California State Board of Pharmacy
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

Enforcement and Compounding Committee Report
January 20, 2021

Maria Serpa, Licensee Member, Chair
Jignesh Patel, Licensee Member, Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

I. Call to Order and Establishment of Quorum

II. Public Comment on Items Not on the Agenda, Matters for Future Meetings

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

III. Approval of October 27, 2020, Enforcement and Compounding Committee Meeting Minutes.

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

IV. Presentation on the Pharmacists Recovery Program

Relevant Law

Business and Professions Code (BPC) section 4360, et seq., establishes the requirement for the Board to operate a Pharmacists Recovery Program (PRP) to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. As specified in statute, the intent of the probation is to return pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

Under the provisions of the statute, the Board is required to contract with one or more qualified contractors to administer the Pharmacists Recovery Program.

BPC section 315 establishes the uniform standards for substance abusing licensees. (Note: SB 1441 (Ridley-Thomas, Chapter 548, Statutes of 2008) created the Substance Abuse Coordination Committee (Committee) under the Department of Consumer Affairs (DCA). The Committee was

tasked with creating a set of uniform standards to be used by the healing arts boards to deal with substance-abusing licensees in the health care professions. The final uniform standards, released in 2011, covered a wide range of issues related to substance abuse rehabilitation, including clinical diagnostic evaluation, testing frequency, standard of treatment, consequences for violations, and more. Subsequent legislation, SB 796 (Hill, Chapter 600, Statutes of 2017) required DCA to reconvene the Committee to specifically review the existing criteria for Uniform Standard #4 related to drug testing and determine if the standard should be updated.

Background

As provided for in the statute, pharmacists and interns can self-refer to the program, can be referred in lieu of discipline or referred as a condition of discipline. As indicated in the statistics provided in Attachment 8, there are currently, 55 participants in the program, including five participants informally referred to the program, one participant referred it in lieu of discipline, and 49 participants referred as a condition of probation. A Board informal referral is typically done through the course of an investigation where Board staff have determined that a pharmacist or intern may benefit from the program. In such instances the licensee is provided with information about the program, but is not mandated to participate. Typically, such a licensee chooses to enter the program as either a self-referral or as a Board informal, participation in the program is considered as mitigation and evidence of rehabilitation for purposes of case settlement.

Further, as provided in the statute, the Board contracts for these services. The current vendor administering the program is MAXIMUS Inc. MAXIMUS provides these services for several Boards within the DCA under a single contract that details out program requirements shared across all of the DCA programs, as well as DCA program specific components. Such an approach ensures compliance with the provisions of uniform standards, but also allows for appropriate monitoring and treatment given the unique practice requirements for the various Boards.

For Committee Discussion

During the meeting members will receive a presentation from Maximus staff on the PRP including typical treatment contract requirements and program outcomes.

Attachment 2 includes a copy of the relevant laws and information from the Board's website describing the program. Statistics on the program are included as part of the enforcement statistics in **Attachment 8**.

V. Discussion and Consideration of Board Policy Related to Transparency Involving the Issuance of Citations and Fines

Background

Under the Board's public disclosure policy, citations are among the types of information disclosed to a member of the public upon request. Whereas disciplinary actions are posted on the website, citations are not.

This committee has previously considered if changes to the Board's current policy would be appropriate. During the April 2018 Enforcement Committee meeting, the committee requested that staff survey all DCA healing arts boards to determine how each of the boards handles general

transparency related to the issuance of citations and fines. Subsequent to that discussion, as part of the June 2018 meeting, the committee voted to recommend that staff to identify possible parameters on posting mechanisms and conditions under which citations and fines would be posted for 3 years. However, during the July 2018 Board Meeting, after discussion and consideration, the Board spoke in support of transparency but expressed concern with posting citations for minor violations that may unnecessarily diminish the public's trust in pharmacists and pharmacies. After discussion the Board decided not to vote on the committee's motion. The Board asked the Enforcement Committee to re-visit the issue at its next meeting. This subsequent discussion did not occur.

In 2018, DCA healing arts boards were surveyed to determine whether each board posted citations and fines issued to licensees on their websites. At that time, the survey showed that fifteen of the eighteen DCA healing art boards post citations and fines on their website; however, the duration of the postings varies. It was noted that most boards surveyed are actively using the BreEZe System, which may be programmed to upload citations and fines to their respective sites.

For Committee Discussion

Members will have the opportunity to further discuss the issue and provide a recommendation to the Board for its consideration. As part of its discussion, it may be appropriate for the committee to consider some larger policy questions including:

1. What is the larger policy goal of the Board?
2. Are there any unintended consequences if the Board changes its current policy?
3. If changes to the policy are recommended, what types of education should to be provided to ensure consumers have a clear understanding of the information?
4. Is there concern that posting citations that are non-disciplinary could be then considered by some as a kind of discipline?
5. Would the citation itself be posted, or a summary of the violations? If an abatement was completed, should that information similarly be posted?

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

a. Community Pharmacy/Hospital Out-Patient Self-Assessment Form (17M-13)
b. Compounding Self-Assessment (17M-39)
c. Hospital Pharmacy Self-Assessment (17M-14)
d. Wholesaler Dangerous Drugs & Devices Self-Assessment (17M-26)
e. Automated Drug Delivery Systems Self-Assessment (17M-112)

Background

Under the law, Board licensees are required to perform self-assessments of its operations to evaluate for compliance with Pharmacy Law, its regulations, and other provisions of state and federal law that govern the practice of pharmacy. As Pharmacy law is dynamic, it is important to maintain current self-assessment forms to assist licensees in remaining compliant.

As these forms are incorporated by reference in the various regulation sections, rulemakings are necessary to permanently update these forms. As a matter of practice, upon approval of the Board,

updated draft forms are posted on the Board's website in advance of the formal rulemaking. To fulfill legal requirements, the Board will accept completion of either the current draft version of the self-assessment form or the version incorporated by reference in the regulation; however, staff typically recommend completion of the most recent draft version as it provides for more meaningful self-assessment.

Several of the Board's current self-assessments are currently in various stages of review and promulgation to make permanent prior versions of the assessment forms. It is staff's hope that the review processes will be completed to allow for the initiation of the formal rulemaking process. Staff recommend that identified updates to the self-assessment forms that have occurred since the Board's initial approval of the forms could be achieved through the formal rulemaking process once initiated. Such an approach would hopefully mitigate any further delays in the regulation process.

For Committee Discussion

During the meeting members will have the opportunity to review the draft updates to the self-assessment forms and provide feedback to staff. Should the committee agree with the edits and or offer changes, Board staff will work to incorporate the additional changes for consideration by Board during the January meeting.

Attachment 3 includes copies of the updated draft self-assessment forms.

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

Relevant Law

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

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

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

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

Background

The Committee and Board have previously contemplated development of an alternative enforcement model. The goal of the alternative model is to reduce the time and cost associated with resolving a disciplinary matter which must be balanced with also continuing to provide dur process to licensees and consumer protection. The original proposal developed and considered by the Committee and Board was based on a model used by the Physical Therapy Board, that provides

an option for pre-pleading settlement of an administrative matter where the outcome of the matter is a Public Letter of Reprimand. The language for such authority is provided below:

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

Subsequent to the initial drafting, additional elements were added to the proposal to include involvement by two Board members in the settlement process. In January 2020, the committee indicated it was interested in exploring oral conferences as part of the process. At that time, counsel advised members of possible concerns and requested time to evaluate the overall proposal as well as the addition of an oral conference as part of the alternative enforcement model.

Most recently, during its October 2020 meeting, members reviewed statistical information regarding disciplinary cases. After discussion, the committee did not reach a conclusion, but determined that additional consideration of both the overall policy goal and proposed solution is appropriate. Provided below are the statistics previously considered. Further, during the meeting, members advised stakeholders that it would welcome input on proposed solutions during its next meeting.

Provided below is the data previously considered by the committee as part of its discussion, with updated benchmark timeframes.

Overall Investigation Statistics by Outcome

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

Overall Disciplinary Cases by Resolution Type

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

Outcomes of Mail Vote Process (Nonadopted versus adopted)

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

Case Outcomes

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

<u>For Committee Discussion</u>

During this meeting members will have the opportunity to further its discussion. Further, stakeholders will be provided the opportunity to present recommended proposals.

To assist in its assessment it may be appropriate for members to consider the following questions.

1. What is the problem seeking to be solved and/or the policy goal?
2. How or is such a change consistent with the Board's consumer protection mandate?
3. If such a change is appropriate, what are some of the basic elements that should be considered to meet the stated policy goal, where in the process should the deviation occur, and should it be limited to certain types of cases?
4. Would such changes provide the appropriate balance of consumer protection and due process?
5. Would such a change increase or decrease the time for case resolution?
6. What are potential impacts on cost is such changes were made.
7. What other government agencies should be considered as part of this proposal?
8. If changes are sought, should a step approach be taken, i.e. seeking authority similar to that of the Physical Therapy Board as a first step.
9. Should delegated authority be granted to the Executive Officer to accept revocation or surrender of a license through a stipulated settlement? Board staff note that some Boards within the DCA have delegated such authority to its Executive Officer.

10. Should additional delegated authority be granted to the Executive Officer to accept default decisions?

Attachment 4 includes a copy of the memo previously provided to members from counsel discussing and analyzing the prior proposal.

VIII. Discussion and Consideration of the Discrepancies Between the State and Federal Controlled Substances Schedules and Its Impact on Healthcare Services

Background

Medications with the potential to be the most highly abused or lead to addiction are classified under separate federal and state laws into five lists of "scheduled" drugs, the lower the number, the higher the potential for abuse.

While the federal controlled substances schedules are promulgated federally, principally by the DEA, and found in Code of Federal Regulations, there does not currently appear to be a regulator principally responsible for evaluation of the California controlled substances schedules, which are codified in the California Health and Safety Code.

Generally, there is a high degree of similarity in how medications are classified under the federal and state schedules. However, there are some differences between the federal and state schedules. In recognition that some discrepancies exist, many times both provisions of Pharmacy Law and of the Health and Safety Code specify as part of the requirements, which schedule, state or federal, shall be used in determining compliance. As an example, HSC Code 11165(d) specifies that the controlling schedule for purposes of reporting to CURES is the federal schedule.

In 2017 this Committee and the Board discuss challenges with the discrepancies between the schedules and voted to pursue legislative changes to synchronize the schedules. At that time the Board's policy goals were not fully realized; however, significant changes were secured that resulting in the harmonizing of hydrocodone containing products.

Below is the proposal approved by the Board at that time:

Business and Professions Code section 4021. "Controlled substance" defined

"Controlled substance" means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code and any substance listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any substance listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.

Health and Safety Code section 11007. Controlled substance

"Controlled substance," unless otherwise specified, means a drug, substance, or immediate

precursor which is listed in any schedule in Section 11054, 11055, 11056, 11057, or 11058 and any drug, substance, or immediate precursor which is listed in the controlled substance schedules in federal law and regulations, specifically sections 1308.11, 1308.12, 1308.13, 1308.14, and 1308.15, respectively, of Title 21 of the Code of Federal Regulations. These schedules shall be cumulative, so that any drug, substance, or immediate precursor listed on either the federal or the California schedules shall be a controlled substance. In the event of any conflict between the federal and California schedules, whichever set of schedules puts the substance on a more closely-regulated schedule shall control, so that a Schedule I listing will prevail over a Schedule II listing, a Schedule II listing over a Schedule III listing, and so forth.

Today, federal law "exempts" from scheduling combination drugs where the ratio of the controlled drug component vs the non-controlled ingredients that federal law "exempts" the drug from being a controlled drug. California HAS NOT adopted the same exemptions.

