section 4192(a) establishes a requirement for a consulting pharmacist to be retained to approve policies and procedures in conjunction with the professional director and the administrator. Further, the consulting pharmacist is required to visit the clinic regularly and, at least quarterly, to review the application of policies and procedures as specified and to certify in writing on a quarterly basis if the clinic is, or is not, operating in compliance with legal requirements.

Background

During public comment received as part of the April 26-27, 2022, Board Meeting, members received comment suggesting that surgical clinics are not being inspected on a quarterly basis by a consulting pharmacist as required. It was suggested that the Board educate licensees about the requirement established in BPC section 4192 related to the consultant pharmacist. Following public comment Member Butler requested that the issue be included on the agenda of the Enforcement and Compounding Committee meeting.

As part of the Committee's August meeting, members considered several policy questions related to the Board's regulation of surgical clinics and efforts to educate such entities about legal requirements. Members also spoke in support of developing a requirement for a surgical clinic to confirm, in writing, compliance with the consulting pharmacist requirement and noted that the requirement could be facilitated through the annual renewal process. Members also spoke in support of developing a self-assessment process and that as part of the self-assessment, data collection on sterile compounding practices would be appropriate.

Following that meeting, inspector staff performed inspections at 14 surgical clinics which revealed the following:

1. The most frequent discussion items and orders or corrections included:
    a. Failure to update the Board regarding a change in professional director (BPC 4192(d).
    b. Failure to update policies and procedures to reflect current laws (BPC 4191(a)).
    c. Purchasing controlled substances using a doctor's DEA registration in lieu of obtaining a DEA registration under the surgical clinic license (21 CFR 1301.12(a)).
    d. Lack of documentation of the consulting pharmacist approving policies and procedures in conjunction with the professional director and administrator (BPC 4192(a)).
    e. Quarterly inventory reconciliation was not performed (CCR 1715.65).
    f. The consultant reports did not include a certification certifying whether the clinic was or was not in compliance (BPC 4192(b).

Inspectors also reported that 50% of the surgical clinics compound sterile preparations for immediate use, usually administered within one hour. No clinics used a primary engineering control for compounding. Compounding occurred in various locations including in a designated area on the counter, in the medication room, on the counter in the supply room, in the operating and recovery room, and on the counter of the pre-op supply area counter. Nurses were generally performing the compounding.

In addition, inspector staff offered comments for members consideration at its October 4 meeting.

1. There does not appear to be consistency regarding what is reviewed for compliance by a consulting pharmacist.
2. Many of the policies and procedures did not appear to have been reviewed or updated for several years.

Summary of Committee Consideration and Discussion

As part of the October 4 meeting, members continued discussion on the Board's regulation of surgical clinics and the subsequent inspection findings. Members noted that the findings support the need to further refine the Board's regulation of surgical clinics and the development of a self-assessment process to facilitate compliance.

Members reviewed a draft statutory proposal developed following the Committee's prior discussion including every renewal requirement confirmation of compliance with quarterly inspections by the consultant pharmacist. Further renewal every odd numbered year submission the most recent self-assessment as well. The proposed changes would further establish the self-assessment requirement.

> **Committee Motion**: Recommend the Board pursue statutory changes to BPC 4204 and 4192 as it relates to surgical clinics, as presented in the meeting materials.

Attachment 1 includes the draft statutory language recommended by the Committee.

b. Discussion and Consideration of Potential Draft Regulations Including a Self-Assessment Form Related to Outsourcing Facilities

Relevant Law

Business and Professions Code sections 4129 – 4129.9 generally establish the licensure and operational requirements for Outsourcing Facilities.

Background

In response to changes in Pharmacy Law related to outsourcing facilities and new authority for such licensed entities to dispense patient-specific compounded preparations pursuant to a prescription, the Board developed FAQs to assist licensees in understanding the relevant provisions of Pharmacy Law applicable to patient-specific compounded preparations.

As part of its August 2022 meeting, the Committee considered if additional action

was appropriate to ensure the Board's regulated outsourcing facilities have a clear understanding of the requirements to operate within or into California related to patient-specific requirements. Members noted agreement with the development of regulations and a self-assessment process.

Summary of Committee Consideration and Discussion
As part of the October 4 meeting, the Committee continued its discussion and considered updated draft regulation language and a self-assessment form for the Committee's consideration.

> **Committee Motion**: Recommend initiation of a rulemaking to add Title 16, California Code of Regulations sections 1750 and 1750.1 Related to Outsourcing Facilities. Delegate to the Executive Officer authority to make any technical or non-substantive changes that are identified through the pre-review process and release for the public comment period. If no adverse comments are received during the 45-day comment period and no hearing is requested, authorize the executive officer to take all steps necessary to complete the rulemaking, make any nonsubstantive changes to the package and adopt the regulation.

Attachment 2 includes a copy of the proposed regulation language and self-assessment form.

c. Discussion and Consideration of Proposed Change to Board's Citation and Fine Authority Related to Unlicensed Activity

Relevant Law
BPC section 125.9 provides authority for the Board (and other specified agencies) to establish by regulation a system for the issuance of a citation to a licensee, which may contain an order of abatement or an order to pay an administration fine. The section generally also provides that the fine assessed shall not exceed five thousand dollars for each inspection or investigation.

BPC section 148 provides authority for the Board (and other specified agencies) to establish by regulation a similar system for the issuance of an administrative citation to an unlicensed person who is acting in the capacity of a licensee or registrant under the Board's (or other agency's) respective jurisdiction.

BPC section 4314 provides additional authority for the Board to issue citations containing fines for violations of specified sections of the Health and Safety Code and Business and Professions Code section 733.

California Code of Regulations sections 1775 – 1775.4 include the Board's regulations further defining the Board's citation and fine program.

BPC section 4316 provides authority for the Board to issue a cease-and-desist order for operating a facility that requires licensure.

BPC section 4126.5 provides authority for the Board to issue a fine of $5,000 for each occurrence of a violation.

Background

The Board investigates allegations of unlicensed activity. Where a violation is confirmed, the Board has authority to issue a citation with a maximum fine of $5,000 or in the case of a facility, the Board also has the authority to issue a cease and desist order.

The Board issued 72 citations for unlicensed activity during the prior fiscal year. Such citations included unlicensed individuals (e.g., performing pharmacy technician duties without a license, performing pharmacist duties while licensed as a pharmacy technician) as well as unlicensed activity by a business, such as operating as a nonresident pharmacy without a license, operating as a nonresident wholesaler without a license, and transferring ownership of a business without securing new licensure.

During its last meeting, members discussed patient risks associated with unlicensed activity including the potential distribution of adulterated products. Members noted that the Board's current authorized maximum fine did not appear sufficient to address unlicensed activity. Public comment received as part of the meeting also appeared supportive of an increase in fine authority noting that minimal penalties do not serve as a deterrent.

For Committee Consideration and Discussion

During the Oct 4 Meeting, members continued their discussion on the issue. Members again noted the patient risks associated with unlicensed activity including the potential distribution of adulterated products. Members also considered a draft statutory proposal that could be used to increase the maximum fine the Board could assess when unlicensed activity is identified consistent with the Committee's prior discussion.

> **Committee Recommendation**: Recommend to the Board pursuit of a statutory proposal consistent with the policy discussion to increase fine assessment for unlicensed activity.

The Committee recommended language is included in **Attachment 3**.

d. Discussion and Consideration of Enrolled or Recently Signed Legislation Impacting the Practice of Pharmacy

On an annual basis, generally as part of the Committee's October meeting, members consider recently passed legislation and discuss implementation. Consistent with this past practice, several measures impacting the practice of

pharmacy were discussed.

a. Assembly Bill 852 (Wood) Health Care Practitioners: Electronic Prescribing
Status: Chaptered September 25, 2022
Summary: This measure makes several changes to the e-prescribing requirements in California including:
1. Provides authority for pharmacies, pharmacists, and authorized practitioners to decline to dispense or furnish an electronic prescription submitted via software that does not meet specified requirements.
2. Creates additional exemptions from electronic prescriptions as specified.
3. Requires a prescriber exempt from electronic prescribing to register with the Board and state they meet one or more of the specified criteria on an annual basis.
4. Exempts the prescription transfer requirements under specified conditions.

