California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 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

Enforcement and Compounding Committee Report
August 25, 2022

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member, President
Ricardo Sanchez, Public Member

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

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

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

III. Discussion, Consideration and Approval of Draft Minutes from the July 19, 2022, Enforcement and Compounding Committee Meeting Minutes

A draft version of the minutes is provided in **Attachment 1.**

IV. 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 section (HSC) 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 such a clinic must comply with as a precursor to licensure.

BPC section 4192 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.

For Committee Consideration and Discussion

During the meeting members will have the opportunity to discuss the issue and determine what, if any, action is appropriate. To assist with the Committee's discussion, staff are offering a few policy questions below that may be helpful for the Committee.

1. Does the Committee wish to provide guidance to staff on the development of educational materials such as development of a newsletter article?
2. A consulting pharmacist is required certify in writing if the clinic is operating in compliance. The clinic is required to maintain the reports; however, there is no mechanism to confirm that a consulting pharmacist has been retained and is completing the quarterly reports. What mechanism may be appropriate to confirm compliance with this provision? Should verification of compliance be incorporated into the annual renewal?
3. The law is silent as to what action must be taken by a surgical clinic when an issue of noncompliance is identified. When a noncompliance is identified does the Committee believe development of a law or regulation to report noncompliance is appropriate.
4. The law does not currently detail out the specific elements of the consulting pharmacists report. Does the Committee believe it is appropriate to develop a standardized reporting template, perhaps similar to a self-assessment form that could be used by the consulting pharmacist?
5. Depending on the types of services provided at a surgical clinic, it is possible that sterile compounding may be performed. Should the self-assessment form include information about sterile compounding practices?

Depending on the direction from the Committee, should recommendations be offered, Board staff can work with counsel in advance of the next meeting do refine a proposal consistent with the direction of the Committee for its future consideration.

V. **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.

For Committee Consideration and Discussion
As the Board continues to implement these new provisions, it may be appropriate for the Committee to consider if additional action is appropriate to ensure the Board's regulated outsourcing facilities have a clear understanding of the requirements to operate within or into California.

The Board has taken differing approaches to such education in the past, including education through newsletters, development of FAQ's, as well as developed requirements for self-assessments of a facility to self-evaluate for compliance with state and federal law.

Board staff is suggesting that development of regulations may be appropriate to provide more direction to licensees on legal requirements while also establishing a requirement for a self-assessment form. Such an approach would be consistent with several other facilities licensed by the Board including pharmacies, hospitals, and wholesalers.

To assist the Committee in its consideration of the issue, Board staff have developed draft concept regulation language to provide members with general understanding of the concept being offered. As included in this concept language the regulation would detail out some of the legal requirements for outsourcing facilities as well as establishment of a self-assessment form.

As the language and self-assessment form are just concept at this time, should the Committee agree that development of regulations and a self-assessment form is appropriate, it is recommended that the Committee consider delegating to the Committee Chair authority to work with staff and counsel on development of a more refined proposal for consideration at a subsequent meeting.

Attachment 2 includes the draft concept regulation language and self-assessment form.

VI. 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 to a licensee of a citation 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 includes 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.

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 also the authority to issue a cease and desist order.

The Board issued 72 citations for unlicensed activity last year. Such citations including 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.

For Committee Consideration and Discussion

As unlicensed activity may in part be driven by financial factors, it appears appropriate to determine if a fine of $5,000 is sufficient to address unlicensed activity, or if authority to issue a larger fine would be more meaningful in some circumstances.

VII. Future Committee Meeting Dates

- October 4, 2022
- October 19, 2022 – This meeting has been cancelled.

Attachment 1

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 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

DRAFT ENFORCEMENT AND COMPOUNDING COMMITTEE MEETING MINUTES

DATE: July 19, 2022

LOCATION: Public Participation Via WebEx
NOTE: Pursuant to the provisions of Government Code section 11133, neither a public location nor teleconference locations are provided.

COMMITTEE MEMBERS PRESENT: Maria Serpa, Licensee Member, Chair
Jig Patel, Licensee Member, Vice Chair
Renee Barker, Licensee Member
Indira Cameron-Banks, Public Member
Seung Oh, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Ricardo Sanchez, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Eileen Smiley, DCA Staff Counsel
Debbie Damoth, Executive Manager Specialist

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

Chairperson Maria Serpa called the meeting to order at 9:02 a.m. Dr. Serpa reminded all present that the Board is a consumer protection agency. Dr. Serpa advised the meeting was being conducted with participation through WebEx and being webcast. The meeting moderator provided updated WebEx instructions.

Chairperson Serpa welcomed Board Member Renee Barker to the Board and Committee.

Chairperson Serpa took roll call. Members present included: Jignesh Patel, Licensee Member; Renee Barker, Licensee Member; Indira Cameron-Banks, Public Member; Seung Oh, Licensee Member; and Maria Serpa; Licensing Member. A quorum was established.