Below are examples of products exempt under federal law but not exempt in CA (meaning they are scheduled drugs in this state):

- Fioricet (CA - CIII), HSC 11056(c)(3) butalbital product with barbituric acid or any salt thereof.
- Donnatal (CA – CIV), HSC 11057(d)(26),
- Phenobarbital Librax (CA-CIV) HSC 11057(d)(5),
- Clordiazepoxide

While being exempt under federal law, these medication products remain controlled drugs in California.

For Committee Discussion

During the meeting members will have the opportunity to consider if additional legislative efforts should be pursued and if so, the appropriate solution. As indicated above, under the Board's proposed solution in 2018, the language, as drafted, would have established that the more restrictive schedule would be controlling. Provided below are some questions that may be helpful to consider.

1. Is it appropriate to pursue a similar approach as was approved by the Board in January 2018 or should the Board consider further opportunities to defer to the federal schedule?
2. Given the evolution of research on drug products, is it appropriate for the Board to recommend a state agency or workgroup to independently evaluate the California schedule to determine what changes are appropriate? **Note**: If California continues to contemplate becoming a drug manufacturer, it may be appropriate for that agency to perform this review.
3. Is it appropriate for the Board to assume the role of ongoing evaluation? Staff notes that a similar process is required in Pharmacy Law, where the Board is required to evaluate changes in Chapter 797, United States Pharmacopeia and the National Formulary within 90 days of changes (BPC 4127(c)).
4. Although the Board's licensees are impacted by this issue, several other licensees and regulators are as well, including DCA Boards regulating prescribers. What actions, if any, should be taken to encourage engagement by other stakeholders?

IX. Discussion and Consideration of FDA's Final MOU on Interstate Distribution of Compounded Drugs Products

Relevant law

Federal law establishes provisions for pharmacy compounding on Section 503A of the FD&C Act. Further, as provided in this section, the FD&C Act directs the FDA to develop a standard Memorandum of Understanding (MOU), in consultation with the National Association of Boards of Pharmacy.

Background

In October 2020, the FDA finalized its draft MOU, that establishes an agreement between the respective state authority and the FDA regarding the distribution of inordinate amounts of compounded human drug products interstate and the appropriate investigation by respective state authority of complaints of such products.

The MOU establishes various conditions that respective state authorities must adhere to as a condition of the agreement including:

1. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State
   The state authority will investigate complaints of adverse drug experiences and product quality issues related to human drug products compounded at a pharmacy in its jurisdiction that is distributed outside of the state. As part of the investigation the state authority must assess whether there is a public health risk association with the compounding product. Further, the state agency must maintain records for at least three years compels the state authority to report complains involving serious adverse drug experience or serious product quality issues within five business days of receipt, and mandated reporting of investigation outcomes to the FDA. The state authority is also required to notify the appropriate regulatory of physicians in the jurisdiction, if the complaint involves product compounded by a physician and distributed interstate.
2. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate
   Defines inordinate amount as the number of prescription orders that the pharmacy distributed interstate during any calendar year that is greater than 50 percent of the number of prescription orders sent out of state versus the total number of prescription orders dispensed. Requires the state authority to identify such compounding pharmacies and notify the FDA within 30 days of such a determination and requires the state authority to notify the appropriate regulator of physicians, if the state authority is aware of a physician distributing an inordinate amount.
3. Submission and Disclosure Information
   Prescribes the minimum information that must be provided, specifies that the information can be provided via the Information Sharing Network, and establishes authority for sharing such information under a separate agreement as provided for in 21 CFR 20.88.

In its evaluation of the MOU, while recognizing some benefits to the MOU, staff have identified some significant challenges with the MOU, most notably the impact to staff resources, potential issues with information sharing, and conflicts with current provisions of pharmacy law. Staff will be prepared to offer some solutions to overcome some of these challenges should the committee seek such information. Such solution which would most likely include statutory changes.

Further, staff note that the NABP is in the process of developing its Compounding Pharmacy Information-Sharing Project, which is intended to help facilitate some of the provisions of the MOU. Staff have been advised that NABP should have additional information available the week of the committee meeting. Based on information currently available, Florida and Idaho will not be participating in the MOU. Nevada has signed the MOU and at least 13 states are considering it, including Texas.

For Discussion and Consideration

During the meeting members will have the opportunity to discuss the MOU. It is recommended that the committee consider larger questions as part of its discussion including:

1. What are the potential benefits and negative impacts to California consumers for the Board to enter into this agreement?
2. What are the potential positive and negative impacts to compounding pharmacies and residents outside of California if the Board does not enter into the MOU?
3. Does the Board's outsourcing proposal provide an alternative solution to the MOU?

Attachment 5 includes a copy of the final MOU, information on the NABP Compounding Pharmacy Information-Sharing Project, and comments received from a stakeholder.

X. Discussion and Consideration of FDA Guidance Document, Insanitary Conditions at Compounding Facilities, Guidance for Industry

Relevant Law

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health . . ." Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b), compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs (including biological products) prepared, packed, or held (hereinafter referred to as "produced") under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the FD&C Act.

Background

In November 2020, the FDA finalized and released its guidance document describing examples of insanitary condition that the FDA has observed. As indicated in the document, the guidance specifically addresses drugs (including biological products) produced in settings including pharmacies and outsourcing facilities that compound, mix, dilute or repackage drugs, including biological products.

The FDA notes in its guidance document the following:
"In addition, to protect the public health, both FDA and state regulatory agencies may take action when compounding facilities produce drugs under insanitary conditions. Based on its inspections, FDA determines whether compounding facilities produce drugs under insanitary conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may initiate regulatory action. However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the states and, as explained above, generally are not routinely inspected by FDA. FDA strongly encourages state regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices, including those described below. Where insanitary conditions are identified, FDA encourages states to take appropriate action, consistent with state laws and regulations, and to contact FDA."

For Committee Discussion and Consideration
During the meeting members will have the opportunity to review the guidance document. As part of its regulation of compounding process, in addition to Pharmacy Law standards, Board staff evaluate for compliance with provisions of federal law. As the guidance document sets forth conditions considered insanitary by the FDA, education on the provisions are important and should be shared with members of the Board's regulated public.

Attachment 6 includes a copy of the guidance document.

XI. Discussion and Consideration of the Compounding of Methylcobalamin

Relevant Law
Section 503A of the Food, Drug & Cosmetic Act (FD&C Act), includes certain restrictions on the bulk drug substances that can be used in compounding and directs the FDA to develop a list of bulk substances that can be used in compounding under section 503A.

Under the conditions of the law, one of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist compounds the drug product using bulk drug substances that:

1. Comply with the standards of an applicable USP-NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary, or,
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.

Note: FDA has interpreted "an applicable USP or NF monograph to mean an official USP or NF drug substance monograph. Accordingly, the FDA does not consider USP monographs for dietary supplements to be "applicable USP or NF monographs within the meaning of section 503A(b)(1)(A(i)(I).

Further, Section 503B of the FD&C Act directs the FDA to develop a list of bulk drug substances for which there is a clinical need. Drug products compounded using bulk drug substances on the 503B bulks list quality for certain exemptions from the FD&C Act provided the other conditions in section 503B are met. As provided in federal law, outsourcing facilities are subject to FDA inspections and

other conditions that help to mitigate the risks of the drug products they compound. Further, bulk drug substances used by outsourcing facilities must be accompanied by a valid certificate of analysis and must have been manufactured by an establishment registered with the FDA under section 510 of the FD&C Act. In addition, if an applicable USP or National Formulary monograph exists, bulk drug substances must comply with the monograph.

Additionally, and discussed under the previous agenda item, under section 501(a)(2)(A) for the FD&C Act, a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health…"

Background

The committee has dedicated significant time to public discussion of outsourcing facilities operating under the authority of Section 503B for the FD&C Act and relevant sections of Pharmacy Law, as well as pharmacies compounding preparations pursuant to the authority of Section 503A of the FD&C Act relevant sections of Pharmacy Law and its regulations.

Both Pharmacy Law and federal law recognize the different requirements under which compounding must be performed in outsourcing facilities versus pharmacies, most notably that outsourcing facilities must perform compounding under current good manufacturing practices. Further, as a condition of FDA registration under the provisions of 503B, outsourcing facilities must prepare a sterile product. Under the provisions of 503A, pharmacies have the authority to perform sterile and nonsterile compounds.

For purposes of the Committee's discussion, it is important to note a few items:

1. Methylcobalamin is included on the "bulks" list for 503A and 503B facilities.
2. Compounding standards and requirements under cGMP far exceeds the standards and requirements used to regulate compounding under Pharmacy Law, USP and 503A. As an example, under requirements of cGMPs, an outsourcer must perform a quality check on bulk drug substances. This quality check may include potency, identify and determine levels of impurities (lead, arsenic, etc.) Additionally, outsourcers are required to run several quality checks throughout the compounding process, including robust testing of the final product at the end of production. Under the provisions of USP Compounding Chapters and Pharmacy Law, pharmacies perform limited end product testing for sterility and potency, but do not test for impurities.
3. The 503A "bulks" list does not differentiate those bulk substances that may be used as ingredients in sterile preparations versus non-sterile preparations.
4. The FDA guidance defining insanitary conditions must also be considered when making a determination if a bulk drug substances can be used in a preparation. It is important to note that the grade of an ingredient for a nonsterile preparation is different than the required grade for a bulk drug substances used in sterile preparation.
5. The FDA has documented observations made during inspections of compounding pharmacies where the pharmacy used a non-pharmaceutical grade component in its formulation of a drug product. In general, depending on the scope of the observations, matters are referred to state

regulators for additional investigation and action.

For Committee Discussion and Consideration
During the meeting members will have the opportunity to discuss the issue, including legal and safety issues. Members may also wish to discuss access issues and options patients have to obtain products under the current provisions.

Attachment 7 includes the FDA bulk substances documents for 503A and 503B as well as a redacted FDA issued 483 that includes, among the observations, use of a non-pharmaceutical grade component in the formulation of a drug product.

XII. Review and Discussion of Enforcement Statistics

Since July 1, the board received 1,073 complaints and has closed 1,118 investigations. The board has issued 120 Letters of Admonishment, 488 Citations and referred 84 cases to the Office of the Attorney General. The board has secured 10 interim suspension orders. Further, the board has revoked 33 licenses, accepted the disciplinary surrender of 40 licenses, denied 4 application, and imposed other levels of discipline against 73 licensees and/or applicants.

As of January 1, 2021, the board has 1,451 field investigations pending. Below is a breakdown providing more detail in the various investigation process:

- 53 cases under review for assignment, averaging 29 days
- 667 cases under investigation, averaging 202 days
- 183 investigations under supervisor review, averaging 57 days
- 106 investigations under second level review, averaging 44 days
- 442 investigations waiting final closure (typically issuance of a citation or letter of admonishment) averaging 42 days

Attachment 8 includes the quarterly enforcement statistics.

XIII. Future Committee Meeting Dates

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

Attachment 1

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

ENFORCEMENT COMMITTEE
Draft MEETING MINUTES

DATE: October 27, 2020

LOCATION: Teleconference

COMMITTEE MEMBERS PRESENT:
Maria Serpa, Licensee Member Chair
Jignesh Patel, Licensee Member Vice-Chair
Greg Lippe, Public Member
Ricardo Sanchez, Public Member
Debbie Veale, Licensee Member
Albert Wong, Licensee Member

STAFF MEMBERS PRESENT:
Anne Sodergren, Executive Officer
Norine Marks, DCA Staff Counsel
Eileen Smiley, DCA Staff Counsel
MaryJo Tobola, Senior Enforcement Manager
Debbie Damoth Admin. & Regulations Manager

1. Call to Order and Establishment of Quorum

Chairperson Maria Serpa called the meeting to order at 12:10 p.m. A quorum was established.

2. Public Comment on Items Not on the Agenda, Matters for Future Meetings

Chairperson Serpa invited public comment.