Implementation: Implementation activities will include development of an online registry be substantially like the online registration process used for drug-take back locations or the Board's health services registry. The online registry will include the prescriber's name, license number, email address, and exemptions being claimed. Except for the email address, this information will be posted and available on the Board's website. As annual registration is required, it is recommended that the annual registration occur consistent with the calendar year. The prescriber's email address will be used to facilitate the reminder.

The Medical Board has also recommended that, if possible, a hyperlink to the prescriber's license lookup be included. While the Board is responsible for maintaining the registry, the respective prescriber board are responsible for enforcement.

Implementation for the remainder of the provisions will focus on educating licensees about the requirements including through the Board's newsletter, online resources, and mandated continuing education (CE) on pharmacy law.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities.

b. Assembly Bill 2194 (Ward) Pharmacists and Technicians; Continuing Education Cultural Competency
Status: Chaptered September 30, 2022
Summary: This measure would require that, effective January 1, 2024, pharmacists and pharmacy technicians must complete at least a one-hour course in cultural competency during the two years preceding the application period. Further the measure would prohibit the Board from renewing a pharmacist or pharmacy technician license unless the individual has completed the course.
Implementation: Under existing law, BPC section 4231(d) provides the Board with authority to not renew an active pharmacist license if the pharmacist does not

comply with CE requirements. This section authorizes the Board to issue an inactive license to the pharmacist until compliance with the CE requirement. This section also establishes the provisions for reactivation of the pharmacist license. As neither current statute nor regulation set forth requirements for completion of CE for pharmacy technicians, establishment of a similar process for the renewal of pharmacy technician licenses may be appropriate.

Further, CCR section 1732.5 establishes renewal requirements for pharmacists related to completion of the Board's pharmacy law and ethics courses, as well as the records retention period for completion certificates. There is no similar regulation for pharmacy technicians.

Implementation activities will include amendments to existing CCR section 1732.5 to update the renewal requirements for pharmacists as well as the addition of regulation establishing the renewal requirements for pharmacy technicians. Education on the changes in the law will also be included in the Board's newsletter, online resources, and Board-provided CE on pharmacy law. Staff will also evaluate the potential to update online, and system generated renewal notices to determine if updates can be made in advance of the effective date.

Further, the Board previously recommended changes to 1732.5 to consolidate all CE related requirements for pharmacists into a single regulation to assist pharmacists with compliance. After that action, staff was advised that such an approach may not be appropriate. At that time, given the pending legislation, it was recommended that the two issues be considered together if AB 2194 was chaptered. Should the Committee and Board agree with the approach offered for implementation of AB 2194, discussion should also resume regarding the larger policy goal to determine what, if any, additional amendments to the section would be appropriate to further the Board's policy goal related to all continuing education requirements.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities and suggest that implementation activities be completed under the purview of the Licensing Committee.

c. Senate Bill 731 (Durazo) Criminal Records: Relief
Status: Chaptered September 29, 2022
Summary: This measure will expand automatic relief to include arrests for felonies punishable by state prison. Further, the measure will expand automatic relief to certain criminal felonies committed after January 1, 2005, under specified conditions. (Excluded from automatic relief are serious and violent felonies, and felonies requiring registration as a sex offender.)
Implementation: Under previous legislation related to automatic relief provisions, staff review all relief notifications to determine what if any action is necessary. With the expansion of the provisions, it is anticipated that staff will continue this

process; however, it is anticipated that the impact will be much smaller because the Board has few licensees serving prison time for felonies.

Staff will also work with the Attorney General's Office to determine any potential impact on pending matters.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities.

d. Senate Bill 872 (Dodd, Chapter 220, Statutes of 2022) Pharmacies: Mobile Units
Status: Chaptered August 29, 2022
Summary: This measure allows a county, city and county, or special hospital authority to operate a mobile unit as an extension of the pharmacy license held. The measure authorizes the mobile unit to dispense prescription medications under specified conditions and requires notification to the Board 30 days prior to commencing use as well as 30 days prior to discontinuing use of a mobile unit.
Implementation: Activities will include development of a standardized notification process that can be used to facilitate the notification process. Further, as part of the Board's discussion at the time the measure was pending, it was recommended that FAQs be developed to address, among other items, direction on operational issues including provisions for pharmacist breaks and lunches and security of the mobile unit during such periods. It may be appropriate for members to identify additional items for inclusion in the FAQs. Development of the FAQs will be completed by the Communication and Public Education Committee.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities. Members supported the development of the FAQs by the Communication and Public Education Committee. Further, the Committee noted the importance of including direction on operational issues including security of the unit while in operation, as part of the FAQs. Public comment suggested that the FAQs also include expectations surrounding security, including who maintains the keys.

e. Senate Bill 988 (Chapter 988, Statutes of 2022) Compassionate Act or Ryan's Law
Status: Chaptered September 2, 2022
Summary: The measure will repeal the requirement that a hospital manage a terminal patient's personal use of medical cannabis in the same manner as Schedule II-IV drugs.
Implementation: Implementation will include education on the changes in the law in the Board's newsletter, online resources, and Board-provided CE on pharmacy law.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities.

f. Senate Bill 1346 (Beck) Surplus Medication Collection and Distribution
Status: Chaptered September 30, 2022
Summary: This measure will expand the entities that are eligible to donate medications to a county operating a surplus medication collection and distribution program. Further, the measure will establish pilot programs in specified counties to allow for the expansion of county run programs. The measure requires the Board to evaluate the pilot program and prepare a report to the Legislature on January 1, 2028.
Implementation: Assuming identified resources are received, recruitment will begin next year and evaluation of the program will begin after onboarding is completed. It is recommended that the Enforcement and Compounding Committee receive updates on implementation. Implementation will also include education on the changes in the law in the Board's newsletter, online resources, and board provided CE on pharmacy law.

Summary of Committee Discussion and Action
Members noted agreement with the proposed implementation activities.

e. Review and Discussion of Enforcement Statistics

Since July 1, 2022, the Board has received 848 complaints and has closed 614 investigations. The Board has issued 42 letters of admonishment, 253 citations with or without a fine, and referred 42 cases to the Office of the Attorney General. The Board has secured 2 interim suspension orders and been granted 1 Penal Code 23 restriction. Further, the Board has revoked 7 licenses, accepted the disciplinary surrender of 11 licenses, denied 3 applications, and imposed other levels of discipline against 21 licensees and/or applicants. A copy of the current statistics is provided in **Attachment 4**.

As of September 26, 2022, the Board had 1,404 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

	January 3, 2022		April 1, 2022		July 1, 2022		September 26, 2022	
	Volume	Average Days	Volume	Average Days	Volume	Average Days	Volume	Average Days
Awaiting Assignment	43	29	43	6	24	6	106	8
Cases Under Investigation	626	136	738	122	793	118	755	130
Pending Supervisor Review	135	41	173	30	171	39	225	52
Pending Second	135	41	94	56	97	58	199	36

Level Review								
Awaiting Final Closure	66	60	50	15	127	10	119	38

Attachment 1

Proposed Amendment to Business and Professions Code section 4204 as follows:

(a) Each application for a license under Section 4190 shall be made on a form furnished by the board. The form of application for a license under this article shall contain the name and address of the applicant, whether the applicant is licensed, the type of services the facility will offer, the name of its professional director, the name of its administrator, and the name of its consulting pharmacist.