II. Public Comments on Items Not on the Agenda/Agenda Items for Future Meetings

Members of the public were provided the opportunity to provide comments for items not on the agenda.

Alan Kim, nuclear pharmacists for Cardinal Health, requested that the Enforcement and Compounding Committee discuss Cardinal Health's request to increase the ratio given the unique operations. Dr. Kim was advised to contact the Executive Officer.

III. Approval of April 20, 2022, Enforcement and Compounding Committee Meeting Minutes

Members were provided an opportunity to provide comments on the draft minutes. Chairperson Serpa requested nonsubstantive changes be made and requested the following substantive change to be made was reflected on the screen:

Agenda Item V. Discussion and Consideration of Compounding by Board Licensees Outside a Pharmacy – Last paragraph edited to reflect:

Chairperson Serpa added the issue of unlicensed locations that do compounding by ~~*non-*~~*Board licensed personnel will be added to a future agenda regarding compounding.*

Motion: Approve the April 20, 2022, Committee Meeting minutes as amended as well as discussed and reflected on the screen with corrections.

M/S: Oh/Patel

Members of the public were provided with an opportunity to provide public comment; however, no comment was provided.

Support: 5 **Oppose: 0** **Abstain: 0** **Not Present: 1**

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

The Committee took a break from 9:12 a.m. to 9:18 a.m. Roll call was taken after break. Members present included Jig Patel, Licensee Member; Renee Barker, Licensee Member; Seung Oh, Licensee Member; Indira Cameron-Banks, Public Member; and Maria Serpa, Licensee Member. A quorum was established.

IV. Discussion, Consideration, and Possible Recommendation to the Board to Approve Draft Changes to CCR Section 1715.1 related to Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge of Unlicensed AUDS

Chairperson Serpa advised relevant sections of Pharmacy Law were detailed in the meeting materials and established requirements for the use of automated unit-dose delivery systems, referred to as AUDS, under specified conditions. Related to this agenda item, are those AUDSs that are exempt from licensure by the Board but must otherwise comply with all other requirements for an automated drug delivery system.

Chairperson Serpa advised one such requirement is the completion of a self-assessment form for AUDS. Although the relevant regulation currently provides that a self-assessment must be completed annually, subsequently enacted statutory changes modified the frequency for completion of a self-assessment to every odd year, which is consistent with the required frequency to complete self-assessment form for other licensees. Dr. Serpa added the Board has previously considered and voted to update regulation section to be consistent with statute.

Chairperson Serpa advised the Committee has the opportunity to consider the policy goal of the self-assessment requirement specifically related to unlicensed AUDSs used in hospitals and determine if the Board should provide clarification of the requirement when a hospital is using the same device, with the same policies and procedures on the same computer platform, and if completion of a single self-assessment would be more appropriate. Dr. Serpa added such devices operated in

the same manner and under the conditions just outlined, would yield the same results related to compliance with provisions of pharmacy law, whether one self-assessment was completed or several of the forms would be the same. Dr. Serpa clarified the policy question for the Committee is whether there is value-added for the PIC to be required to complete a self-assessment for each AUDS or if a single self-assessment is sufficient.

Chairperson Serpa advised with a background was in hospital pharmacy, she knew that a large hospital could use over 100 AUDSs in a single building. Dr. Serpa believed a single self-assessment was appropriate because the manufacturer, policies and procedures, and staff are the same and coupled with the fact that programming managing the devices' operations is on a single platform. Dr. Serpa added there was no need for the PIC to complete over 100 forms containing the same information.

Dr. Serpa referenced the meeting materials that included draft language to further amend CCR Section 1715.1 that could be used to clarify the Board's expectations specifically related to the self-assessment requirement for unlicensed AUDS used in a hospital. Dr. Serpa noted the Board had previously taken action to amend this section which is currently pending. The language presented at the meeting has the additional changes recommended reflected in double underline and double strike-through. Dr. Serpa reviewed the specific changes related to the discussion:

- 1715.1(b)(2) – suggested change to simplify the language.
- 1715.1(c)(5) & (c)(6) – updated language to be gender neutral.
- 1715.1(f) – added new language that would clarify the Board's expectation related to completing the self-assessment form for the unlicensed AUDSs used in a hospital. Specified conditions include that to qualify for this modified self-assessment requirement, the mechanical devices used to store, dispense, or distribute dangerous drugs must be from the same vendor and controlled by the same software on a single system and must operate under the same policies and procedures.

Chairperson Serpa recommend replacing the term "vendor" with "manufacturer" and encouraged discussion and feedback on the suggested word change and policy decision.

Members were provided the opportunity to provide comment.

Member Oh inquire if BPC 4427.2 would allow the Board to add an additional layer that would allow an exemption for hospitals to not have to do the same self-assessment as BPC 4427.2 states for unlicensed everything else shall be the same.