Members of the public requested the following items be placed on the agenda for future meetings: Discussion of the compounding of methylcobalamin; consideration of an additional meeting prior to the scheduled January 2021 Enforcement Committee meeting to discuss the Board's enforcement regarding the compounding of methylcobalamin; discussion regarding auxiliary warning labels; and discussion regarding the FDA's finalized Memorandum of Understanding regarding compounding.

Motion: Agendize discussion of compounding methylcobalamin for a future Enforcement & Compounding meeting.
M/S: Lippe/Veale
Support: 6 Oppose: 0 Abstain: 0

Motion: Agendize discussion of auxiliary labels to assist with naloxone accessibility for a future Enforcement & Compounding meeting.

M/S: Lippe/Veale
Support: 6 Oppose: 0 Abstain: 0

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

Chairperson Serpa referred members to copies of measures provided to each member prior to the meeting. Chairperson Serpa provided a review of recently signed legislation.

a. Assembly Bill 1710 (Wood, Chapter 123, Statutes of 2020) Pharmacy Practice: Vaccines
The first measure for the committee's discussion is AB 1710.

Chairperson Serpa stated this measure provides pharmacists with the authority to independently order and administer FDA authorized or approved COVID-19 vaccines. She shared the committee had a support position on the bill.

The Chairperson acknowledged the recent immunization alert that was released by the Board strongly encouraged pharmacies, designated pharmacists-in-charge, and pharmacists to evaluate their practices of initiating and administering vaccinations and take immediate corrective action to ensure that their practices comply with regulations. She stated it was her understanding that a number of inquiries had been submitted via the Board's ask.inspector email address and to staff directly requesting that the Board evaluate scenarios to determine compliance. She explained, such an assessment must be done on a case by case basis by the pharmacy and its staff. She noted, it was her understanding that there is a wide range of processes being used. She suggested that if anyone sought clarification regarding whether their own current process complies the with law, they should consult with an attorney. Chairperson Serpa provided the following questions to help in the assessment of operations:

1. Who is writing the order for the immunization or directly ordering in the pharmacy system?
2. Who is interacting with the patient regarding health, allergy, and other information?
3. What functions are currently being performed by non-pharmacist staff and do any such functions require judgement?
4. To what extent is the pharmacist involved in the system process? Is it just at the point of administration?

Specific to AB 1710, Chairperson Serpa stated that she agrees that early education on the measure is important to ensure that pharmacists are well positioned to begin initiating and administering COVID-19 vaccines on January 1, assuming there is an FDA approved or authorized vaccine available.

There were no comments from committee members

A member of the public requested clarity regarding COVID-19 vaccination FDA

compliance and Advisory Committee on Immunization Practices (ACIP) approved protocols.

In response, Executive Officer (EO) Anne Sodergren clarified that pharmacists under their authority to provide immunizations in California may already perform this pursuant to BPC section 4052.8; therefore, their authority for ACIP already exists and the provisions are well established in California law and regulation. She explained AB 1710 expands the authority to also apply to COVID-19 vaccines that are either authorized or approved.

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

Chairperson Serpa provided background information on AB 2077. She stated the bill extends provisions for needle exchange programs. She explained existing law provides authority for a pharmacy to furnish hypodermic needles and syringes for human use without a prescription under specified conditions, including knowledge that such furnishing are for a legitimate medical use. She stated, the section provides, that as a public health measure, such furnishing must also occur to prevent the transition of specified conditions, until January 1, 2021. Further, the section provides that as a condition of furnishing, a pharmacy must also provide information on access to drug treatment, access to testing information, and information on safely disposing of sharps waste. The bill extends the date to January 1, 2026.

Chairperson Serpa stated that she agreed that inclusion in the Pharmacy Law 2021 webinar was appropriate as well as inclusion in the Script. She did not believe additional action beyond that was required.

There were no comments from committee members.

There were no comments from the public.

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

Chairperson Serpa provided background information on AB 2113. She stated that as detailed in the meeting material, AB 2113 will require the Board to expedite applications for an applicant who supplies satisfactory evidence to the Board that the applicant is a refugee, has been granted political asylum, or possesses a special immigrant visa.

She stated that in reviewing the information provided in the chair report, she did not believe this measure would have an impact from an enforcement perspective; however, she noted that staff will need to make changes to forms, etc. to implement. She added that staff also recommends developing an FAQ to provide guidance to applicants and as

implementation it may become necessary to promulgate regulations.

There were no comments from committee members.

There were no comments from the public.

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

Chairperson Serpa provided background information on AB 3330. She stated that this measure increases the CURES fee that licensees pay to support the CURES System operated by the DOJ. The annual CURES fee will be $11 for annual renewals or $22 for licenses that renew biennially for a two-year period. The fees will then be reduced to $9/year or $18 for biennial renewals.

She stated her agreement with the implementation details in the chair report and would encourage the Board to send out reminders also as the implementation date gets closer.

There were no comments from committee members.

There were no comments from the public.

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

Chairperson Serpa provided background information on SB 878. She informed the committee that this measure requires the Board to post its application and renewal processing times.

There were no comments from committee members.

There were no comments from the public.

f. Senate Bill 1474 (Committee on Business, Professions and Economic Development, Chapter 312, Statutes of 2020)

Chairperson Serpa provided background information for SB 1474. She stated SB 1471 extends the Board's Sunset date for one year.

There were no comments from committee members.

There were no comments from the public.

4. Discussion and Consideration of Compounding Animal Drugs from Bulk Drug Substances,

Including Federal Law and the FDA Draft Guidance, #256

Chairperson Serpa reminded the committee that during the July Board meeting, the board received a request to agendize a discussion on this topic. The Chairperson stated she requested staff review the matter and determine if any changes had occurred in federal law. Subsequent to that, in late August, CPhA submitted a written request as well.

She stated, while there have not been any changes to federal law, this had been confused recently with the FDAs attempt to provide guidance and deserves discussion. Chairperson Serpa provided the background information. As indicated in the chair report, Under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the compounding of an animal drug from bulk drug substances results in a "new animal drug" that must comply with the FD&C Act's approval, conditional approval, or indexing requirements (sections 512, 571, and 572 of the FD&C Act (21 U.S.C. §§ 360b, 360ccc, 360ccc-1)). Further, all animal drugs are required to be made in accordance with current good manufacturing practice (cGMP) requirement (section 501(a)(2)(B)) of the FD&C Act (21 U.S.C. § 351(a)(2)(B)) and 21 CFR parts 210 and 211) and have adequate directions for use (section 502(f)(1) of the FD&C Act (21 U.S.C. § 352(f)(1)). The FDA has historically exercised enforcement discretion with regards to animal drug compounding from bulk substances under circumstances when no other medically appropriate treatment options exist.

Chairperson Serpa also provided information on the FDA website which provides the following: Compounding Under AMDUCA, 21 CFR 530.13 provides specific conditions under which extralabel use from compounding of approved animal drugs or approved human drugs is permitted. The compounding must be in compliance with all relevant provisions of 21 CFR 530. The extralabel drug use regulation does not permit animal drug compounding from active pharmaceutical ingredients (bulk drugs); this is the current law.

Chairperson Serpa informed the committee, in November 2019, the FDA released for comment draft guidance for industry (GFI) #256, entitled, "Compounding Animal Drugs from Bulk Drug Substances." The FDA noted that the draft guidance, if finalized, would advise veterinarians on when the FDA does not intend to take enforcement action for certain violations of the FD&C Act when pharmacists and veterinarians compound or oversee the compounding of animal drugs from bulk substances. The comment period for this draft guidance was extended on two occasions, with the most recent comment period expiring on October 15, 2020. Although still in its draft form, the draft guidance provides conditions under which the FDA states that it will generally exercise enforcement discretion for violations of the FD&C's requirements but it also notes that the Agency may take action when animal drugs are compounded from bulk drug substances that (1) present particular human or animal safety concerns or (2) do not meet other manufacturing, product, quality, labeling, or packaging requirements as required. The FDA notes that regardless of whether it intends to take action, the FDA may refer a case to the appropriate state entity. The draft guidance also states that FDA intends "to generally defer to State licensing boards for day-to-day oversight."

Chairperson Serpa stated that earlier this year, the Board received information about

compounding by California pharmacies using bulk substances, rather than sourced products from FDA approved drugs as required. In addition, the Board received information that pharmacies may be compounding from bulk substances, instead of from commercially available drugs, purportedly to reduce costs. To clarify this complicated issue, staff requested information from the FDA; the FDA's response is included in the meeting materials and includes much of the same information just provided.

Chairperson Serpa invited EO Sodergren to provide information about what board staff are identifying during inspections and how staff are currently handling the issues.

EO Sodergren informed the committee that as part of the Board's regulatory oversight of compounding facilities, the Board and its partner agencies are finding the marketplace to be non-compliant with federal law. She stated Board inspectors have been discussing federal requirements and, in some cases, issued Orders of Correction. An Order of Correction is not an "enforcement action", but typically requests the licensee to evaluate their practice and take the necessary steps to get into compliance. She stated that Orders of Correction usually require a licensee develop a Plan of Correction. The Board would then follow up with the corrective plans in 2021 as part of the Board's normal oversight. EO Sodergren stated there may have been some misunderstanding about the Board's actions thus far. She clarified the Board had not issued any Cease and Desist Orders or any similar action with respect to the inspections that had been conducted thus far.

DCA Counsel Eileen Smiley conducted research of current state of the law, the draft guidance and the information provided by the FDA. She stated the FDA has made clear that some of the different organizations who submitted letters disagree with the FDAs interpretation, but the FDAs interpretation is clearly set out so far. The draft guidance would demonstrate when the FDA intends to begin using its enforcement discretion. Ms. Smiley reiterated some of the supplemental associations disagree vehemently with the FDA and its interpretation of the Food, Drug and Cosmetic Act, but reminded the Board, Congress entrusted the interpretation and administration of this act to the FDA. The Board simply does not have the legal authority to dispute the FDA's interpretation.

Chairperson Serpa stated that she believed it is appropriate for Board staff to continue its educational efforts, orders of corrections and monitoring for compliance while balancing enforcement discretion and assessment of individual cases specific information to determine when additional action beyond education and orders of correction is appropriate. I believe this is not only consistent with the current actions being taken by staff but could also be viewed as consistent with the thinking of the FDA as we understand it.

Committee member discussion included concerns regarding whether or when the draft guidance will be finalized as well as when animal drugs are compounded from bulk drug substances when there is a medical necessity versus when there is a cost issue.

Public comment discussion included a request to the Board to reconsider the issuing of orders of corrections, opting rather to wait until a finalized guidance was approved. Additionally, there were two members of the public who expressed their disagreement with the draft guidance.

Motion: Board staff shall monitor this issue and keep the committee informed of emerging issues on the federal level, especially in regard to the draft guidance. The Board shall continue its educational role. The Board should evaluate situations on a case-by-case basis as they come up regarding this federal law.
M/S: Serpa/Wong
Support: 6 Oppose: 0 Abstain: 0

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

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

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

Chairperson Serpa informed the committee that Board staff continues to conduct investigations where appropriate. Further, staff is aware of pharmacies that have been issued 483 Observations by the FDA; these are inspection reports from the FDA noting observed violations.

Break: 1:25
Return: 1:36 Quorum established

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

Chairperson Serpa reminded the committee of the presentation on the Administrative Case Process, offered at the last meeting. She stated following the meeting, it was suggested that it may be helpful to provide some general information to aid respondents in gaining a general understanding of the process and licensee's rights.

She stated for the committee's review, attachment 3 included draft frequently asked questions (FAQ) as well as a flow chart. If members agreed with the concept, she suggested that they recommend to the Board the finalization of the informational tool; this tool could be posted on the Board website. The Chairperson stated her interest in staff exploring the possibility of the AG's Office including this information as part information provided with the service of the documents.

Committee members agreed with the concept and were supportive of this method of educating licensees.