(b) Each initial application shall contain a statement from a consulting pharmacist certifying that the policies and procedures of the clinic's drug distribution service, relative to inventories, security procedures, training, protocol development, recordkeeping, packaging, labeling, dispensing, and patient consultation are consistent with the promotion and protection of health and safety of the public. Upon the filing of the application and the payment of a fee in subdivision (s) of Section 4400, the board shall make a thorough investigation to determine whether the applicant and the premises for which application for a license is made qualify for a license. The board shall also determine whether this article has been complied with, and shall investigate all matters directly related to the issuance of the license. The board shall not however, investigate any matters connected with the operation of a premises, including operating hours, parking availability, or operating noise, except those matters relating to the furnishing, sale, or dispensing of drugs or devices. The board shall deny an application for a license if either the applicant or the premises for which application for a license is made do not qualify for a license under this article.

(c) If the board determines that the applicant and the premises for which application for a license is made qualify for a license under Section 4190, the executive officer of the board shall issue a license authorizing the clinic to which it is issued to purchase drugs at wholesale pursuant to Section 4190. The license shall be renewed annually upon payment of a renewal fee prescribed in subdivision (s) of Section 4400 and shall not be transferable. <u>As part of the renewal process the consulting pharmacist shall certify compliance with the quarterly inspections as required in Section 4192. Further, as part of the renewal process of every odd numbered year, the most recent self-assessment form completed as provided in Section 4192 shall also be provided to the Board.</u>

Proposed Amendment to Business and Professions Code section 4192 as follows:

(a) Each clinic that makes an application for a license under this article shall show evidence that the professional director is responsible for the safe, orderly, and lawful provision of pharmacy services. In carrying out the professional director's responsibilities, a consulting pharmacist shall be retained to approve the policies and procedures in conjunction with the professional director and

the administrator. In addition, the consulting pharmacist shall be required to visit the clinic regularly and at least quarterly. However, nothing in this section shall prohibit the consulting pharmacist from visiting more than quarterly to review the application of policies and procedures based on the agreement of all the parties approving the policies and procedures.

(b) The consulting pharmacist shall certify in writing quarterly that the clinic is, or is not, operating in compliance with the requirements of this article. Each completed written certification shall be kept on file in the clinic for three years and shall include recommended corrective actions, if appropriate. Before July 1 of every odd-numbered year, the consulting pharmacist shall complete a Surgical Clinic Self-Assessment Form as determined by the board as a means to promote compliance through self-examination and education. The self-assessment shall assess the clinic's compliance with current laws and regulations and include information on compounding practices as specified on the most recent version of the Surgical Clinic Self-Assessment Form approved by the Board and posted on its website. The professional director of the clinic and consulting pharmacist shall certify on the final page of the Surgical Clinic Self-Assessment Form that they have read, reviewed and completed self-assessment to the best of their professional ability and acknowledge that failure to correct any deficiency identified could result in action by the Board. The completed form shall be signed under penalty of perjury and kept on file in the clinic for three years and made available to the Board or its designee upon request.

(c) For the purposes of this article, "professional director" means a physician and surgeon acting in his or her capacity as medical director or a dentist or podiatrist acting in his or her capacity as a director in a clinic where only dental or podiatric services are provided.

(d) Licensed clinics shall notify the board within 30 days of any change in professional director on a form furnished by the board.

Attachment 2

Title 16. Board of Pharmacy

Proposal To Add Article 6.5 and Sections 1750 and 1750.1 in Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 6.5 Outsourcing Facilities

1750 Outsourcing Facility Requirements

(a) Each outsourcing facility defined under section 4034 of the Business and Professions Code shall compound all sterile products and nonsterile products in compliance with federal current good manufacturing practices (cGMP) applicable to outsourcing facilities under section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (21 USC § 351(a)(2)(B)) and shall meet the requirements of this Article.

(b) In addition to subsections (a) and (c), an outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall comply with all applicable federal and state laws and regulations, including all of the following:

(1) Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 (commencing with section 1700.1) – Poison Prevention Packaging,

(2) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 (commencing with section 210.1) – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General,

(3) Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 (commencing with section 211.1) – Current Good Manufacturing Practice for Finished Pharmaceuticals,

(4) Code of Federal Regulations, Title 21, Chapter II, Parts 1301 (commencing with section 1301.01) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances,

(5) Code of Federal Regulations, Title 21, Chapter II, Part 1304 (commencing with section 1304.01) – Records and Reports of Registrants with the Drug Enforcement Administration,

(6) Code of Federal Regulations, Title 21, Chapter II, Part 1305 (commencing with section 1305.01) -- Orders for Schedule I and II Controlled Substances,

(7) Code of Federal Regulations, Title 21, Chapter II, Part 1306 (commencing with section 1306.01) -- Prescriptions,

(8) Code of Federal Regulations, Title 21, Chapter II, Part 1311 (commencing with section 1311.01 -- Requirements for Electronic Orders and Prescriptions,

(9) The Uniform Controlled Substances Act (Health and Safety Code, Division 10 (commencing with section 11000),
(10) Chapters 1, 4, 6 and 8 of the Sherman Food, Drug, and Cosmetics Law (Health and Safety Code, Division 104, Part 5 (commencing with Section 109875) -,
(11) United States Code, Title 21, Chapter 9, Subchapter V, Part A (commencing with section 351) – Drugs and Devices, and,
(12) United States Code, Title 21, Chapter 13, Part C (commencing with section 821) – Registration of Manufacturers, Distributors, and Dispensers of Controlled Substances, except for sections 821, 822a, and 826a of that Part.

(c) An outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall dispense patient-specific compounded preparations pursuant to a prescription for an individual patient in compliance with all applicable provisions of state and federal laws and regulations relating to a pharmacy as follows:
(1) Orally transmitted prescriptions are received and reduced to writing by a pharmacist consistent with the provisions of Business and Professions Code section 4070 and section 1717(c) of this Division and are issued by an appropriately licensed prescriber.
(2) Internet prescriptions are only dispensed pursuant to a prior good faith examination as required in Business and Professions Code section 4067(a) and are issued only by an appropriately licensed prescriber.
(3) Electronic prescriptions meeting the requirements of Business and Professions Code section 688 are issued only by an appropriately licensed prescriber.
(4) Controlled substances prescriptions meet the requirements of Health and Safety Code sections 11164(a), 11164.5, 11167.5, and 11162.1 and Business and Professions Code section 688.
(5) Each prescription contains all information required by Business and Professions Code sections 4040 and 4070.
(6) Each prescription label complies with the provisions of Business and Professions Code sections 4076, 4076.5, and 4076.6 and section 1707.5 of this Division.
(7) Drug warnings are provided orally or in writing consistent with the provisions of Business and Professions Code sections 4074 and 4076.7, section 1744 of this Division, and section 290.5 of Title 21 of the Code of Federal Regulations.

(8) Prescriptions are dispensed in containers meeting the requirements of section 1473(b) of Title 15 of the United States Code, section 1700.15 of Title 16 of the Code of Federal Regulations, and section 1717(a) of this Division.
(9) Patient consultation is provided consistent with the provisions of section 1707.2 of this Division.
(10) Prior to consultation as required in section 1707.2, a pharmacist shall review drug therapy and patient medication records consistent with the provisions of section 1707.3 of this Division.
(11) The facility shall maintain medication profiles consistent with the provisions of section 1707.1 of this Division.
(12) All Schedule II through V controlled substance dispensing data are reported to the CURES Prescription Drug Monitoring Program as required in Health and Safety Code section 11165.
(13) A pharmacist communicates with the patient or patient's agent if a medication error occurs consistent with the provisions of section 1711.
(14) Medication errors must be documented as part of the facility's quality assurance program consistent with the provisions of Business and Professions Code section 4125 and section 1711 of this Division.
(15) Patient information and prescriptions are kept confidential consistent with the provisions of the Confidentiality of Medical Information Act (Civil Code sections 56 and following), and section 1764 of this Division.
(16) Prescription refills must comply with Business and Professions Code section 4063, Health and Safety Code section 11200, and sections 1717 and 1717.5 of this Division.
(17) All records of disposition are maintained for at least three years consistent with Business and Professions Code sections 4081 and 4105.