Dr. Oh also inquired if the current proposed regulation would be pulled back to make the changes.

Ms. Sodergren confirmed with the Department of Consumer Affairs (DCA) Regulation and Legal Counsel that the Board has the authority to do what is in the language presented. The statue provides general authority and the regulation further clarifies the statutory authority. The current proposed regulation change to CCR section 1715.1 was under review by DCA and has not been publicly noticed so staff recommendation is if the Committee and Board agree appropriate, the current regulations undergoing review will be modified to incorporate additional changes.

Member Barker commented in agreement to change "vendor" to "manufacturer" as those types of equipment are discussed in terms of manufacturers.

Motion: Recommend incorporation of the additional proposed changes to CCR Section 1715.1 as proposed into the Board's current regulation proposal with the change of "vendor" to "manufacturer" in CCR Section 1715.1 (f)(1) giving the Chairperson and Executive Officer the authority to make nonsubstantive changes for the regulation to be approved.

M/S: Oh/Patel

Proposed Amendment to § 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge. Changes in ~~double strike~~ through and <u>double underline</u> are possible changes for the Committee's consideration.

(a) The pharmacist-in-charge of each automated drug delivery system as defined under section 4119.11, 4187.5 or section 4427.3 of the Business and Professions Code <u>(BPC)</u> shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed ~~annually~~ before July 1 of every <u>odd-numbered</u> year. The primary purpose of the self-assessment is to promote compliance through self-examination and education.

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
(1) A new automated drug delivery system license has been issued.

(2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
(3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~ 22) entitled "Automated Drug Delivery System Self-Assessment". Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
(1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
(A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
(B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
(C) DEA registration number, expiration date, and date of most recent DEA inventory;
(D) Hours of operation of the pharmacy; and
(E) ADDS license number, address, and hours of operation.
(2) The pharmacist-in-charge shall respond "yes", "no", or "not applicable" (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
(3) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
(4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.
(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that they have ~~he or she has~~ completed the self-assessment of the automated drug delivery system of which they are ~~he or she is~~ the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. 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.

(6) The automated drug delivery system owner shall certify on the final page of the self-assessment that they have ~~he or she has~~ read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the automated dispensing system's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California with an original handwritten signature in ink or digitally signed in compliance Civil Code Section 1633.2(h) on the self-assessment form.

(d) Each self-assessment shall be completed in its entirety and kept on file in the underlying pharmacy for three years after it is performed. The completed, initialed, and signed original must be readily available for review during any inspection by the board.

(e) Any identified areas of noncompliance shall be corrected as specified in the assessment.

(f) The pharmacist-in-charge of a hospital using more than one unlicensed automated drug delivery system as authorized in BPC section 4427.2(i) may complete a single self-assessment of the hospital's compliance with federal and state pharmacy law for all automated drug delivery systems under the following conditions:

(1) The mechanical devices used as part of the ADDS to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and

(2) The same policies and procedures required by Section 4427.2 of BPC are used.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4 and 4427.5, Business and Professions Code; and Section 16.5, Government Code.

The Committee heard a comment from a Kaiser representative indicating continued belief that the changes are inconsistent with BPC 4427.2 (i) and 4427.7 (a). The commenter appreciated the Committee's recognition that one self-

assessment should be required for all of the exempt AUDS operated by a hospital that will minimize the administrative burden and the direction taken.

Support: 5 **Oppose: 0** **Abstain: 0** **Not Present: 1**

Committee Member	**Vote**
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

V. Discussion and Consideration of the Proposed Revisions to Frequently Asked Questions Related to Automated Drug Delivery System (ADDS)

Chairperson Serpa recalled as part of the July 2021 Board meeting, the Board approved draft FAQs related to ADDS. To ensure that Board FAQs remain relevant, updates are necessary when changes in the law occur. Dr. Serpa referenced the meeting materials that include draft updated FAQs. Dr. Serpa thanked Supervising Inspector Janice Dang and DCA Legal Counsel Eileen Smiley for their work to update these FAQs.

Members were provided the opportunity to comment. Member Patel commented the FAQs were excellent.

Motion: Recommend approval of the proposed revisions to the frequently asked questions related to automated drug delivery systems.

M/S: Patel/Oh

Members of the public were provided the opportunity to comment. No public comments were made.

Support: 5 **Oppose: 0** **Abstain: 0** **Not Present: 1**

Committee Member	Vote
Barker	Support
Cameron-Banks	Support
Oh	Support
Patel	Support
Sanchez	Not Present
Serpa	Support

VI. Discussion and Consideration of Committee's Strategic Objectives

Chairperson Serpa advised on an annual basis the Board receives recommendations from the various strategic committees. Dr. Serpa referenced the meeting materials include the strategic objectives for the Committee. Dr. Serpa noted later in the meeting, the Committee will receive presentations on the Board's inspection program and citation program, which is in part how the Committee monitors some of the Committee's strategic objectives.