Motion: Finalize the Administrative Case Process Information Tools and distribute them.
M/S: Serpa/Lippe
Support: 6 Oppose: 0 Abstain: 0

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

Chairperson Serpa stated members of this committee have had previous discussions regarding the potential of an alternative enforcement model to reduce both time and costs associated with resolving of a disciplinary matter. She informed, the original discussion was based on a model used by the Physical Therapy Board that provides an option for pre-pleading settlement of a matter where the outcome is public letter of reprimand. Details of the law granting the Physical Therapy Board such authority is in the Chair's report. Subsequent discussions included proposals to include two board members in the settlement process or to include an oral conference as a part of the process. At that time Board Counsel had concerns regarding these concepts and requested time to evaluate those suggestions. She explained, the committee has also recently received a presentation on the Administrative Case process. She continued, as was shared during that presentation, the administrative case process has two fundamental guiding principles: due process of the respondent and public protection. Deputy Attorney General Jarvis reminded the committee, the state has the duty and responsibility to ensure a licensee is competent and trustworthy.

Chairperson Serpa stated one of the concerns brought up during the public comment was that the administrative case process presented a perceived assumption of guilt. She clarified, there is no presumption of guilt after the filing of an Accusation. The board carries the burden of proof to establish a basis for discipline until that burden of proof is met. There is no presumption that the basis of discipline exists.

It is essential for the committee to be mindful of the state's responsibility as well as the policy goal the board is seeking to achieve by reducing time and costs associated with resolving a disciplinary matter.

Chairperson Serpa provided data provided in the Chair's report. She noted that over the past three years, only about 11% of substantiated investigations resulted in referral to the Office of the Attorney General. Additionally, 32% of the cases referred result in a default decision and 55% are resolved through a stipulated settlement. Only about 14% of the cases referred to the Office of the Attorney General actually go to an administrative hearing. Stipulated settlements appear to achieve the same the goal the Board is seeking through this alternative model, including risk avoidance, saving time and saving expense.

Chairperson Serpa wondered why the data also showed average processing times for stipulated settlements were greater than those set for hearing.

EO Sodergren explained there are pressure points in the administrative case process. When a matter is set for hearing, there is a pressure point because there is going to be a hearing scheduled. When a matter is not set for hearing because there's going to be a stipulated settlement, there may not necessarily be that same drive for resolution. In those cases, negotiations of a settlement can sometimes take longer and be a little more extensive especially if there is substantial negotiation.

Chairperson Serpa also presented another data point she found very interesting regarding the adopted versus nonadopted statistics. Based on the data presented, Ms. Serpa noted the Board is far more likely to nonadopt a proposed decision issued by an administrative law judge than a stipulated settlement negotiated by Board staff.

Ms. Smiley stated she reviewed the proposal considering what the current process is and where some pressure points could be. She stated one of the biggest concerns would be the involvement of board members because of the potential quorum issues that could develop later. Another concern was exactly how that hearing would be conducted. Would it be a paper process? What would be the impact be if a judgement or a settlement is not reached between the parties? It is those practical concerns, along with board member involvement that becomes potentially problematic. She then asked, if there was going to be a hearing component and they do not reach a judgment or settlement, then are they going to have two hearings? Would that just result in longer delays and greater cost? Particularly, who would administer an initial hearing? Who would determine the type of admissible evidence if there is an oral conference? How would the conference be treated if settlement is not reached?

Chairperson Serpa speculated about the requirements to participate in this alternative model and unintended outcomes. She stated a licensee would have to waive their rights to administrative adjudication and also admit to the allegation to participate in an alternative enforcement process. Any disagreement with the allegations would not qualify for the alternative model.

Secondly, if an agreement was not reached, this could result in additional time and cost for a second hearing in addition to the many legal issues that arise regarding the admissibility of the record. Additionally, if board members participate in alternative process that it could present a problem with the Open Meetings Act and may require those members to recuse themselves from future discussions if an agreement is not reached. It was also mentioned that board member presence may also require that a meeting becomes public.

Chairperson Serpa stated having discussed the background and some of the challenges that have been identified, she was interested in members thoughts about how the committee should proceed. Specifically, given the information received should they continue to move forward with development of an alternative enforcement model? Should the committee look more closely at the process used by the Physical Therapy Board, which is a very different and limited process? Should the committee take no action at this time?

Committee member discussion included inquiries regarding Physical Therapy Board's use of a letter of reprimands and when they are used. EO Sodergren informed the committee that the Board modeled its pre-pleading process from the Physical Therapy Board; the Physical Therapy Board has a range of outcomes like the Board's but have specific statutory authority to enter into an agreement where it's appropriate for a letter of reprimand as part of a pre-pleading settlement. Members expressed concern that this method may not resolve issues regarding costs savings.

Committee members asked DCA Counsel for clarification on when a stipulated settlement could occur. In response, Ms. Smiley stated, a stipulated settlement may occur any time after the filing of an accusation; it does not have to go to hearing. As with some of the stipulated judgements those will generally refer over to the accusation to give more context to the person signing it that they have fully and with knowledge waived their rights under the Administrative Procedure Act. It can occur at either time, but it occurs after the filing of the Accusation.

EO Sodergren informed the committee that investigations are conducted and reviewed by licensed pharmacists. Additionally, when expert knowledge is needed, the Board can hire via contract. EO Sodergren assured the committee that each investigator has pharmacy knowledge and cases referred to the Office of the Attorney General are the most egregious violations that could warrant removal or restriction of the license. She informed the committee when the case outcomes are reviewed and we look at the Board's actions specific to stipulations, Board members agree with the settlements that come before it for vote. EO Sodergren stated that this speaks to the fact that staff are executing stipulated settlements consistent with the Board's policy and its Disciplinary Guidelines and reflective of the collective decision of the Board.

Motion: No action at this time, but continue to evaluate the issue of the development of an Alternative Enforcement Model
M/S: Wong/Veale

Danny Martinez of CDPH requested that the committee's motion be withdrawn; instead he requests that this same item be placed on the next agenda and provide CPHa the opportunity to present a revised plan for consideration.

Two other members of the public expressed support of an alternative enforcement model.

In response to Mr. Martinez's request the motion was amended.

Motion: No action at this time but continue to discuss and evaluate the issue of the development of an Alternative Enforcement Model
M/S: Wong/Veale
Support: 6 Oppose:0 Abstain:0

8. <u>Discussion and Consideration of Proposal of Board's Policy Encouraging Pharmacies to Report to Law Enforcement Acts involving Drug Diversion by an Employee</u>

Chairperson Serpa stated during the January 2020 Board meeting, the Board approved a policy statement intended to encourage pharmacies to refer drug diversion cases to local law enforcement agencies for possible prosecution. Such referral would be in addition to mandatory reporting to the Board.

She stated the data provided in the meeting materials indicate that referrals to law enforcement are occurring; however, it may not be occurring with the frequency the Board would expect.

Motion: Recommendation to include the Board's policy statement in communications with licensees when seeking additional information regarding drug losses.
M/S: Serpa/Lippe
Support: 6 Oppose:0 Abstain:0

9. <u>Discussion and Consideration of Disciplinary Cases and Incorporation of the Ethics Program Requirement.</u>

Chairperson Serpa stated, the requirements for the ethics program are established in CCR section 1773.5. She informed the committee, recently the Board received a request to discuss what appeared to be a decrease in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course.

She referred the committee to the information about the ethics program detailed in the chair report. She highlighted the program must include a minimum of 22 hours, at least 14 of which are contact hours and at least eight additional hours for preparation, evaluation, and assessment. She provided, the cost for the program offered by PBI Education is $1875. Also, calendar year data for those individuals that completed the PBI training is provided.

Chairperson Serpa stated that IMQ was another course provider but has recently closed.

Chairperson Serpa informed the committee the data in the chair report confirms that there has been a decline in the number of disciplinary orders that include, as a condition of probation, completion of an ethics course. EO Sodergren added that there are several respondents that now proactively complete the ethics course in advance of settlement and provide it as part of the mitigation. In those cases, it is not going to be included in the settlement because they have already completed the ethics course, which may be part of the reason for the decline.

During public comment it was stated that a possible reason for decline may be the high cost. It was suggested that ethics courses could be offered through a more affordable system such as a school/university system.

10. Review and Discussion of Enforcement Statistics

Chairperson Serpa reviewed enforcement statistics. She informed the committee since July 1, 2020, the board received 643 complaints and has closed 635 investigations. Additionally, as of October 1, 2020, the board currently has 1,345 field investigations pending. She directed the committee to review a breakdown on page 10 of the Chair's Report.

11. Future Committee Meeting Dates

Chairperson Serpa directed the members to the Chair's Report for future meeting dates.

12. Adjournment

Chairperson Serpa adjourned the meeting at 3:13 p.m.

Attachment 2

State of California

BUSINESS AND PROFESSIONS CODE

Section 4360

4360. The board shall operate a pharmacists recovery program to rehabilitate pharmacists and intern pharmacists whose competency may be impaired due to abuse of alcohol, drug use, or mental illness. The intent of the pharmacists recovery program is to return these pharmacists and intern pharmacists to the practice of pharmacy in a manner that will not endanger the public health and safety.

(Amended by Stats. 2005, Ch. 621, Sec. 63. Effective January 1, 2006.)

State of California

BUSINESS AND PROFESSIONS CODE

Section 315

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315. (a) For the purpose of determining uniform standards that will be used by healing arts boards in dealing with substance-abusing licensees, there is established in the Department of Consumer Affairs the Substance Abuse Coordination Committee. The committee shall be comprised of the executive officers of the department's healing arts boards established pursuant to Division 2 (commencing with Section 500), the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, and a designee of the State Department of Health Care Services. The Director of Consumer Affairs shall chair the committee and may invite individuals or stakeholders who have particular expertise in the area of substance abuse to advise the committee.

(b) The committee shall be subject to the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Division 3 of Title 2 of the Government Code).

(c) By January 1, 2010, the committee shall formulate uniform and specific standards in each of the following areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program:

(1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in paragraph (1) and any treatment recommended by the evaluator described in paragraph (1) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status and condition.

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators,

frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

(7) Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

(8) Procedures to be followed when a licensee tests positive for a banned substance.

(9) Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

(10) Specific consequences for major violations and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation similar to the stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency unless or until the licensee commits a major violation, in which case it is revived and the license is surrendered.

(11) Criteria that a licensee must meet in order to petition for return to practice on a full-time basis.

(12) Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

(13) If a board uses a private-sector vendor that provides diversion services, standards for immediate reporting by the vendor to the board of any and all noncompliance with any term of the diversion contract or probation; standards for the vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and standards for a licensee's termination from the program and referral to enforcement.

(14) If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

(15) If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

(16) Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

(d) Notwithstanding any other law, by January 1, 2019, the committee shall review the existing criteria for Uniform Standard #4 established pursuant to paragraph (4) of subdivision (c). The committee's review and findings shall determine whether the existing criteria for Uniform Standard #4 should be updated to reflect recent developments in testing research and technology. The committee shall consider

information from, but not limited to, the American Society of Addiction Medicine, and other sources of best practices.

(Amended by Stats. 2017, Ch. 600, Sec. 1. (SB 796) Effective January 1, 2018.)