(d) For the purposes of this section, "appropriately licensed prescriber" shall mean any health care professional listed in Section 4040(a)(2) of the Business and Professions Code.

Proposal to Add Section 1750.1 to Article 6.5 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1750.1 Self-Assessment of an Outsourcing Facility (Resident and Nonresident)

(a) Each outsourcing facility as defined under section 4034 of the Business and Professions Code shall complete a self-assessment of its compliance with federal and state pharmacy law. The assessment shall be performed by the outsourcing facility's designated quality control personnel, before July 1 of

every odd-numbered year. The primary purpose of the self-assessment is to promote compliance through self-examination and education, for compliance with federal current good manufacturing practices as referenced in section 1750 (cGMP) and provisions of state law related to pharmacies, Pharmacy law and this Division related to patient specific prescriptions. For the purposes of this section, "designated quality control personnel" shall mean an individual or individuals from the quality control unit as defined in section 211.22 of Title 21 of the Code of Federal Regulations ("quality control unit") identified by the outsourcing facility as the person or persons responsible for the facility's operations as detailed in the FDA Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, Guidance for Industry.

(b) Each outsourcing facility shall designate a member of the quality control unit to be responsible for compliance with this section. The name and job title of the designated member must be maintained as part of the records of the outsourcing facility in accordance with Business and Professions Code section 4081.

(c) In addition to the self-assessment required in subdivision (a) of this section, the designated quality control personnel shall complete a self-assessment within 30 days whenever:
   (1) A new outsourcing facility license is issued.
   (2) There is a change in the designated quality control personnel.
   (3) There is a change in the licensed physical location of an outsourcing facility to a new address.

(d) Each outsourcing facility licensed pursuant to Business and Professions Code sections 4129.1 or 4129.2 shall complete the "Outsourcing Facility Self-Assessment," Form 17M-117 (New. 9/2022), which is hereby incorporated by reference and contains the following components:
   (1) The designated quality control personnel shall provide identifying information about the outsourcing facility including:
      (A) Name, license number of the premises, and the license expiration date;
      (B) Address, phone number, website address, if applicable, and type of ownership;
      (C) U.S. Food and Drug Administration (FDA) Federal Establishment Identification number, expiration date and date of most recent

inspection completed by the FDA pursuant to Section 360 of Title 21 of the United States Code;

(D) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory pursuant to Title 21, Code of Federal Regulations section 1304.11; and,

(E) Hours of operation of the licensee.

(2) The designated quality control personnel shall list the name of each staff person involved in the dispensing of patient specific prescriptions at the facility at the time the self-assessment is completed, and each person's role within the facility's operations.

(3) The designated quality control personnel shall respond "yes", "no" or "not applicable" (N/A) about whether the licensed premises is, at the time of the self-assessment, in compliance with each of the requirements.

(4) For each "no" response, the designated quality control personnel shall provide a written corrective action or action plan describing the actions to be taken to come into compliance with the applicable law or regulation cited on the self-assessment form for which a "no" response was provided.

(5) The designated quality control personnel shall initial each page of the self-assessment form with original handwritten initials in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(6) The designated quality control personnel shall certify, under penalty of perjury of the laws of the State of California, on the final page of the self-assessment that:

(A) They have completed the self-assessment of the licensed premises for which they are responsible;

(B) Any deficiency identified within the self-assessment will be corrected and list the timeframe for correction;

(C) They acknowledge receiving the following notice: "All responses on this form are subject to verification by the Board of Pharmacy"; and,

(D) The information provided in the self-assessment form is true and correct.

(E) The certification, made under penalty of perjury of the laws of the State of California that the information provided in the self-

assessment form is true and correct, may be an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that they have read and reviewed the completed self-assessment and have received notice that failure to correct any deficiency identified in the self-assessment could result in the revocation of the license issued by the board. The certification shall be made, under penalty of perjury of the laws of the State of California, that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code section 1633.2(h) on the self-assessment form.

(e) Each self-assessment shall be completed in its entirety and kept on file in the licensed premises for three years after it is completed. The completed, initialed, and signed original must be readily available for review during any inspection in accordance with Business and Professions Code section 4081.

(f) The outsourcing facility is responsible for compliance with this article.

(g) Any identified areas of deficiency identified in the self-assessment shall be corrected as specified in the timeframe listed in the certification as provided in subsection (d)(6).

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4034, 4129- 4129.9, Business and Professions Code.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Ste. 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

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

Outsourcing Facility Self-Assessment

Sections 4129.1(b) and 4129.2(b) of the Business and Professions Code (BPC) and section 1750 of Title 16 of the California Code of Regulations (CCR) require any Outsourcing Facility licensed in the state of California to be compliant with federal current Good Manufacturing Practices (cGMP) and other federal laws as specified in Section 1750.**The assessment shall be performed before July 1 of every odd-numbered year by the facility's designated quality control person (as defined in CCR section 1750.1).** The designated quality control personnel must also complete a self-assessment within 30 days whenever: (1) a new outsourcing license has been issued; (2) there is a change in the designated quality control personnel; or (3) there is a change in the licensed physical location of the outsourcing facility. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

This self-assessment should be completed in its entirety, may be completed online, printed, initialed, signed and readily retrievable and available for Board inspection in the pharmacy as required by BPC section 4081. Do not copy a previous assessment. This is meant as a guide for Board requirements for filling a patient specific prescription to be furnished within and into the state of California by a licensed Outsourcing Facility.

Note: The licensed Outsourcing Facility can only dispense compounded drug preparations from its licensed location pursuant to a prescription within or into the state of California. Further, Outsourcing Facilities are not licensed pharmacies and may not provide or accept transferred prescriptions from pharmacies or other outsourcing facilities.

All references to the Business and Professions Code (BPC) are to Division 2, Chapter 9. All references to the California Code of Regulations (CCR) are to Title 16.

Each self-assessment must be kept on file in the facility for three years after it is performed.

Facility Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐

Other ☐ (please specify) _____

License #: _____ Exp. Date:_____ Date of Last FDA Inspection: _____

FDA EIN #: _____ Registration Date: _____ _____ DEA Number: _____

Name(s) of Designated Quality Control Personnel Responsible for Compliance (attach additional sheets if necessary): _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

Website address (optional): _____

_____
Initials

Facility Staff (Please include license type and license number where appropriate): (Please use additional sheets if necessary)

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____
9. _____
10. _____
11. _____
12. _____
13. _____
14. _____
15. _____
16. _____
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19. _____
20. _____

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Initials

Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

Section I
Prescription Specific Regulations

Duties of a pharmacist in an Outsourcing Facility filling patient specific prescriptions

1. A pharmacist:

Yes No N/A

☐ ☐ ☐ 1.1 Transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
☐ ☐ ☐ 1.2 Provides consultation, training, and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
☐ ☐ ☐ 1.3 Receives a new prescription order from the prescriber; (BPC 4070[a]), (CCR 1793.1[a])
☐ ☐ ☐ 1.4 Consults with the patient; (BPC 4052[a][8], CCR 1707.2, CCR 1793.1[b])
☐ ☐ ☐ 1.5 Identifies, evaluates, and interprets a prescription; (CCR 1793.1[c])
☐ ☐ ☐ 1.6 Interprets the clinical data in a patient medication record; (CCR 1793.1[d])
☐ ☐ ☐ 1.7 Consults with any prescriber, nurse, health professional or agent thereof; (1793.1[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Patient Consultation