- 2.1 Evaluate, and take necessary actions, regarding the causes and effects of medication errors to reduce errors.
  Status: Medication Error Reduction and Task Force Ad Hoc Committee established and has begun convening public meetings.
- 2.2 Analyze enforcement outcomes to identify trends to educate licensees of common violations and improve patient outcomes.
  Status: Annual presentation on the Board's Citation and Fine Program and Board's Inspection Program provided and top violations published in the Board's newsletter.
- 2.3 Complete routine inspections of all licensed pharmacies at least every four years to proactively assess pharmacy operations and educate licensees.
  Status: In FY 2021/22, Board staff conducted 1,598 routine inspections.
- 2.4 Determine and reduce barriers to timely case resolution to improve consumer protection.
- 2.5 Assess, and pursue where appropriate, further use of a Standard of Care Enforcement Model to protect consumers.
  Status: Standard of Care Ad Hoc Committee established and has begun convening public meetings.
- 2.6 Establish greater consistency in how inspectors interpret the law and carry

our inspections to improve compliance, support licensees, and further patient care.

- 2.7 Write a Budget Change Proposal to increase the number of enforcement staff to ensure more regular inspections and investigations, and to improve case processing times.
  Status: New inspector position received to perform inspections and related investigations stemming from new legislative mandates.
- 2.8 Educate licensees about enforcement responsibilities to improve compliance and build relationships.
- 2.9 Assess pharmacist involved in medication handling at locations not regulated by the Board of Pharmacy to increase patient safety and standardize care.
- 2.10 Evaluate if regulations align with federal regulations and standard governing the practice of compounding and pursue changes, if appropriate, to ensure patient safety and assist licensees with education about standards.

Chairperson Serpa stated she believed the established strategic objectives are appropriate and did not believe any changes are required. Dr. Serpa anticipated there will be significant Committee activity related to strategic objective 2.10 as USP completes its work to revise and release chapters related to compounding.

Members were provided the opportunity to provide comments; however, no comments were made.

Members of the public were provided the opportunity to provide comments; however, no comments were made.

VII. Presentation and Discussion on Board's Inspection Program

Chairperson Serpa welcomed Chief of Enforcement Julie Ansel to provide a presentation on the Board's Inspection program.

Ms. Ansel reviewed the Board's mandate of consumer protection and policy goals to inspect locations every four years. Ms. Ansel reviewed the inspection process including observations of the Inspector when on an inspection including consultation procedure; notice to consumer poster, language sign, pharmacy permit; security features; nametags; audio and visual privacy; staffing ratio and duties being performed; and professional interactions. She referenced the Board's video on the Board's website entitled "How to Prepare for an Inspection." Ms. Ansel reviewed the items reviewed by the Inspector including self-assessment forms; transmissions to CURES; enrollment in the Board's subscriber alert system; quality assurance policy and medication error reports; and policies and procedures.

Ms. Ansel reviewed items inspected during an inspection to include the physical facility; security; cleanliness and orderliness; and expiration dates on labels. Ms. Ansel provided an overview of the educational opportunities an Inspector might discuss with a licensee to include questions from licensees and providing reminders of the Board's continuing education requirements, newsletter, website, pamphlets, written notice of right to consultation and self-assessments as a tool for compliance. She added Inspectors also discuss staffing at community pharmacies, keeping a log and signed policies and procedures, requirements for email address, and vaccine requirements. The education is to allow for dialogue with the Inspector and licensees.

Ms. Ansel reviewed the total inspections completed for the past five years highlighting in FY 21/22 2,938 inspections were completed consisting of 2,862 in person inspections and 76 desk audits. Ms. Ansel reviewed the types of inspections to include 1,099 routine pharmacy inspections for PHY/PHE; 313 compliance inspections; 331 pharmacist recovery program/probation; and 935 compounding inspections consisting of 64 new inspections, 799 renewal in person inspections and 72 renewal desk audit inspections. Ms. Ansel reviewed the inspections by type for FY 21/22.

Ms. Ansel provided a breakdown of outcomes by routine inspection outcomes for FY 21/22 including types (routine, complaint, probation) of inspections and outcomes including no violations, corrections and violation notices issued. Ms. Ansel reviewed the top corrections and violations for routine pharmacy inspections. She advised of the 66 routine inspections completed in FY 21/22, an Inspector observed that consultation was not provided to the patient in 9 inspections and in 57 inspections, the Inspector found that the site was not providing written notice of consultation on delivered or mail order prescriptions. Ms. Ansel provided an update on the policy goal of inspecting licensed facilities every four years. Ms. Ansel advised the Board has inspected 92 percent of the current pharmacy population since January 2013.