Uniform Standards Regarding Substance-Abusing Healing Arts Licensees

Senate Bill 1441 (Ridley-Thomas)

Implementation by
Department of Consumer Affairs,
Substance Abuse Coordination Committee

Brian J. Stiger, Director
April 2011

STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

Substance Abuse Coordination Committee

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Donald Krpan, D.O.
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Francine Davies
Naturopathic Medicine Committee

Virginia Herold
California State Board of Pharmacy

Steve Hartzell
Physical Therapy Board of California

Elberta Portman
Physician Assistant Committee

Jim Rathlesberger
Board of Podiatric Medicine

Robert Kahane
Board of Psychology

Louise Bailey
Board of Registered Nursing

Stephanie Nunez
Respiratory Care Board of California

Annemarie Del Mugnaio
Speech-Language Pathology & Audiology & Hearing Aid Dispenser Board

Susan Geranen
Veterinary Medical Board

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#1 SENATE BILL 1441 REQUIREMENT

Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

#1 Uniform Standard

If a healing arts board orders a licensee who is either in a diversion program or whose license is on probation due to a substance abuse problem to undergo a clinical diagnosis evaluation, the following applies:

1. The clinical diagnostic evaluation shall be conducted by a licensed practitioner who:

    - holds a valid, unrestricted license, which includes scope of practice to conduct a clinical diagnostic evaluation;

    - has three (3) years experience in providing evaluations of health professionals with substance abuse disorders; and,

    - is approved by the board.

2. The clinical diagnostic evaluation shall be conducted in accordance with acceptable professional standards for conducting substance abuse clinical diagnostic evaluations.

3. The clinical diagnostic evaluation report shall:

    - set forth, in the evaluator's opinion, whether the licensee has a substance abuse problem;

    - set forth, in the evaluator's opinion, whether the licensee is a threat to himself/herself or others; and,

    - set forth, in the evaluator's opinion, recommendations for substance abuse treatment, practice restrictions, or other recommendations related to the licensee's rehabilitation and safe practice.

The evaluator shall not have a financial relationship, personal relationship, or business relationship with the licensee within the last five years. The evaluator shall provide an objective, unbiased, and independent evaluation.

If the evaluator determines during the evaluation process that a licensee is a threat to himself/herself or others, the evaluator shall notify the board within 24 hours of such a determination.

For all evaluations, a final written report shall be provided to the board no later than ten (10) days from the date the evaluator is assigned the matter unless the evaluator requests additional information to complete the evaluation, not to exceed 30 days.

#2 SENATE BILL 1441 REQUIREMENT

Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in subdivision (a) and any treatment recommended by the evaluator described in subdivision (a) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

#2 Uniform Standard

The following practice restrictions apply to each licensee who undergoes a clinical diagnostic evaluation:

1. The Board shall order the licensee to cease practice during the clinical diagnostic evaluation pending the results of the clinical diagnostic evaluation and review by the diversion program/board staff.

2. While awaiting the results of the clinical diagnostic evaluation required in Uniform Standard #1, the licensee shall be randomly drug tested at least two (2) times per week.

After reviewing the results of the clinical diagnostic evaluation, and the criteria below, a diversion or probation manager shall determine, whether or not the licensee is safe to return to either part-time or fulltime practice. However, no licensee shall be returned to practice until he or she has at least 30 days of negative drug tests.

- the license type;
- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use
- the scope and pattern of use;
- the treatment history;
- the licensee's medical history and current medical condition;
- the nature, duration and severity of substance abuse, and
- whether the licensee is a threat to himself/herself or the public.

#3 SENATE BILL 1441 REQUIREMENT

Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status or condition.

#3 Uniform Standard

If the licensee who is either in a board diversion program or whose license is on probation has an employer, the licensee shall provide to the board the names, physical addresses, mailing addresses, and telephone numbers of all employers and supervisors and shall give specific, written consent that the licensee authorizes the board and the employers and supervisors to communicate regarding the licensee's work status, performance, and monitoring.

#4 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomnicity, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

#4 Uniform Standard

The following standards shall govern all aspects of testing required to determine abstention from alcohol and drugs for any person whose license is placed on probation or in a diversion program due to substance use:

TESTING FREQUENCY SCHEDULE

A board may order a licensee to drug test at any time. Additionally, each licensee shall be tested RANDOMLY in accordance with the schedule below:

Level	Segments of Probation/Diversion	Minimum Range of Number of Random Tests
I	Year 1	52-104 per year
II*	Year 2+	36-104 per year

*The minimum range of 36-104 tests identified in level II, is for the second year of probation or diversion, and each year thereafter, up to five (5) years. Thereafter, administration of one (1) time per month if there have been no positive drug tests in the previous five (5) consecutive years of probation or diversion.

Nothing precludes a board from increasing the number of random tests for any reason. Any board who finds or has suspicion that a licensee has committed a violation of a board's testing program or who has committed a Major Violation, as identified in Uniform Standard 10, may reestablish the testing cycle by placing that licensee at the beginning of level I, in addition to any other disciplinary action that may be pursued.

EXCEPTIONS TO TESTING FREQUENCY SCHEDULE

I. PREVIOUS TESTING/SOBRIETY
In cases where a board has evidence that a licensee has participated in a treatment or monitoring program requiring random testing, prior to being subject to testing by the board, the board may give consideration to that testing in altering the testing

frequency schedule so that it is equivalent to this standard.

II. VIOLATION(S) OUTSIDE OF EMPLOYMENT
An individual whose license is placed on probation for a single conviction or incident or two convictions or incidents, spanning greater than seven years from each other, where those violations did not occur at work or while on the licensee's way to work, where alcohol or drugs were a contributing factor, may bypass level I and participate in level II of the testing frequency schedule.

III. NOT EMPLOYED IN HEALTH CARE FIELD
A board may reduce testing frequency to a minimum of 12 times per year for any person who is not practicing OR working in any health care field. If a reduced testing frequency schedule is established for this reason, and if a licensee wants to return to practice or work in a health care field, the licensee shall notify and secure the approval of the licensee's board. Prior to returning to any health care employment, the licensee shall be subject to level I testing frequency for at least 60 days. At such time the person returns to employment (in a health care field), if the licensee has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

IV. TOLLING
A board may postpone all testing for any person whose probation or diversion is placed in a tolling status if the overall length of the probationary or diversion period is also tolled. A licensee shall notify the board upon the licensee's return to California and shall be subject to testing as provided in this standard. If the licensee returns to employment in a health care field, and has not previously met the level I frequency standard, the licensee shall be subject to completing a full year at level I of the testing frequency schedule, otherwise level II testing shall be in effect.

V. SUBSTANCE USE DISORDER NOT DIAGNOSED
In cases where no current substance use disorder diagnosis is made, a lesser period of monitoring and toxicology screening may be adopted by the board, but not to be less than 24 times per year.

OTHER DRUG STANDARDS

Drug testing may be required on any day, including weekends and holidays.

The scheduling of drug tests shall be done on a random basis, preferably by a computer program, so that a licensee can make no reasonable assumption of when he/she will be tested again. Boards should be prepared to report data to support back-to-back testing as well as, numerous different intervals of testing.

Licensees shall be required to make daily contact to determine if drug testing is required.

Licensees shall be drug tested on the date of notification as directed by the board.

Specimen collectors must either be certified by the Drug and Alcohol Testing Industry Association or have completed the training required to serve as a collector for the U.S. Department of Transportation.

Specimen collectors shall adhere to the current U.S. Department of Transportation Specimen Collection Guidelines.

Testing locations shall comply with the Urine Specimen Collection Guidelines published by the U.S. Department of Transportation, regardless of the type of test administered.

Collection of specimens shall be observed.

Prior to vacation or absence, alternative drug testing location(s) must be approved by the board.

Laboratories shall be certified and accredited by the U.S. Department of Health and Human Services.

A collection site must submit a specimen to the laboratory within one (1) business day of receipt. A chain of custody shall be used on all specimens. The laboratory shall process results and provide legally defensible test results within seven (7) days of receipt of the specimen. The appropriate board will be notified of non-negative test results within one (1) business day and will be notified of negative test results within seven (7) business days.

A board may use other testing methods in place of, or to supplement biological fluid testing, if the alternate testing method is appropriate.

PETITIONS FOR REINSTATEMENT

Nothing herein shall limit a board's authority to reduce or eliminate the standards specified herein pursuant to a petition for reinstatement or reduction of penalty filed pursuant to Government Code section 11522 or statutes applicable to the board that contains different provisions for reinstatement or reduction of penalty.

OUTCOMES AND AMENDMENTS

For purposes of measuring outcomes and effectiveness, each board shall collect and report historical and post implementation data as follows:

Historical Data - Two Years Prior to Implementation of Standard

Each board should collect the following historical data (as available), for a period of two years, prior to implementation of this standard, for each person subject to testing for banned substances, who has 1) tested positive for a banned substance, 2) failed to

appear or call in, for testing on more than three occasions, 3) failed to pay testing costs, or 4) a person who has given a dilute or invalid specimen.

Post Implementation Data- Three Years

Each board should collect the following data annually, for a period of three years, for every probationer and diversion participant subject to testing for banned substances, following the implementation of this standard.

Data Collection

The data to be collected shall be reported to the Department of Consumer Affairs and the Legislature, upon request, and shall include, but may not be limited to:

Probationer/Diversion Participant Unique Identifier
License Type
Probation/Diversion Effective Date
General Range of Testing Frequency by/for Each Probationer/Diversion Participant
Dates Testing Requested
Dates Tested
Identify the Entity that Performed Each Test
Dates Tested Positive
Dates Contractor (if applicable) was informed of Positive Test
Dates Board was informed of Positive Test
Dates of Questionable Tests (e.g. dilute, high levels)
Date Contractor Notified Board of Questionable Test
Identify Substances Detected or Questionably Detected
Dates Failed to Appear
Date Contractor Notified Board of Failed to Appear
Dates Failed to Call In for Testing
Date Contractor Notified Board of Failed to Call In for Testing
Dates Failed to Pay for Testing
Date(s) Removed/Suspended from Practice (identify which)
Final Outcome and Effective Date (if applicable)

#5 SENATE BILL 1441 REQUIREMENT

Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

#5 Uniform Standard

If a board requires a licensee to participate in group support meetings, the following shall apply:

When determining the frequency of required group meeting attendance, the board shall give consideration to the following:

- the licensee's history;
- the documented length of sobriety/time that has elapsed since substance use;
- the recommendation of the clinical evaluator;
- the scope and pattern of use;
- the licensee's treatment history; and,
- the nature, duration, and severity of substance abuse.

Group Meeting Facilitator Qualifications and Requirements:

1. The meeting facilitator must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse, and shall be licensed or certified by the state or other nationally certified organizations.

2. The meeting facilitator must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year.

3. The group meeting facilitator shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

4. The facilitator shall report any unexcused absence within 24 hours.

#6 SENATE BILL 1441 REQUIREMENT

Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

#6 Uniform Standard

In determining whether inpatient, outpatient, or other type of treatment is necessary, the board shall consider the following criteria:

- recommendation of the clinical diagnostic evaluation pursuant to Uniform Standard #1;
- license type;
- licensee's history;
- documented length of sobriety/time that has elapsed since substance abuse;
- scope and pattern of substance use;
- licensee's treatment history;
- licensee's medical history and current medical condition;
- nature, duration, and severity of substance abuse, and
- threat to himself/herself or the public.

#7 SENATE BILL 1441 REQUIREMENT

Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

#7 Uniform Standard

A board may require the use of worksite monitors. If a board determines that a worksite monitor is necessary for a particular licensee, the worksite monitor shall meet the following requirements to be considered for approval by the board.

1. The worksite monitor shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.

2. The worksite monitor's license scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

3. If the worksite monitor is a licensed healthcare professional he or she shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

4. The worksite monitor shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.

5. The worksite monitor must adhere to the following required methods of monitoring the licensee:

    a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.

    b) Interview other staff in the office regarding the licensee's behavior, if applicable.

    c) Review the licensee's work attendance.

Reporting by the worksite monitor to the board shall be as follows:

1. Any suspected substance abuse must be verbally reported to the board and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.

2. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

    - the licensee's name;
    - license number;
    - worksite monitor's name and signature;
    - worksite monitor's license number;
    - worksite location(s);
    - dates licensee had face-to-face contact with monitor;
    - staff interviewed, if applicable;
    - attendance report;
    - any change in behavior and/or personal habits;
    - any indicators that can lead to suspected substance abuse.