Yes No N/A

☐ ☐ ☐ 2.1 Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)
- ☐ 2.1.1 Whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 2.1.2 Whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 2.1.3 Upon request;
- ☐ 2.1.4 Whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment; and
- ☐ 2.1.5 All the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

☐ ☐ ☐ 2.2 The facility maintains patient profile information including allergies, date of birth or age, gender and other prescription and nonprescription drugs that the patient takes. (CCR 1707.1)
☐ ☐ ☐ 2.3 The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)
☐ ☐ ☐ 2.4 Consultation is performed in a manner that protects the patient's protected health care information and in an area suitable for confidential patient consultation and provided in accordance with nondisclosure obligations of Civil Code 56.10. (Civil Code 56.10, CCR 1714[a], 1764)

Yes No N/A

☐ ☐ ☐ 2.5 Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)
☐ ☐ ☐ 2.6 If prescription medication is mailed or delivered, the facility ensures that: (CCR 1707.2[b][1])
- ☐ 2.6.1 The patient receives written notice of his or her right to request consultation (CCR 1707.2 [b][1][A]);
- ☐ 2.6.2 The patient receives written notice of the hours of availability and the telephone number from which the patient may obtain oral consultation (CCR 1707.2 [b][1][B]);
- ☐ 2.6.3 A pharmacist is available to speak with the patient or patient's agent during any regular hours of operation, within an average of ten (10) minutes or less, unless a return call is schedule to occur within one business hour, for no fewer than six days per week, and for a minimum of 40 hours per week (CCR 1707.2 [b][1][C]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Prescription Requirements

Yes No N/A

☐ ☐ ☐ 3.1 Prescriptions or electronic data transmission prescriptions are complete with all the required information and, if electronic, reduced to the required writing by a pharmacist. (BPC 4040, 4070)
☐ ☐ ☐ 3.2 Orally transmitted prescriptions are received and reduced to writing only by a Pharmacist. (BPC 4070[a], CCR 1717[c])
☐ ☐ ☐ 3.3 If a prescription is orally or electronically transmitted by the prescriber's agent, the pharmacist makes a reasonable attempt to verify that the prescriber's agent is authorized to do so, and the agent's name is recorded. (BPC 4071)
☐ ☐ ☐ 3.4 If orally transmitted, the pharmacist who received the prescription is identified by initialing the prescription, and if dispensed by another pharmacist, the dispensing pharmacist also initials the prescription. (CCR 1717[c], 1712)
☐ ☐ ☐ 3.5 The security, accuracy and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])
☐ ☐ ☐ 3.6 Facsimile prescriptions are received from a prescriber's office. (BPC 4040[c])
☐ ☐ ☐ 3.7 Internet prescriptions for patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 4067[a])
☐ ☐ ☐ 3.8 Except for those prescriptions written under Health and Safety Code (HSC) sections 11159.2, 11159.3 and 11167.5, all written controlled substances prescriptions (Schedules II - V) are on California Security Prescription forms meeting the requirements of HSC 11162.1. (HSC 11162.1, 11164[a], 11167.5)
☐ ☐ ☐ 3.9 All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)
☐ ☐ ☐ 3.10 All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)
☐ ☐ ☐ 3.11 The facility confirms compliance with the following: “No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank. A person may dispense a dangerous drug that is not a controlled substance pursuant to a preprinted multiple checkoff prescription blank and may dispense more than one dangerous drug, that is not a controlled substance,

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Initials

pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs they have prescribed. 'Preprinted multiple checkoff prescription blank,' as used in this section means any form listing more than one dangerous drug where the intent is that a mark next to the name of a drug, i.e., a 'checkoff,' indicates a prescription order for that drug." (CCR 1717.3)

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Refill Authorization

Yes No N/A

☐ ☐ ☐ 4.1 Refill authorization from the prescriber for dangerous drugs or dangerous devices is obtained before refilling a prescription. (BPC 4063, 4064[a])

☐ ☐ ☐ 4.2 Prescriptions for dangerous drugs or devices are only filled without the prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's ongoing care and have a significant adverse effect on the patient's well-being. (BPC 4064)

☐ ☐ ☐ 4.3 Refills are documented. (CCR 1717)

☐ ☐ ☐ 4.4 Refills for Schedule II controlled substances are prohibited. (HSC 11200[c])

☐ ☐ ☐ 4.5 Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply. (HSC 11200[a]-[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Medication Errors related to a patient specific prescription

Yes No N/A

☐ ☐ ☐ 5.1 The facility has an established quality assurance program that documents medication errors attributable, in whole or in part, to the facility or its personnel. (BPC 4125, CCR 1711)

☐ ☐ ☐ 5.2 Quality assurance policies and procedures are maintained in the facility and are immediately retrievable. (CCR 1711[c])

☐ ☐ ☐ 5.3 The pharmacist communicates with the patient or patient's agent that a medication error has occurred, and the steps required to avoid injury or mitigate the error. (CCR 1711[c][2][A], 1711[c][3])

☐ ☐ ☐ 5.4 When a medication error has occurred (drug was administered to or by the patient or resulted in a clinically significant delay in therapy) the pharmacist communicates to the prescriber that a medication error has occurred. (CCR 1711[c][2][B], 1711[c][3])

☐ ☐ ☐ 5.5 Investigation of the medication errors is initiated within two business days from the date the medication error is discovered. (CCR 1711[d])

Yes No N/A

☐ ☐ ☐ 5.6 In addition to all complaint and adverse drug reaction tracking compliant with the

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Initials

CFR, the record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ 5.6.1 Date, location, and participants in the quality assurance review;
☐ 5.6.2 Pertinent data and other information related to the medication error(s) reviewed;
☐ 5.6.3 Findings and determinations; and
☐ 5.6.4 Recommended changes to policy, procedure, systems, or processes, if any.

☐ ☐ ☐ 5.7 The record of the quality assurance review is immediately retrievable in the facility and is maintained in the facility for at least one year from the date it was created. (CCR 1711[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Erroneous or Uncertain prescriptions

Yes No N/A

☐ ☐ ☐ 6.1 If a prescription contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration, the pharmacist contacts the prescriber to obtain information needed to validate the prescription. (CCR 1761[a])

☐ ☐ ☐ 6.2 Pharmacists are aware of their corresponding responsibility to determine that a prescription written for a controlled substance was issued for legitimate medical purposes only. (HSC 11153)

☐ ☐ ☐ 6.3 Even after conferring with the prescriber, the pharmacist does not dispense a controlled substance prescription if they know or have objective reason to know that the prescription was not issued for a legitimate medical purpose. (CCR 1761[b], HSC 11153)

☐ ☐ ☐ 6.4 Internet prescriptions for controlled substances are only dispensed if in compliance with the Ryan Haight Online Pharmacy Consumer Protection Act of 2008. (21 USC 802, 829[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Labeling for a patient specific prescription

Yes No N/A

☐ ☐ ☐ 7.1 In addition to the requirements for labeling listed in the CFR, the prescription label contains all the required information specified in BPC 4076. (BPC 4076)

☐ ☐ ☐ 7.2 The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707.5)

☐ ☐ ☐ 7.3 The beyond use date of a drug's effectiveness is accurately identified on the label. (BPC 4076[a][9])

☐ ☐ ☐ 7.4 The trade name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record and includes the statement "generic for __ " where the brand name is inserted, and the name of the

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Initials

manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer's name may be listed outside the patient-centered area. (BPC 4076[a][1], CCR 1707.5[a][1][B], CCR 1717[b][2])

☐ ☐ ☐ 7.5 The federal warning label prohibiting transfer of controlled substances is on the prescription container. (21 CFR 290.5)

☐ ☐ ☐ 7.6 The label includes a physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules. (BPC 4076[a][11])