Chairperson Serpa thanked Ms. Ansel and the staff's efforts towards meeting the Board's strategic objective related to routine inspections. Dr. Serpa was pleased to see the data shows that pharmacies with no inspection or no inspection since 2013 has dropped from 2080 pharmacies 2 years ago to 463 this year. Dr. Serpa noted it appears this issue may be completely addressed within this fiscal year. Dr. Serpa advised this goal was established without additional resources noting these inspections were completed in addition to the current workload of the Board's inspections. Dr. Serpa expressed gratefulness to staff's efforts. Dr. Serpa expressed concern with pharmacist consultation not being provided to patients.

Members were provided the opportunity to provide comments.

Member Oh thanked Ms. Ansel, Ms. Sodergren, and staff for the amazing job of working on the policy goal. Dr. Oh stated the Board will have to continue to communicate the importance of consultation.

Member Patel commented consultation is key to medication error reduction and the safety of the consumers. With new electronic prescriptions and changes in how prescriptions are being filled, patients and pharmacy staff view prescriptions as refills. Member Patel stated the Board needs to communicate using email notification and statistics to help reduce medication error reduction.

Members of the public were provided the opportunity to provide comments; however, no comments were made.

VIII. Presentation and Discussion on Board's Citation and Fine program

Chairperson Serpa welcomed the Board's Executive Officer Anne Sodergren to provide a presentation on the Board's Citation and Fine Program.

Ms. Sodergren explained the citation is one type of outcome from an investigation. She provided a review of the citation program relevant law and citation program overview. Ms. Sodergren stated the Board uses its authority to issue citations and fines to address significant violations but not those that warrant removal or restriction of a license to ensure consumer protection. The Board's fine authority is typically $5,000 with few exceptions including internet prescriptions which is $25,000 per prescription; purchasing from unlicensed source is $5,000 per invoice; up to a fine of $100,000 for violations found in three or more community pharmacies that are similar and up to $150,000 for violations that result from a written policy of community chain policy that resulted in the violations of pharmacy law.

Ms. Sodergren reviewed the factors to consider in assessing administration fines. She further explained the citation process: investigation is completed; supervising inspector review; second level review; citation issued without fine and with/without abatement; citation completed with fine or abatement accepted; and appeal informally by office conference and/or formal appeal through the Office of Attorney General's (AG) office.

Ms. Sodergren reviewed the citations and fines collected over the past seven years. She reviewed the average process time from receipt to issuance in FY 21/22 is less than a year.

Ms. Sodergren advised in 2018 the Board provided direction to the staff to fully realize the order of abatement tool. The Board has been using the order of abatement tool more frequently since 2018. Ms. Sodergren reviewed the abatement types including requested/required continuing education to be completed by the licensee; internal policy training/in service training; updated self-

assessment; and updated policies and procedures. Ms. Sodergren advised 168 of 269 abatements were satisfied in FY 21/22. She noted not all abatements are required and some take a longer time to complete.

Ms. Sodergren reviewed violations that lend themselves to abatements such as pharmacy shall be clean and orderly; pharmacy security; medication error; vaccine/immunization; and compounding violations. She reviewed the appeal process through the office conference or formally appeal through the AG.

Ms. Sodergren reviewed the past seven years of citations completed or contested as well as the outcomes after office conference or AG. She reviewed the 10 violations for pharmacies and pharmacist with medication error being the most prevalent. The list of top violations is used for education in the Board's newsletter. Ms. Sodergren reviewed the top 10 violations for pharmacy technician with self-administer drugs/alcohol and conviction of a crime substantially related to pharmacy were the most prevalent. She reviewed the outcomes for the duty to consult for the past three fiscal years and outcomes as well as noted there were two citations issued to community pharmacies under common ownership or management.

Chairperson Serpa thanked Ms. Sodergren and noted consistent with the Board's strategic objective the common violations will be used as educational materials.

Members were provided the opportunity to provide comments. Member Oh thanked Ms. Sodergren.

Members of the public were provided the opportunity to provide comments; however, no comments were made.

IX. Discussion and Consideration of Community Pharmacy Staff Requirements including Business and Professions Code Section 4113.5 and Title 16, California Code of Regulations Section 1714.3

Chairperson Serpa referenced the meeting materials that detailed out the relevant sections of pharmacy law specifically BPC 4113.5 that provides a pharmacist shall not be required to engage in the practice of pharmacy unless another employee of the pharmacy or an employee of the establishment is made available to assist the pharmacist at all times. She noted the Board's regulation details out the requirements pharmacies must meet to satisfy the requirements of the statute.

Chairperson Serpa advised as there are investigations pending in this area, she requested members, staff, and the public keep comments general in nature to ensure members avoid any inadvertent exposure to information that would then preclude members from involvement in our role as a decision maker in an enforcement matter.

Chairperson Serpa advised the materials detailed out the implementation strategy used by staff, where staff initially focused efforts on education of the requirements. Staff efforts transitioned to issuing orders of correction to gain compliance. However, after a significant period of time to allow pharmacies to comply with the provisions, depending on the egregiousness of the violation staff determine the appropriate outcomes. To date the Board has issued two citations for violations of these provisions.