The licensee shall complete the required consent forms and sign an agreement with the worksite monitor and the board to allow the board to communicate with the worksite monitor.

#8 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee tests positive for a banned substance.

#8 Uniform Standard

When a licensee tests positive for a banned substance:

1. The board shall order the licensee to cease practice;

2. The board shall contact the licensee and instruct the licensee to leave work; and

3. The board shall notify the licensee's employer, if any, and worksite monitor, if any, that the licensee may not work.

Thereafter, the board should determine whether the positive drug test is in fact evidence of prohibited use. If so, proceed to Standard #9. If not, the board shall immediately lift the cease practice order.

In determining whether the positive test is evidence of prohibited use, the board should, as applicable:

1. Consult the specimen collector and the laboratory;

2. Communicate with the licensee and/or any physician who is treating the licensee; and

3. Communicate with any treatment provider, including group facilitator/s.

#9 SENATE BILL 1441 REQUIREMENT

Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

#9 Uniform Standard

When a board confirms that a positive drug test is evidence of use of a prohibited substance, the licensee has committed a major violation, as defined in Uniform Standard #10 and the board shall impose the consequences set forth in Uniform Standard #10.

#10 SENATE BILL 1441 REQUIREMENT

Specific consequences for major and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency until or unless licensee commits a major violation, in which case it is revived and license is surrendered.

#10 Uniform Standard

Major Violations include, but are not limited to:

1. Failure to complete a board-ordered program;
2. Failure to undergo a required clinical diagnostic evaluation;
3. Multiple minor violations;
4. Treating patients while under the influence of drugs/alcohol;
5. Any drug/alcohol related act which would constitute a violation of the practice act or state/federal laws;
6. Failure to obtain biological testing for substance abuse;
7. Testing positive and confirmation for substance abuse pursuant to Uniform Standard #9;
8. Knowingly using, making, altering or possessing any object or product in such a way as to defraud a drug test designed to detect the presence of alcohol or a controlled substance.

Consequences for a major violation include, but are not limited to:

1. Licensee will be ordered to cease practice.
    a) the licensee must undergo a new clinical diagnostic evaluation, and
    b) the licensee must test negative for at least a month of continuous drug testing before being allowed to go back to work.
2. Termination of a contract/agreement.
3. Referral for disciplinary action, such as suspension, revocation, or other action as determined by the board.

Minor Violations include, but are not limited to:

1. Untimely receipt of required documentation;
2. Unexcused non-attendance at group meetings;
3. Failure to contact a monitor when required;
4. Any other violations that do not present an immediate threat to the violator or to the public.

Consequences for minor violations include, but are not limited to**:**

1. Removal from practice;
2. Practice limitations;
3. Required supervision;
4. Increased documentation;
5. Issuance of citation and fine or a warning notice;
6. Required re-evaluation/testing;
7. Other action as determined by the board.

#11 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for return to practice on a full time basis.

#11 Uniform Standard

"Petition" as used in this standard is an informal request as opposed to a "Petition for Modification" under the Administrative Procedure Act.

The licensee shall meet the following criteria before submitting a request (petition) to return to full time practice:

1. Demonstrated sustained compliance with current recovery program.

2. Demonstrated the ability to practice safely as evidenced by current work site reports, evaluations, and any other information relating to the licensee's substance abuse.

3. Negative drug screening reports for at least six (6) months, two (2) positive worksite monitor reports, and complete compliance with other terms and conditions of the program.

#12 SENATE BILL 1441 REQUIREMENT

Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

#12 Uniform Standard

"Petition for Reinstatement" as used in this standard is an informal request (petition) as opposed to a "Petition for Reinstatement" under the Administrative Procedure Act.

The licensee must meet the following criteria to request (petition) for a full and unrestricted license.

1. Demonstrated sustained compliance with the terms of the disciplinary order, if applicable.

2. Demonstrated successful completion of recovery program, if required.

3. Demonstrated a consistent and sustained participation in activities that promote and support their recovery including, but not limited to, ongoing support meetings, therapy, counseling, relapse prevention plan, and community activities.

4. Demonstrated that he or she is able to practice safely.

5. Continuous sobriety for three (3) to five (5) years.

#13 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, (1) standards for immediate reporting by the vendor to the board of any and all noncompliance with process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; (3) standards requiring the vendor to disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services; and (4) standards for a licensee's termination from the program and referral to enforcement.

#13 Uniform Standard

1. A vendor must report to the board any major violation, as defined in Uniform Standard #10, within one (1) business day. A vendor must report to the board any minor violation, as defined in Uniform Standard #10, within five (5) business days.

2. A vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors is as follows:

   (a) Specimen Collectors:

   (1) The provider or subcontractor shall possess all the materials, equipment, and technical expertise necessary in order to test every licensee for which he or she is responsible on any day of the week.

   (2) The provider or subcontractor shall be able to scientifically test for urine, blood, and hair specimens for the detection of alcohol, illegal, and controlled substances.

   (3) The provider or subcontractor must provide collection sites that are located in areas throughout California.

   (4) The provider or subcontractor must have an automated 24-hour toll-free telephone system and/or a secure on-line computer database that allows the participant to check in daily for drug testing.

   (5) The provider or subcontractor must have or be subcontracted with operating collection sites that are engaged in the business of collecting urine, blood, and hair follicle specimens for the testing of drugs and alcohol within the State of California.

   (6) The provider or subcontractor must have a secure, HIPAA compliant, website or computer system to allow staff access to drug test results and compliance reporting information that is available 24 hours a day.

(7) The provider or subcontractor shall employ or contract with toxicologists that are licensed physicians and have knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate laboratory drug test results, medical histories, and any other information relevant to biomedical information.

(8) A toxicology screen will not be considered negative if a positive result is obtained while practicing, even if the practitioner holds a valid prescription for the substance.

(9) Must undergo training as specified in Uniform Standard #4 (6).

(b) Group Meeting Facilitators:

A group meeting facilitator for any support group meeting:

(1) must have a minimum of three (3) years experience in the treatment and rehabilitation of substance abuse;

(2) must be licensed or certified by the state or other nationally certified organization;

(3) must not have a financial relationship, personal relationship, or business relationship with the licensee within the last year;

(4) shall report any unexcused absence within 24 hours to the board, and,

(5) shall provide to the board a signed document showing the licensee's name, the group name, the date and location of the meeting, the licensee's attendance, and the licensee's level of participation and progress.

(c) Work Site Monitors:

The worksite monitor must meet the following qualifications:

(1) Shall not have financial, personal, or familial relationship with the licensee, or other relationship that could reasonably be expected to compromise the ability of the monitor to render impartial and unbiased reports to the board. If it is impractical for anyone but the licensee's employer to serve as the worksite monitor, this requirement may be waived by the board; however, under no circumstances shall a licensee's worksite monitor be an employee of the licensee.

(2) The monitor's licensure scope of practice shall include the scope of practice of the licensee that is being monitored, be another health care professional if no

monitor with like practice is available, or, as approved by the board, be a person in a position of authority who is capable of monitoring the licensee at work.

(3) Shall have an active unrestricted license, with no disciplinary action within the last five (5) years.

(4) Shall sign an affirmation that he or she has reviewed the terms and conditions of the licensee's disciplinary order and/or contract and agrees to monitor the licensee as set forth by the board.

2. The worksite monitor must adhere to the following required methods of monitoring the licensee:

   a) Have face-to-face contact with the licensee in the work environment on a frequent basis as determined by the board, at least once per week.

   b) Interview other staff in the office regarding the licensee's behavior, if applicable.

   c) Review the licensee's work attendance.

3. Any suspected substance abuse must be verbally reported to the contractor, the board, and the licensee's employer within one (1) business day of occurrence. If occurrence is not during the board's normal business hours the verbal report must be within one (1) hour of the next business day. A written report shall be submitted to the board within 48 hours of occurrence.

4. The worksite monitor shall complete and submit a written report monthly or as directed by the board. The report shall include:

   - the licensee's name;
   - license number;
   - worksite monitor's name and signature;
   - worksite monitor's license number;
   - worksite location(s);
   - dates licensee had face-to-face contact with monitor;
   - staff interviewed, if applicable;
   - attendance report;
   - any change in behavior and/or personal habits;

- any indicators that can lead to suspected substance abuse.

(d) Treatment Providers

Treatment facility staff and services must have:

(1) Licensure and/or accreditation by appropriate regulatory agencies;

(2) Sufficient resources available to adequately evaluate the physical and mental needs of the client, provide for safe detoxification, and manage any medical emergency;

(3) Professional staff who are competent and experienced members of the clinical staff;

(4) Treatment planning involving a multidisciplinary approach and specific aftercare plans;

(5) Means to provide treatment/progress documentation to the provider.

(e) General Vendor Requirements

The vendor shall disapprove and discontinue the use of providers or contractors that fail to provide effective or timely diversion services as follows:

(1) The vendor is fully responsible for the acts and omissions of its subcontractors and of persons either directly or indirectly employed by any of them. No subcontract shall relieve the vendor of its responsibilities and obligations. All state policies, guidelines, and requirements apply to all subcontractors.

(2) If a subcontractor fails to provide effective or timely services as listed above, but not limited to any other subcontracted services, the vendor will terminate services of said contractor within 30 business days of notification of failure to provide adequate services.

(3) The vendor shall notify the appropriate board within five (5) business days of termination of said subcontractor.

#14 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

#14 Uniform Standard

The board shall disclose the following information to the public for licensees who are participating in a board monitoring/diversion program regardless of whether the licensee is a self-referral or a board referral. However, the disclosure shall not contain information that the restrictions are a result of the licensee's participation in a diversion program.

- Licensee's name;
- Whether the licensee's practice is restricted, or the license is on inactive status;
- A detailed description of any restriction imposed.

#15 SENATE BILL 1441 REQUIREMENT

If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

#15 Uniform Standard

1. If a board uses a private-sector vendor to provide monitoring services for its licensees, an external independent audit must be conducted at least once every three (3) years by a qualified, independent reviewer or review team from outside the department with no real or apparent conflict of interest with the vendor providing the monitoring services. In addition, the reviewer shall not be a part of or under the control of the board. The independent reviewer or review team must consist of individuals who are competent in the professional practice of internal auditing and assessment processes and qualified to perform audits of monitoring programs.

2. The audit must assess the vendor's performance in adhering to the uniform standards established by the board. The reviewer must provide a report of their findings to the board by June 30 of each three (3) year cycle. The report shall identify any material inadequacies, deficiencies, irregularities, or other non-compliance with the terms of the vendor's monitoring services that would interfere with the board's mandate of public protection.

3. The board and the department shall respond to the findings in the audit report.

#16 SENATE BILL 1441 Requirement

Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

#16 Uniform Standard

Each board shall report the following information on a yearly basis to the Department of Consumer Affairs and the Legislature as it relates to licensees with substance abuse problems who are either in a board probation and/or diversion program.

- Number of intakes into a diversion program
- Number of probationers whose conduct was related to a substance abuse problem
- Number of referrals for treatment programs
- Number of relapses (break in sobriety)
- Number of cease practice orders/license in-activations
- Number of suspensions
- Number terminated from program for noncompliance
- Number of successful completions based on uniform standards
- Number of major violations; nature of violation and action taken
- Number of licensees who successfully returned to practice
- Number of patients harmed while in diversion

The above information shall be further broken down for each licensing category, specific substance abuse problem (i.e. cocaine, alcohol, Demerol etc.), whether the licensee is in a diversion program and/or probation program.

If the data indicates that licensees in specific licensing categories or with specific substance abuse problems have either a higher or lower probability of success, that information shall be taken into account when determining the success of a program. It may also be used to determine the risk factor when a board is determining whether a license should be revoked or placed on probation.