☐ ☐ ☐ 7.7 Whenever an opioid prescription drug is dispensed to patient for outpatient use, the facility prominently displays on the label or container or by a flag or other notification to the container, a notice that states, "Caution: Opioid. Risk of overdose and addiction." (BPC 4076.7)

☐ ☐ ☐ 7.8 When requested by a patient or patient representative, the facility provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If it is not possible for the English-language directions to appear on the container or label, the English-language directions are provided on a supplemental document. (BPC 4076.6[a])

☐ ☐ ☐ 7.9 The pharmacist includes a written label on the drug container indicating that the drug may impair a person's ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container. (BPC 4074[b], BPC 4076.7, CCR 1744[a])

☐ ☐ ☐ 7.10 The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container. (CCR 1744[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Furnishing and Dispensing

Yes No N/A

☐ ☐ ☐ 8.1 If the prescription is filled by a pharmacy technician, before dispensing, the prescription is checked for accuracy by a licensed pharmacist and that pharmacist initials the prescription label or records by their identity as the reviewing pharmacist in a computer system by a secure means. (BPC 4115, 4115.5[b][3], CCR 1712, 1793.7[a])

Yes No N/A

☐ ☐ ☐ 8.2 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. (15 USC 1473[b], 16 CFR 1700.15, CCR 1717[a])

☐ ☐ ☐ 8.3 Patient package inserts are dispensed with all estrogen medications.

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Initials

(21 CFR 310.515)

☐ ☐ ☐ 8.4 The facility provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c]. (21 CFR 201.57[c])

☐ ☐ ☐ 8.5 Medication guides are provided on required medications. (21 CFR, Part 208)

☐ ☐ ☐ 8.6 The facility furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription. (BPC 4126.5[a][5])

☐ ☐ ☐ 8.7 Controlled substance prescriptions are not filled or refilled more than six months from the date written. (HSC 11200[a])

☐ ☐ ☐ 8.8 Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (HSC 11200[b])

☐ ☐ ☐ 8.9 The facility dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, under the following provisions: (BPC 4064.5).

- ☐ 8.9.1 The prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; (BPC 4064.5[a])
- ☐ 8.9.2 The prescriber has not indicated "no change to quantity" or words of similar meaning; (BPC 4064.5[d])
- ☐ 8.9.3 The patient has completed an initial 30-day supply (this is not required where the prescription continues the same medication as previously dispensed in a 90-day supply); (BPC 4064.5[a][1], 4064.5[b])
- ☐ 8.9.4 The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
- ☐ 8.9.5 The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; (BPC 4064.5[a][3])
- ☐ 8.9.6 The pharmacist is exercising their professional judgment; and (BPC 4064.5[a][4])
- ☐ 8.9.7 The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Confidentiality of Prescriptions

Yes No N/A

☐ ☐ ☐ 9.1 Patient information is maintained to safeguard confidentiality. (Civil Code 56 et seq.)

☐ ☐ ☐ 9.2 All prescriptions are kept confidential and only disclosed as authorized by law. (CCR 1764)

☐ ☐ ☐ 9.3 The facility ensures electronically transmitted prescriptions are received maintained and transmitted in a secure and confidential manner. (CCR 1717.4[h])

Yes No N/A

☐ ☐ ☐ 9.4 If electronically transmitted prescriptions are received by an interim storage device (to allow for retrieval at a later time), the facility maintains the interim storage device in a manner to prevent unauthorized access. (CCR 1717.4[d])

☐ ☐ ☐ 9.5 If the facility has established and utilizes common electronic prescription files to maintain required dispensing information, the system shall not permit disclosure

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Initials

of confidential medical information except as authorized by law. (CCR 1717.1)

☐ ☐ ☐ 9.6 Destruction or disposal of patient records preserves the confidentiality of the information contained therein. (Civil Code 56.101)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Record Keeping Requirements in addition to compliance with cGMP

Yes No N/A

☐ ☐ ☐ 10.1 Completed self-assessments are kept on file in the facility and maintained for three years after completion. (CCR 1750.1[e])

☐ ☐ ☐ 10.2 All drug acquisition and disposition records (complete accountability) are maintained for at least three years. For any record maintained electronically, a hardcopy is able to be produced upon inspection and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records, including: (BPC 4081, 4105, 4169, 4333, CCR 1718)

- ☐ 10.2.1 Prescription records (BPC 4081[a])
- ☐ 10.2.2 Purchase Invoices for all prescription drugs (BPC 4081[b])
- ☐ 10.2.3 Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 10.2.4 Biennial controlled substances inventory (21 CFR 1304.11)
- ☐ 10.2.5 U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 10.2.6 Power of Attorney for completion of DEA 222 forms (21 CFR 1305.05)
- ☐ 10.2.7 Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Patient specific prescriptions may not be returned and reused by the facility.

Yes No N/A

☐ ☐ ☐ 11.1 Patient specific prescriptions are not returned and reused by the facility**.**

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

Section II
Code of Federal Regulation Part 211 for all Outsourcing Facilities

Quality Systems, validation control, facility control and training

12. CFR Part 211, Subpart B, Organization and Personnel

Yes No N/A
☐ ☐ ☐ 12.1 Compliance with sections 211.22 through 211.34 in their entirety

Facility

13. CFR Part 211, Subpart C Buildings and Facilities

Yes No N/A
☐ ☐ ☐ 13.1 Compliance with Sections 211.42 through 211.58 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Equipment

14. CFR Part 211, Subpart D Equipment

Yes No N/A
☐ ☐ ☐ 14.1 Compliance with sections 211.63 through 211.72 in their entirely.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Compounding and manufacture of the product

15. CFR Part 211, Subpart E Control of Components and Drug Product Containers and Closures

Yes No N/A
☐ ☐ ☐ 15.1 Compliance with sections 211.80 through 211.94 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. CFR Part 211, Subpart F—Production and Process Controls

Yes No N/A
☐ ☐ ☐ 11.1 Compliance with sections 211.100 through 211.115 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

17. CFR Part 211, Subpart G—Packaging and Labeling Control

Yes No N/A

☐ ☐ ☐ 17.1 Compliance with sections 211.122 through 211.137 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Distribution, storage,

18. CFR Section 211, Subpart H—Holding and Distribution

Yes No N/A

☐ ☐ ☐ 19.1 Compliance with sections 211.142 through 211.150

CORRECTIVE ACTION OR ACTION PLAN: _____

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Release of product for sale

19. CFR Section 211, Subpart I—Laboratory Controls

Yes No N/A

☐ ☐ ☐ 18.1 Compliance with sections 211.160 through 211.176 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Record keeping

20. CFR Part 211, Subpart J—Records and Reports

Yes No N/A

☐ ☐ ☐ 20.1 Compliance with sections 211.180 through 211.198 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Returns

21. CFR part 211, Subpart K—Returned and Salvaged Drug Products

Yes No N/A

☐ ☐ ☐ 21.1 Compliance with sections 211.204 through 211.208 in their entirety for products not sold pursuant to a patient specific prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Initials