Chairperson Serpa noted there appears to be a misunderstanding by some about the requirements of the statute as well as frustration by some pharmacists who are not requesting assistance because such assistance would not be made available even if such a request was made. Dr. Serpa thanked the staff for the review of the implementation efforts.

Members were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to provide comment.

The Committee heard comments from a representative from UFCW who expressed appreciation for agendizing the item and implementing the statute. The commenter underscored the importance of education in addition to three observations: confusion about the requirements; ongoing need to continue public education; and recognition of the Board that at the core a true health and safety issue if a licensee is unable to do their job if the pharmacy is not properly staffed.

Chairperson Serpa noted a recent alert sent to licensees via subscriber alert. Ms. Sodergren indicated an alert was sent about SB 362 but noted the information about retaliation, whistleblowing protections and filing complaints would apply to this as well.

X. Review and Discussion of Enforcement Statistics

Chairperson Serpa provided the year end and three-year comparison on the enforcement statistics were included in meeting materials.

Members were provided the opportunity to provide comment; however, no comments were made.

Members of the public were provided the opportunity to provide comment; however, no comments were made.

XI. Future Committee Meeting Dates

Chairperson Serpa advised there are several meetings planned through the end of the year due in part to ensure sufficient time to consider revised USP compounding chapters. Dr. Serpa noted unfortunately, there is no timing on when the revised chapters will be released. Depending on the release, the Committee may need to adjust its meeting schedule. Dr. Serpa advised as part of its May 14, 2022, announcement, USP indicated that it did not have an anticipated date for final publication. Updates will continue to be monitored and may impact to the meeting schedule.

XII. Adjournment

The meeting adjourned at 10:45 a.m.

Attachment 2

Title 16. Board of Pharmacy

Create a new article

Proposed Addition to sections 17XX and 17XX of Article XX of Division 17 of Title 16 of the California Code of Regulations to read as follows:

17xx 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 applicable to outsourcing facilities under § 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: [insert all other provisions listed on the self-assessment form not covered in subsection (c) below].

(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 be issued by an appropriately licensed prescriber or healthcare professional as set forth in Business and Professions Code section 4040.
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 practitioner.
3. Electronic prescriptions meeting the requirements of Business and Professions Code Section 688 are issued only by an appropriately licensed practitioner.
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 and 4076.5 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 (CFR), and section 1717(a) of this Division.
9. Patient consultation is provided consistent with the provisions of section 1707.2.
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.
11. The facility shall maintain medication profiles consistent with the provisions of 1707.1.
12. Prescriptions for controlled substances as defined in Business and Professions Code section 4021 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 at Civil Code section 56.10, and section 1764 of this Division.
16. Prescription refills must comply with the relevant provisions of 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.
18. Patient package inserts, medication guides and Black Box Warning Information must be provided consistent with provisions of Title 21 of the Code of Federal Regulations sections 310.515, 201.57c and 21 CFR Part 208, Section 208.24(e)

17XX. 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 17XX (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 compliance with this section.

(b) Each outsourcing facility shall designate a member of the quality control unit to be responsible for compliance with this section. Confirmation by the designated individual 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 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 4129.2 or 4129.2 shall complete the "Outsourcing Facility Self-Assessment," Form 17M-117 (Rev. 7/1/2022), which is hereby incorporated by reference. The form shall include the information required by this section.

(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) issued outsourcing number, expiration date and dates of most recent inspection completed by the FDA

(D) Federal Drug Enforcement Administration (DEA) registration number and expiration date and date of most recent DEA inventory;

(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 corrective action or action plan describing the actions to be taken to come into compliance with the applicable law or regulation cited on the form for which a "no" response was provided.

(5) The designated quality control personnel shall initial each page of 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 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.

(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. This certification shall be made under penalty of perjury of the laws of the State of California.

(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 jointly responsible with the designated quality control personnel for compliance with this section.

(g) Any identified areas of deficiency in the certification specified in (d)(6) of this section shall be corrected as specified and corrected in the timeframe listed in the certification.

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

DRAFT CONCEPT - Outsourcing Facility Self-Assessment

The California Code of Regulations section 4129.1(b) and 4129.2(b) require any Outsourcing Facility licensed in the state of California to be compliant with current Good Manufacturing Practices (Section 21 Code of Federal Regulations (CFR) parts 210 and 211 and any associated parts and subparts). These shall supersede California Pharmacy Regulation except as noted below in this self-assessment for the express purpose of dispensing/furnishing patient specific prescriptions in or into California. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever: (1) a new pharmacy permit has been issued; or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. 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 and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment. This is meant as a guide of the regulations when filling a patient specific prescription to be furnished to and into the state of California by a licensed Outsourcing Facility. The licensed Outsourcing Facility can only furnish their own compounded products pursuant to a prescription in or into the state of California. No commercially available products can be furnished to any patients residing in California as the licensed outsourcing facility is not a licensed pharmacy with all the rights and requirements of said license.