The board shall use the following criteria to determine if its program protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

- At least 100 percent of licensees who either entered a diversion program or whose license was placed on probation as a result of a substance abuse problem successfully completed either the program or the probation, or had their license to practice revoked or surrendered on a timely basis based on noncompliance of those programs.

- At least 75 percent of licensees who successfully completed a diversion program or probation did not have any substantiated complaints related to substance abuse for at least five (5) years after completion.

Senate Bill No. 796

CHAPTER 600

An act to amend Sections 315, 2450.3, 3621, 3623, 3630, 3635, 3644, 3645, 3660, 3680, 3686, 3710, 3716, and 3772 of, and to add Sections 3635.1 and 3635.2 to, the Business and Professions Code, relating to healing arts.

[Approved by Governor October 8, 2017. Filed with Secretary of State October 8, 2017.]

LEGISLATIVE COUNSEL'S DIGEST

SB 796, Hill. Uniform Standards: Naturopathic Doctors Act: Respiratory Care Practice Act.

(1) The Department of Consumer Affairs is comprised of healing arts boards that are responsible for the licensure and regulation of healing arts licensees. Under existing law, the Substance Abuse Coordination Committee is created within the department and the committee is required to formulate uniform and specific standards in specified areas that each healing arts board is required to use in dealing with substance-abusing licensees. Existing law, by January 1, 2010, requires the committee to formulate uniform and specific standards in specified areas, including standards governing all aspects of required testing, that each healing arts board is required to use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program.

This bill, by January 1, 2019, would require the committee to review the existing criteria for those standards governing all aspects of required testing to determine whether the existing criteria should be updated to reflect recent developments in testing research and technology.

(2) Existing law, the Naturopathic Doctors Act, establishes the Naturopathic Medicine Committee within the Osteopathic Medical Board of California for the licensure and regulation of naturopathic doctors. Existing law requires the committee to consist of 9 members appointed by the Governor, including 2 public members. Existing law requires a public member to be a citizen of the state for at least 5 years preceding his or her appointment.

This bill would instead require 7 professional members to be appointed by the Governor, one public member to be appointed by the Senate Committee on Rules, and one public member to be appointed by the Speaker of the Assembly. The bill would instead require a public member to be a resident of the state for at least 5 years preceding his or her appointment.

Existing law repeals the act on January 1, 2018. Existing law also specifies that the committee is subject to review by the appropriate policy committees of the Legislature on January 1, 2018.

This bill would instead repeal the act and subject the committee to legislative review on January 1, 2022.

Existing law requires an applicant for a license as a naturopathic doctor to file a written application with the committee, as specified. Existing law requires the committee to establish the amount of the fee assessed to conduct activities of the committee, including the amount of fees for applicant licensure, licensure renewal, late renewal, and childbirth certification. Existing law requires the committee to require the satisfactory completion of 60 hours of approved continuing education biennially, as specified, for licensure renewal.

This bill would remove the requirement that an application be written. The bill would specify the amount or maximum amount for each of the fees. The bill would require a licensee to retain certificates of continuing education course completion for 6 years. The bill would authorize the committee to audit licensees' continuing education records to ensure that continuing education requirements are met. The bill would specify that furnishing false or misleading information to the committee regarding continuing education constitutes unprofessional conduct.

Existing law requires the committee to approve a specified naturopathic medical education program. Existing law requires boards within the Department of Consumer Affairs to adopt rules and regulations to provide for methods of evaluating education, training, and experience obtained in the armed services, if applicable to the requirements of the business, occupation, or profession regulated, and to specify how this education, training, and experience may be used to meet the licensure requirements for the particular business, occupation, or profession regulated. Existing law also requires these boards to consult with the Department of Veterans Affairs and the Military Department before adopting these rules and regulations.

This bill would require that the naturopathic medical program, pursuant to those provisions, evaluate an applicant's education, training, and experience obtained in the armed services, and provide course credit where applicable.

Existing law requires the satisfactory completion of specified hours of approved continuing education biennially in order to renew a license. Existing law requires the continuing education to meet certain requirements and to be provided by an approved continuing education provider.

This bill would additionally require the course content to pertain to the practice of naturopathic, osteopathic, or allopathic medicine. The bill would require continuing education providers to comply with certain conflict-of-interest requirements. The bill would also require these providers to submit a related annual declaration to the committee. The bill would require the committee to maintain a list of these providers meeting those requirements on its Internet Web site.

Existing law does not prevent or restrict the practice, services, or activities of a person who makes recommendations regarding or is engaged in the sale of, among other things, food or vitamins.

This bill would authorize an unlicensed person to represent that he or she "practices naturopathy" if certain requirements related to restrictions on services provided and specified disclosures and acknowledgments are met.

(3) Existing law, the Respiratory Care Practice Act, establishes the Respiratory Care Board of California for the licensure and regulation of respiratory care practitioners. Existing law specifies that the board is subject to review by the appropriate policy committees of the Legislature upon repeal of the provision establishing the board. Existing law also authorizes the board to employ an executive officer. Existing law repeals these provisions on January 1, 2018.

This bill would instead repeal those provisions on January 1, 2022.

Existing law establishes the Respiratory Care Fund in the State Treasury to carry out the purposes of the act, and requires all collections from persons licensed or seeking to be licensed under the Respiratory Care Practice Act to be paid into the fund, as specified.

This bill would make the availability of the moneys in the fund contingent upon appropriation by the Legislature.

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

SECTION 1. Section 315 of the Business and Professions Code is amended to read:

315. (a) For the purpose of determining uniform standards that will be used by healing arts boards in dealing with substance-abusing licensees, there is established in the Department of Consumer Affairs the Substance Abuse Coordination Committee. The committee shall be comprised of the executive officers of the department's healing arts boards established pursuant to Division 2 (commencing with Section 500), the State Board of Chiropractic Examiners, the Osteopathic Medical Board of California, and a designee of the State Department of Health Care Services. The Director of Consumer Affairs shall chair the committee and may invite individuals or stakeholders who have particular expertise in the area of substance abuse to advise the committee.

(b) The committee shall be subject to the Bagley-Keene Open Meeting Act (Article 9 (commencing with Section 11120) of Division 3 of Title 2 of the Government Code).

(c) By January 1, 2010, the committee shall formulate uniform and specific standards in each of the following areas that each healing arts board shall use in dealing with substance-abusing licensees, whether or not a board chooses to have a formal diversion program:

(1) Specific requirements for a clinical diagnostic evaluation of the licensee, including, but not limited to, required qualifications for the providers evaluating the licensee.

(2) Specific requirements for the temporary removal of the licensee from practice, in order to enable the licensee to undergo the clinical diagnostic evaluation described in paragraph (1) and any treatment recommended by

the evaluator described in paragraph (1) and approved by the board, and specific criteria that the licensee must meet before being permitted to return to practice on a full-time or part-time basis.

(3) Specific requirements that govern the ability of the licensing board to communicate with the licensee's employer about the licensee's status and condition.

(4) Standards governing all aspects of required testing, including, but not limited to, frequency of testing, randomness, method of notice to the licensee, number of hours between the provision of notice and the test, standards for specimen collectors, procedures used by specimen collectors, the permissible locations of testing, whether the collection process must be observed by the collector, backup testing requirements when the licensee is on vacation or otherwise unavailable for local testing, requirements for the laboratory that analyzes the specimens, and the required maximum timeframe from the test to the receipt of the result of the test.

(5) Standards governing all aspects of group meeting attendance requirements, including, but not limited to, required qualifications for group meeting facilitators, frequency of required meeting attendance, and methods of documenting and reporting attendance or nonattendance by licensees.

(6) Standards used in determining whether inpatient, outpatient, or other type of treatment is necessary.

(7) Worksite monitoring requirements and standards, including, but not limited to, required qualifications of worksite monitors, required methods of monitoring by worksite monitors, and required reporting by worksite monitors.

(8) Procedures to be followed when a licensee tests positive for a banned substance.

(9) Procedures to be followed when a licensee is confirmed to have ingested a banned substance.

(10) Specific consequences for major violations and minor violations. In particular, the committee shall consider the use of a "deferred prosecution" stipulation similar to the stipulation described in Section 1000 of the Penal Code, in which the licensee admits to self-abuse of drugs or alcohol and surrenders his or her license. That agreement is deferred by the agency unless or until the licensee commits a major violation, in which case it is revived and the license is surrendered.

(11) Criteria that a licensee must meet in order to petition for return to practice on a full-time basis.

(12) Criteria that a licensee must meet in order to petition for reinstatement of a full and unrestricted license.

(13) If a board uses a private-sector vendor that provides diversion services, standards for immediate reporting by the vendor to the board of any and all noncompliance with any term of the diversion contract or probation; standards for the vendor's approval process for providers or contractors that provide diversion services, including, but not limited to, specimen collectors, group meeting facilitators, and worksite monitors; standards requiring the vendor to disapprove and discontinue the use of

providers or contractors that fail to provide effective or timely diversion services; and standards for a licensee's termination from the program and referral to enforcement.

(14) If a board uses a private-sector vendor that provides diversion services, the extent to which licensee participation in that program shall be kept confidential from the public.

(15) If a board uses a private-sector vendor that provides diversion services, a schedule for external independent audits of the vendor's performance in adhering to the standards adopted by the committee.

(16) Measurable criteria and standards to determine whether each board's method of dealing with substance-abusing licensees protects patients from harm and is effective in assisting its licensees in recovering from substance abuse in the long term.

(d) Notwithstanding any other law, by January 1, 2019, the committee shall review the existing criteria for Uniform Standard #4 established pursuant to paragraph (4) of subdivision (c). The committee's review and findings shall determine whether the existing criteria for Uniform Standard #4 should be updated to reflect recent developments in testing research and technology. The committee shall consider information from, but not limited to, the American Society of Addiction Medicine, and other sources of best practices.

SEC. 2. Section 2450.3 of the Business and Professions Code is amended to read:

2450.3. There is within the jurisdiction of the Osteopathic Medical Board of California a Naturopathic Medicine Committee authorized under the Naturopathic Doctors Act (Chapter 8.2 (commencing with Section 3610)). This section shall become inoperative on January 1, 2022, and as of that date is repealed. Notwithstanding any other provision of law, the repeal of this section renders the Naturopathic Medicine Committee subject to review by the appropriate policy committees of the Legislature.

SEC. 3. Section 3621 of the Business and Professions Code is amended to read:

3621. (a) The committee shall consist of nine members, consisting of seven professional members appointed by the Governor, one public member appointed by the Senate Committee on Rules, and one public member appointed by the Speaker of the Assembly. Members of the committee shall include five members who are California licensed naturopathic doctors, two members who are California licensed physicians and surgeons, and two public members.

(b) A member of the committee shall be appointed for a four-year term. A person shall not serve as a member of the committee for more than two consecutive terms. A member shall hold office until the appointment and qualification of his or her successor, or until one year from the expiration of the term for which the member was appointed, whichever first occurs. Vacancies shall be filled by appointment for unexpired terms.

(c) (1) A public member of the committee shall be a resident of this state for at least five years preceding his or her appointment.

(2) A person shall not be appointed as a public member if the person or the person's immediate family in any manner owns an interest in a college, school, or institution engaged in naturopathic education, or the person or the person's immediate family has an economic interest in naturopathy or has any other conflict of interest. "Immediate family" means the public member's spouse, parents, children, or his or her children's spouses.

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

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

SEC. 4. Section 3623 of the Business and Professions Code is amended to read:

3623. (a) The committee shall approve a naturopathic medical education program accredited by the Council on Naturopathic Medical Education or an equivalent federally recognized accrediting body for the naturopathic medical profession that has the following minimum requirements:

(1) Admission requirements that include a minimum of three-quarters of the credits required for a bachelor's degree from a regionally accredited or preaccredited college or university or the equivalency, as determined by the council.