Section III
DEA Controlled Substances Inventory, as applicable to your facility

22. Inventory:

Yes No N/A

☐ ☐ ☐ 22.1 Is completed biennially (every two years). (21 CFR 1304.11[c])
☐ ☐ ☐ 22.2 Schedule II inventory is separate from Schedule III, IV and V. (21 CFR 1304.04[h][1])
☐ ☐ ☐ 22.3 All completed inventories are available for inspection for three years. (CCR 1718)
☐ ☐ ☐ 22.4 Indicates on the inventory record whether the inventory was taken at the open of business or at the close of business. (21 CFR 1304.11 [a])
☐ ☐ ☐ 22.5 Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])
☐ ☐ ☐ 22.6 Schedule III-V prescriptions are filed separately from all prescription records or are designated with a red "C." However, the red C requirement is waived if the facility uses an automated data processing or other record keeping system for identification of controlled substances by prescription number and the original prescription documents can be retrieved promptly. (21 CFR 1304.04[h][4])
☐ ☐ ☐ 22.6 Inventories and records for Schedule III-V controlled substances are filed separately or are designated in some manner that makes the required information readily retrievable from ordinary business records. (21 CFR 1304.04)
☐ ☐ ☐ 22.7 A U.S. Official Order Form (DEA Form 222) or electronic equivalent (CSOS) is utilized when ordering all Schedule II-controlled substances. When Schedule II Controlled substance orders are received by the facility, for each item received, the date and quantity received is indicated on the DEA Form 222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[g])
☐ ☐ ☐ 22.8 When dispensed upon an "oral" order for a true emergency, a Schedule II prescription is provided by the prescriber by the 7th day following the transmission of the oral order. If not received, the facility reports failure to provide prescription document to the California Bureau of Narcotic Enforcement within 144 hours of the failure to provide the prescription. (HSC 11167[c]-[d])
☐ ☐ ☐ 22.9 The facility generates a controlled substances printout for refills of Schedule II-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the facility maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.
☐ ☐ ☐ 22.10 Any controlled substances drug theft or significant loss is reported within one business day of discovery to the DEA (21 CFR 1301.74[c].)
☐ ☐ ☐ 22.11 A report is submitted to the Board within 30 days of the date of discovery of any loss of a controlled substance or any other significant drug losses as specified in Section 1715.6. (CCR 1715.6)
☐ ☐ ☐ 22.12 Pharmacists are creating initial prescription records and prescription labels by hand, or a pharmacist initials or signs prescription records and prescription labels by recording the identity of the pharmacist in a computer system by a secure means. This computer system does not permit the record to be altered after made and the record of the pharmacist's identity made in the computer system is immediately retrievable in the facility. (CCR 1712, 1717[b][1], 1717[f])

Yes No N/A

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Initials

☐ ☐ ☐ 22.13 All Schedule II through V controlled substances dispensing data is successfully transmitted within one working day from the date the controlled substance is released to the patient through the CURES System Administrator. [HSC 11165(d)])

☐ ☐ ☐ 22.14 The facility has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon discovering a suspicious order or series of orders, notify the DEA administration and the Special Agent in charge of DEA in their area. (21 USC 832[a])

CORRECTIVE ACTION OR ACTION PLAN: _____

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DESIGNATED QUALITY CONTROL PERSONNEL CERTIFICATION:

I, (please print) _____, Title _____ hereby certify that I have completed the self-assessment of this outsourcing facility of which I am the designated quality control person. Any deficiency identified herein will be corrected by _____(date). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Designated Quality Control Personnel)

ACKNOWLEDGEMENT BY FACILITY OWNER OR OFFICER:

I, (please print) _____, hereby certify under penalty of perjury of the laws of the State of California that I have read and reviewed this completed self-assessment. I understand that failure to correct any deficiency identified in this self-assessment in the timeframe identified in the Designated Quality Control Personnel Certification above could result in the revocation of the outsourcing facility's license issued by the California State Board of Pharmacy.

Signature _____ Date _____
(Outsourcing Facility Owner or Officer)

_____
Initials

The following **Legal References** are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy Web site at www.pharmacy.ca.gov (see *Laws and Regulations*), at the California State Law Library, or at other libraries or Internet web sites.

- Business and Professions Code, Division 1, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 1 – General Provisions
- Business and Professions Code, Division 2, Chapter 9 – Pharmacy
- California Code of Regulation, Title 16, Division 17 – California State Board of Pharmacy
- Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
- Code of Federal Regulations, Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
- Code of Federal Regulations, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Code of Federal Regulations, Title 21, Chapter II, Parts 1301, 1304, 1305, 1306, 1311
- Health and Safety Code, Division 10 – Uniform Controlled Substances Act
- Health and Safety Code, Division 104, Part 5 - Sherman Food, Drug, and Cosmetics Law
- United States Code, Title 21, Chapter 9, Subchapter V, Part A – Federal Food, Drug, and Cosmetic Act
- United States Code, Title 21, Chapter 13 – Drug Abuse Prevention and Control

Initials

Attachment 3

Statutory Proposal to Add Business and Professions Code Section 4316.5

Notwithstanding any other law, the Board may assess administrative fines and issue orders of abatement to any unlicensed entity who engages in any action that requires licensure under the jurisdiction of the Board, not to exceed $5,000 for each occurrence pursuant to a citation issued by the Board.

Attachment 4

Board of Pharmacy

Enforcement Workload Statistics FY 2022/23

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	912	0	0	0	912
Closed	637	0	0	0	637
Pending	1,875	0	0	0	1,875
Average Days for Investigation	173	0	0	0	173

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	716	0	0	0	716
Drug Diversion / Fraud	251	0	0	0	251
Prescription Drug Abuse	273	0	0	0	273
Compounding	62	0	0	0	62
Outsourcing	20	0	0	0	20
Probation / PRP	87	0	0	0	87
Enforcement	14	0	0	0	14
Criminal Conviction	452	0	0	0	452

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	60	0	0	0	60
Closed					
Approved	30	0	0	0	30
Denied	20	0	0	0	20
Total Closed (includes withdrawn)	***50***	***0***	***0***	***0***	***50***
Pending	100	0	0	0	100

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	135	0	0	0	135
Non-Jurisdictional	135	0	0	0	135
No Violation	67	0	0	0	67
No Further Action	27	0	0	0	27
Other - Non-Substantiated	33	0	0	0	33
Subject Educated	20	0	0	0	20

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	44	0	0	0	44
Citations Issued	281	0	0	0	281
Proof of Abatement Requested	68	0	0	0	68
Appeals Referred to AG's Office	6	0	0	0	6
Dismissed	1	0	0	0	1
Total Fines Collected	***$448,797***	***$0***	***$0***	***$0***	***$448,797***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	51	0	0	0	51
Pleadings Filed	34	0	0	0	34
Pending					Quarter Ending
Pre-Accusation	94	0	0	0	94
Post-Accusation	140	0	0	0	140
Total Pending	**234**	**0**	**0**	**0**	**234**
Total Closed	46	0	0	0	46

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	7	0	0	0	7
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	2	0	0	0	2
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***10***	***0***	***0***	***0***	***10***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	1	0	0	0	1
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	***1***	***0***	***0***	***0***	***1***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	11	0	0	0	11
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	1	0	0	0	1
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	***17***	***0***	***0***	***0***	***17***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	5	0	0	0	5
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	3	0	0	0	3
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	7	0	0	0	7
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***15***	***0***	***0***	***0***	***15***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	4	0	0	0	4
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	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***5***	***0***	***0***	***0***	***5***

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	1	0	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***1***	***0***	***0***	***0***	***1***

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	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	1	0	0	0	1
Pharmacy	2	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***3***	***0***	***0***	***0***	***3***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$340,239***	***$0***	***$0***	***$0***	***$340,239***
Cost Recovery Collected	***$154,930***	***$0***	***$0***	***$0***	***$154,930***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	2	0	0	0	2
Automatic Suspension Orders	2	0	0	0	2
Penal Code 23 Restrictions	2	0	0	0	2
Cease and Desist - Outsourcing	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	208	0	0	0	208
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	17	0	0	0	17
Designated Representative	2	0	0	0	2
Wholesaler / 3PL	3	0	0	0	3
Pharmacy	1	0	0	0	1
Sterile Compounding	57	0	0	0	57
Outsourcing	8	0	0	0	8
Total	***297***	***0***	***0***	***0***	***297***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	16	0	0	0	16
Probation Site Inspections	97	0	0	0	97
Probation Terminated / Completed	35	0	0	0	35
Referred to AG for Non-Compliance	2	0	0	0	2