Outsourcing Facilities are not licensed pharmacies and may not provide or accept transferred prescriptions.

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

Facility Name: _____

Address: _____ Phone: _____

Ownership: Sole Owner ☐ Partnership ☐ Corporation ☐ LLC ☐ Trust ☐
Non-Licensed Owner ☐ Other ☐ (please specify) _____

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

FDA EIN #: _____ Issue Date: _____ Exp. Date: _____

Accredited by: _____ From: _____ To: _____

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

Website address (optional): _____

_____
Initials

Facility Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to dispensing duties): (Please use additional sheets if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

2. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
   DEA # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ INT # _____ Exp. Date: _____

10. _____ INT # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

12. _____ TCH # _____ Exp. Date: _____

13. _____ TCH # _____ Exp. Date: _____

14. _____ TCH # _____ Exp. Date: _____

15. _____ TCH # _____ Exp. Date: _____

_____
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. Only 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 drug 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[el)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Patient Consultation

Yes No N/A

☐ ☐ ☐ 2.1 The facility has an area suitable for confidential patient consultation. (CCR 1764, 1714)
☐ ☐ ☐ 2.2 Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707 .2)
- ☐ 2.2.1 Whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 2.2.2 Whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 2.2.3 Upon request;
- ☐ 2.2.4 Whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment; and
- ☐ 2.2.5 All the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

☐ ☐ ☐ 2.3 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)
☐ ☐ ☐ 2.4 The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707 .3)
☐ ☐ ☐ 2.5 Consultation is performed in a manner that protects the patient's protected health care information and, in an area, suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a], 1764)

_____
Initials

Yes No N/A

☐ ☐ ☐ 2.6 Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)
☐ ☐ ☐ 2.7 If prescription medication is mailed or delivered, the facility ensures that: (CCR 1707.2[b][1])
- ☐ 2.7.1 The patient receives written notice of his or her right to request consultation (CCR 1707.2 [b][2][A]);
- ☐ 2.7.2 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][2][B]);
- ☐ 2.7.3 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 less than six days per week, and for a minimum of 40 hours per week (CCR 1707.2 [b][2][C]).

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

3. Prescription Requirements

Yes No N/A

☐ ☐ ☐ 3.1 Prescriptions are complete with all the required information. (BPC 4040, 4070)
☐ ☐ ☐ 3.2 Orally transmitted prescriptions are received and reduced to writing only by a pharmacist (BPC 4070, CCR 1717)
☐ ☐ ☐ 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, 1712)
☐ ☐ ☐ 3.5 The security and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])
☐ ☐ ☐ 3.6 Facsimile prescriptions are received only from a prescriber's office. (BPC 4040[c])
☐ ☐ ☐ 3.7 Internet prescriptions patients (human or animal) in this state are only dispensed or furnished pursuant to a prior good faith examination. (BPC 2290.5, 2242, 2242.1, 4067[a])
☐ ☐ ☐ 3.8 Except for those prescriptions written under HSC 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 11164[a], HSC 11167.5, HSC 11162.1)
☐ ☐ ☐ 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 No person shall dispense a controlled substance pursuant to a preprinted multiple check-off prescription blank. (b) 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

_____
Initials

substance, pursuant to such a blank if the prescriber has indicated on the blank the number of dangerous drugs he or she has prescribed. (c) “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. (BPC 4005, 4040, CCR 1717.3)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Refill Authorization

Yes No N/A

☐ ☐ ☐ 4.1 Refill authorization from the prescriber is obtained before refilling a prescription. (BPC 4063)

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

☐ ☐ ☐ 4.3 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)

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

☐ ☐ ☐ 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. (H&SC 11200)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Medication Errors related to a patient specific prescription

Yes No N/A

☐ ☐ ☐ 6.1 The firm 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)

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

☐ ☐ ☐ 6.3 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])

☐ ☐ ☐ 6.4 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])

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

_____
Initials

Yes No N/A

☐ ☐ ☐ 6.6 In addition to all complaint and adverse drug reaction tracking compliant with the CFR, the record for quality assurance review for a medication error contain (CCR 1711[e])
- ☐ 6.6.1 Date, location, and participants in the quality assurance review;
- ☐ 6.6.2 Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 6.6.3 Findings and determinations; and
- ☐ 6.6.4 Recommended changes to policy, procedure, systems, or processes, if any.

☐ ☐ ☐ 6.7 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 [fj)

☐ ☐ ☐ 6.8 Pharmacists are not deviating from the requirements of a prescription except upon the prior consent of the prescriber, and selection of the drug product is in accordance with BPC 4073 (generic substitution). (CCR 1716)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Erroneous or Uncertain prescriptions

Yes No N/A

☐ ☐ ☐ 7.1 Before dispensing a prescription that 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])

☐ ☐ ☐ 7.2 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)

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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.