As of 9/30/2022

Board of Pharmacy

Citation and Fine Statistics FY 2022/23

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	41	0	0	0	41
Pharmacist-in-Charge with Fine*	30	0	0	0	30
Pharmacist no Fine	67	0	0	0	67
Pharmacist-in-Charge no Fine*	44	0	0	0	44
Pharmacy with Fine	110	0	0	0	110
Pharmacy no Fine	30	0	0	0	30
Pharmacy Technician with Fine	5	0	0	0	5
Pharmacy Technician no Fine	1	0	0	0	1
Wholesalers	5	0	0	0	5
Designated Representative	0	0	0	0	0
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	1	0	0	0	1
Hospital Pharmacy	6	0	0	0	6
Miscellaneous**	16	0	0	0	16
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	1	0	0	0	1

*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

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	28%	4301/1793.7(a) - Unprofessional Conduct…/Requirements for pharmacies employing pharmacy technicians - any pharmacy employing pharmacy technicians	17%	4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	17%
1751.4(f) - Facility and Equipment Standards for Sterile Compounding; Pharmacies preparing sterile compounded preparations require the use of a PEC that provides ISO Class 5 air or better air quality	18%	4301/1714(d) - Unprofessional Conduct…/Operational Standards and Security; Pharmacist responsible for pharmacy security	17%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	15%
1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	11%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	16%	1716 - Variation from prescription	15%
4081(a) - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory	8%	1716 - Variation from prescription	16%	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	11%
4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	6%	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	8%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	9%
4059(a) - Furnishing dangerous drugs without a prescription	6%	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	7%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	9%
1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	6%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%	1715(a) - Self-assessment form of a pharmacy by the pharmacist-in-charge; shall complete a self-assessment of pharmacy compliance with federal and state pharmacy law	9%
4081(a)/1718 - Records of Dangerous Drugs and Devices Kept Open for Inspection; Maintenance of Records, Current Inventory/Current Inventory Defined	6%	4301(g) - Unprofessional Conduct - Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts	5%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
4301(f) - Unprofessional Conduct - Acts of moral turpitude, dishonesty, fraud, deceit or corruption	6%	4115(e) - No person shall act as a pharmacy technician without first being licensed by the board as a pharmacy technician	4%	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	6%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	4%	1714.3(a)(4) - (a) When a pharmacy is open to the public and a pharmacist is working without another pharmacy employee currently working, the pharmacy shall make another person who is an employee of t	4%

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. This data includes July 2022 through September 2022.

Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	22/23
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals					
PRP Under Investigation	3				3
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes	3				3
New Probationers					
Pharmacists	2				2
Intern Pharmacists					
Pharmacy Technicians					
Total New Probationers	2				2
PRP Participants and Recovery Agreements					
Total PRP Participants	39				39
Recovery Agreements Reviewed	26				26
Probationers and Inspections					
Total Probationers	48				48
Inspections Completed	31				31
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)	2				2
Drug Tests					
Drug Test Ordered (PRP and Probationers)	435				435
Drug Tests Conducted (PRP and Probationers)	431				431
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)					
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3				3
Termination from PRP					
Probationers Referred for Discipline					
Closure					
Successful Completion (PRP and Probationers)	12				12
Termination (Probation)	1				1
Voluntary Surrender (Probation)					
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	9				9
Other (PRP)	1				1
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					Zero

Drug of Choice at PRP Intake or Probation

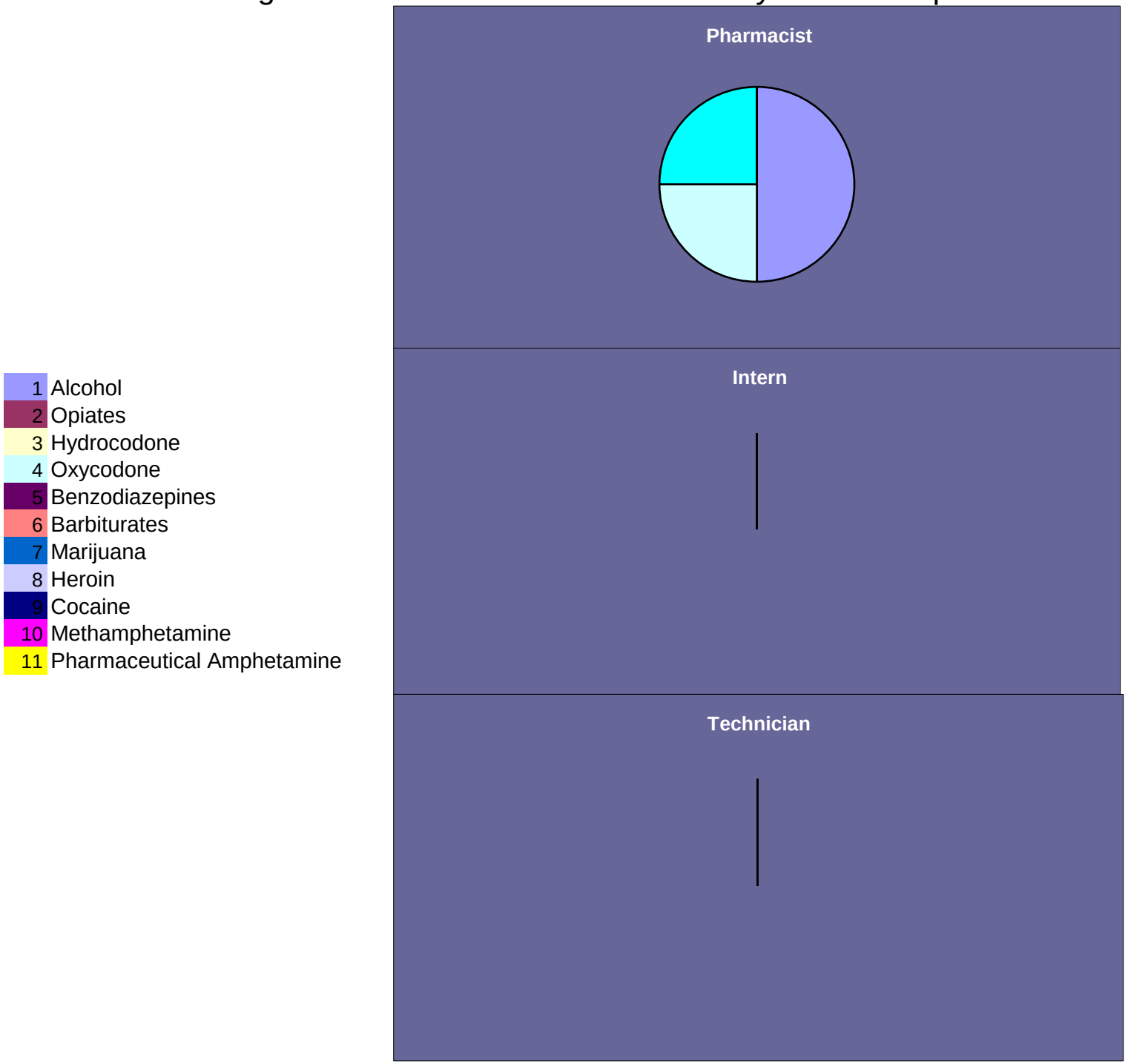
Pharmacists	July-Sep	Oct-Dec	Jan-Mar	Apr-Jun	Total 22/23
Alcohol	2				2
Ambien					
Opiates					
Hydrocodone	1				1
Oxycodone					
Morphine					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					

SB 1441 Uniform Standards

The data includes licensees participating in the Pharmacist Recovery Program (PRP) and licensees on probation with substance use disorders. This data includes July 2022 through September 2022.

Board of Pharmacy	July Sep	Oct Dec	Jan-Mar	Apr-Jun	22/23
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 22/23**
Alcohol					
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 22/23**
Alcohol					
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 2022 to September 2022



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