☐ ☐ ☐ 7.2 The prescription label is formatted in accordance with patient centered labeling requirements. (CCR 1707 .5)

_____
Initials

Yes No N/A

☐ ☐ ☐ 7.3 The expiration date of a drug's effectiveness is accurately identified on the label. (BPC 4076)

☐ ☐ ☐ 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 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, CCR 1717[b][2], CCR 1707.5[a][1][B])

☐ ☐ ☐ 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)

☐ ☐ ☐ 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 appears 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 the English-language directions is not possible to appear on the container or label, the english-language directions is provided on a supplemental document. (BPC 4076.6)

☐ ☐ ☐ 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[a][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. (BPC 4074[a], CCR 1744[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Furnishing and Dispensing

Yes No N/A

☐ ☐ ☐ 8.1 Generic substitution is communicated to the patient. (BPC 4073)

☐ ☐ ☐ 8.2 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, CCR 1793.7, CCR 1712)

_____
Initials

Yes No N/A

☐ ☐ ☐ 8.3 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. SC 1473[b], 16 CFR 1700.15, CCR 1717)

☐ ☐ ☐ 8.4 Patient package inserts are dispensed with all estrogen medications. (21 CFR 310.515)

☐ ☐ ☐ 8.5 The facility provides patients with Black Box Warning Information in conformance with 21 CFR 01.57[c].

☐ ☐ ☐ 8.6 Medication guides are provided on required medications. FR, Part 208, Section 208.24[e])

☐ ☐ ☐ 8.7 The facility furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription.

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

☐ ☐ ☐ 8.9 Refills for Schedule lll 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])

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

☐ 8.10.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; and where: (BPC 4064.5[a])

☐ 8.10.2 The prescriber has not indicated "no change to quantity" or words of similar meaning; (BPC 4064.5[d])

☐ 8.10.3 The patient has completed an initial 30-day supply; (BPC 064.5[a][1]) (This is not required where the prescription continues the same medication as previously dispensed in a 90-day supply. BPC 4064.5[b])

☐ 8.10.3 The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])

☐ 8.10.4 The prescriber has not specified on the prescription that dispensing the prescription in an initial amount, followed by periodic refills, is medically necessary; and (BPC 4064.5[a][3])

☐ 8.10.5 The pharmacist is exercising his or her professional judgment. (BPC 4064.5[a][4]) The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.S[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

9. Confidentiality of Prescriptions

Yes No N/A

☐ ☐ ☐ 9.1 Patient information is maintained to safeguard confidentiality. (Civil Code 56.10 et seq.)

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

_____
Initials

Yes No N/A

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

☐ ☐ ☐ 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 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: _____

_____

10. Record Keeping Requirements in addition to compliance with cGMP

Yes No N/A

☐ ☐ ☐ 10.1 It is encouraged for completed self-assessments to be on file in the facility and maintained for three years.

☐ ☐ ☐ 10.2 All drug acquisition and disposition records (complete accountability) are maintained for at least three years. 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 maintained electronically. These records include (BPC 4081, 4105, 4169, 4333):

- ☐ 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, CCR 1718)
- ☐ 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])
- ☐ 10.2.8 Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)
- ☐ 10.2.9 Records of receipt and shipment (BPC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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: _____

_____
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, Personnel training, qualification, & monitoring

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: _____

_____

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: _____

_____

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 211.8- through 211.94 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

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: _____

_____

_____
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: _____

_____

Release of product for sale

18. 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: _____

_____

Distribution, storage,

19. 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: _____

_____

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: _____

_____

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: _____

_____
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).

☐ ☐ ☐ 22.2 Schedule II inventory is separate from Schedule III, IV and V. See also Section 21. (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 111-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 111-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 U.S. Official Order Form (DEA Form222) 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 Form222. (21 CFR 1305.03, 1305.12, 1305.13, 1305.21, 1305.22[9])

☐ ☐ ☐ 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 prescription. (HSC 11167[d])

☐ ☐ ☐ 22.9 The facility generates a controlled substance printout for refills of Schedule 111-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 21CFR 1306.22.

☐ ☐ ☐ 22.10 Any controlled substances drug loss is reported within one business day of discovery to the DEA and within 30 days of discovery to the Board of Pharmacy. (21 CFR 1301.74[c], CCR 1715.6)

☐ ☐ ☐ 22.11 Are the staff doing hand initial prescription records or prescription labels, or does the facility comply with the requirement for a pharmacist to initial or sign a prescription record or prescription label by recording the identity of the reviewing pharmacist in a computer system by a secure means. This computer 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])

_____
Initials

Yes No N/A

☐ ☐ ☐ 22.12 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)])

☐ ☐ ☐ 22.13 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)

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

_____
Initials