(2) Program requirements for its degree or diploma of a minimum of 4,100 total hours in basic and clinical sciences, naturopathic philosophy, naturopathic modalities, and naturopathic medicine. Of the total requisite hours, not less than 2,500 hours shall consist of academic instruction, and not less than 1,200 hours shall consist of supervised clinical training approved by the naturopathic medical school.

(b) A naturopathic medical education program in the United States shall offer graduate-level full-time studies and training leading to the degree of Doctor of Naturopathy or Doctor of Naturopathic Medicine. The program shall be an institution, or part of an institution of, higher education that is either accredited or is a candidate for accreditation by a regional institutional accrediting agency recognized by the United States Secretary of Education and the Council on Naturopathic Medical Education, or an equivalent federally recognized accrediting body for naturopathic doctor education.

(c) To qualify as an approved naturopathic medical school, a naturopathic medical program located in Canada or the United States shall offer a full-time, doctoral-level, naturopathic medical education program with its graduates being eligible to apply to the committee for licensure and to the North American Board of Naturopathic Examiners that administers the naturopathic licensing examination.

(d) The naturopathic medical program shall evaluate an applicant's education, training, and experience obtained in the armed services, pursuant to Section 35, and provide course credit where applicable.

SEC. 5. Section 3630 of the Business and Professions Code is amended to read:

3630. An applicant for a license as a naturopathic doctor shall file an application with the committee on a form provided by the committee that shows, to the committee's satisfaction, compliance with all of the following requirements:

(a) The applicant has not committed an act or crime that constitutes grounds for denial of a license under Section 480, and has complied with the requirements of Section 144.

(b) The applicant has received a degree in naturopathic medicine from an approved naturopathic medical school where the degree substantially meets the educational requirements in paragraph (2) of subdivision (a) of Section 3623.

SEC. 6. Section 3635 of the Business and Professions Code is amended to read:

3635. (a) In addition to any other qualifications and requirements for licensure renewal, the committee shall require the satisfactory completion of 60 hours of approved continuing education biennially. This requirement is waived for the initial license renewal. The continuing education shall meet the following requirements:

(1) At least 20 hours shall be in pharmacotherapeutics.

(2) No more than 15 hours may be in naturopathic medical journals or osteopathic or allopathic medical journals, or audio or videotaped presentations, slides, programmed instruction, or computer-assisted instruction or preceptorships.

(3) No more than 20 hours may be in any single topic.

(4) No more than 15 hours of the continuing education requirements for the specialty certificate in naturopathic childbirth attendance shall apply to the 60 hours of continuing education requirement.

(5) Course content shall pertain to the practice of naturopathic, osteopathic, or allopathic medicine.

(b) The continuing education requirements of this section may be met through continuing education courses approved by the committee, the California Naturopathic Doctors Association, the American Association of Naturopathic Physicians, the California State Board of Pharmacy, the State Board of Chiropractic Examiners, or other courses that meet the standards for continuing education for licensed physicians and surgeons in California. All continuing education providers shall comply with Section 3635.2. Continuing education providers shall submit an annual declaration to the committee that their educational activities satisfy the requirements described in Section 3635.2 and the committee shall maintain a list of these providers on its Internet Web site.

SEC. 7. Section 3635.1 is added to the Business and Professions Code, to read:

3635.1. (a) A licensee shall retain certificates of continuing education course completion for six years.

(b) The committee may audit licensees' continuing education records to ensure that continuing education requirements are met.

(c) It shall be unprofessional conduct for a licensee to furnish false or misleading information to the committee regarding continuing education.

SEC. 8. Section 3635.2 is added to the Business and Professions Code, to read:

3635.2. In addition to complying with subdivision (b) of Section 3635, the following shall apply to providers of continuing education:

(a) The content of continuing education courses and related materials shall provide balance, independence, objectivity, and scientific rigor. All patient care recommendations from continuing education courses involving clinical medicine shall be based on evidence accepted by naturopathic doctors. All scientific research used to support patient care recommendations shall conform to generally accepted standards of experimental design, data collection, and analysis.

(b) A conflict of interest is created when an individual in a position to control the content of a continuing education course, or his or her spouse or partner, has a relevant personal financial relationship within the past 12 months with a commercial entity that produces, markets, resells, or distributes health care goods or services consumed by, or used on patients that benefits the individual in any financial amount and therefore, may bias his or her opinions and teachings with respect to the content of continuing education courses. This may include receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest such as stocks, stock options or other ownership interest, excluding diversified mutual funds, or other financial benefit. Financial benefits are generally associated with roles such as employment, a management position, or an independent contractor position, including contracted research and clinical trials, consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities for which remuneration is received or expected.

(c) Prior to a course being presented, continuing education providers shall identify, disclose, and resolve all conflicts of interest. Individuals who fail or refuse to disclose relevant financial relationships shall not be approved as a provider of continuing education as described in subdivision (b) of Section 3635.

(d) Conflicts of interests shall be resolved by one of the following mechanisms:

(1) Altering financial relationships. Individuals may change their relationships with commercial interests, such as discontinuance of contracted services, thereby eliminating any conflict of interest related to the continuing education content.

(2) Altering control over content. An individual’s control of continuing education content may be altered in several ways to remove the opportunity to affect content related to the products and services of a commercial interest. These include the following:

(A) Choose someone else to control that part of the content. If a proposed presenter or planner has a conflict of interest related to the content, someone

else who does not have a relationship to the commercial interests related to the content may present or plan that part of the content.

(B) Change the focus of the continuing education activity so that the content is not about products or services of the commercial interest that is the basis of the conflict of interest.

(C) Change the content of the individual's assignment so that it is no longer about products or services of the commercial interest. For example, an individual with a conflict of interest regarding products for treatment of a condition could address the pathophysiology or diagnosis of the condition, rather than therapeutics.

(D) Limit the content to a report without recommendations. If an individual has been funded by a commercial entity to perform research, the individual's presentation may be limited to the data and results of the research. Someone else may be assigned to address broader implications and recommendations.

(E) Limit the sources for recommendations. Rather than having a person with a conflict of interest present personal recommendations or personally select the evidence to be presented, limit the role of the person to reporting recommendations based on formal structured reviews of the literature with the inclusion and exclusion criteria stated "evidence-based."

(3) Conflict of interest may be resolved if the continuing education material is peer reviewed and both of the following are met:

(A) All the recommendations involving clinical medicine are based on evidence that is accepted within the profession of naturopathic medicine as adequate justification for indications and contraindications in the care of patients.

(B) All scientific research referred to, reported, or used in the continuing education activity in support or justification of patient care recommendations conforms to the generally accepted standards of experimental design, data collection, and analysis.

SEC. 9. Section 3644 of the Business and Professions Code is amended to read:

3644. This chapter does not prevent or restrict the practice, services, or activities of any of the following:

(a) A person licensed, certified, or otherwise recognized in this state by any other law or regulation if that person is engaged in the profession or occupation for which he or she is licensed, certified, or otherwise recognized.

(b) A person employed by the federal government in the practice of naturopathic medicine while the person is engaged in the performance of duties prescribed by laws and regulations of the United States.

(c) A person rendering aid to a family member or in an emergency, if no fee or other consideration for the service is charged, received, expected, or contemplated.

(d) (1) A person who makes recommendations regarding or is engaged in the sale of food, extracts of food, nutraceuticals, vitamins, amino acids, minerals, enzymes, botanicals and their extracts, botanical medicines, homeopathic medicines, dietary supplements, and nonprescription drugs or

other products of nature, the sale of which is not otherwise prohibited under state or federal law.

(2) An unlicensed person described in this subdivision may represent that he or she "practices naturopathy" if he or she complies with Section 2053.6. However, an unlicensed person may not use the title "naturopathic doctor" unless he or she has been issued a license by the committee.

(e) A person engaged in good faith in the practice of the religious tenets of any church or religious belief without using prescription drugs.

(f) A person acting in good faith for religious reasons as a matter of conscience or based on a personal belief, while obtaining or providing information regarding health care and the use of any product described in subdivision (d).

(g) A person who provides the following recommendations regarding the human body and its function:

(1) Nonprescription products.

(2) Natural elements such as air, heat, water, and light.

(3) Class I or class II nonprescription, approved medical devices, as defined in Section 360c of Title 21 of the United States Code.

(4) Vitamins, minerals, herbs, homeopathics, natural food products and their extracts, and nutritional supplements.

(h) A person who is licensed in another state, territory, or the District of Columbia to practice naturopathic medicine if the person is incidentally called into this state for consultation with a naturopathic doctor.

(i) A student enrolled in an approved naturopathic medical program whose services are performed pursuant to a course of instruction under the supervision of a naturopathic doctor.

SEC. 10. Section 3645 of the Business and Professions Code is amended to read:

3645. (a) This chapter permits, and does not restrict, the use of the following titles by persons who are educated and trained as any of the following:

(1) "Naturopath."

(2) "Naturopathic practitioner."

(3) "Traditional naturopathic practitioner."

(b) This chapter permits, and does not restrict, the education of persons as described in paragraphs (1) to (3), inclusive, of subdivision (a). Those persons are not required to be licensed under this chapter.

SEC. 11. Section 3660 of the Business and Professions Code is amended to read:

3660. Except as provided in subdivision (h) of Section 3644, a person shall have a valid, unrevoked, or unsuspended license issued under this chapter to do any of the following:

(a) To claim to be a naturopathic doctor, licensed naturopathic doctor, doctor of naturopathic medicine, doctor of naturopathy, or naturopathic medical doctor.

(b) To use the professional designation "N.D." or other titles, words, letters, or symbols with the intent to represent that he or she practices, is

authorized to practice, or is able to practice naturopathic medicine as a naturopathic doctor.

SEC. 12. Section 3680 of the Business and Professions Code is amended to read:

3680. (a) The application fee for a doctor of naturopathic medicine shall be no more than four hundred dollars ($400).

(b) The initial license fee shall be no more than eight hundred dollars ($800).

(c) The renewal fee for a license shall be no more than eight hundred dollars ($800).

(d) The late renewal fee for a license shall be no more than one hundred fifty dollars ($150).

(e) The fee for processing fingerprint cards shall be the current fee charged by the Department of Justice.

(f) The fee for a duplicate or replacement license shall be no more than twenty-five dollars ($25).

SEC. 13. Section 3686 of the Business and Professions Code is amended to read:

3686. This chapter shall remain in effect only until January 1, 2022, and as of that date is repealed.

SEC. 14. Section 3710 of the Business and Professions Code is amended to read:

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

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

SEC. 15. Section 3716 of the Business and Professions Code is amended to read:

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

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

SEC. 16. Section 3772 of the Business and Professions Code is amended to read:

3772. There is established in the State Treasury the Respiratory Care Fund. All collections from persons licensed or seeking to be licensed under this chapter shall be paid by the board into the fund after the report to the Controller at the beginning of each month of the amount and source of the collections. Moneys in the fund shall be available to the board, upon appropriation by the Legislature.

O

Pharmacist Recovery Program

Why this Program?

Substance abuse can strike anyone. A recent study indicated that 46% of the pharmacists and 62% of the pharmacy students studied had used controlled substances at some time without a prescription. That does not mean that everyone who has used drugs improperly becomes a substance abuser, but highly educated and trained health professionals are not immune to alcoholism, other chemical dependencies or mental illness. Indeed, their greater access to abusable substances may increase potential risk.

The Pharmacists Recovery Program provides a significant resource toward solving such problems for both pharmacists and registered pharmacy interns.

Problems Grow

Problems can become more serious and more difficult to solve when not recognized quickly. If you are too close to the problem, you lose objectivity, and half-hearted or misdirected efforts often serve only to increase frustration and stress, making the problem seem unsolvable. For the pharmacist or pharmacy student, substance abuse or mental illness can impair one's professional judgment, putting at risk one's professional career and, even worse, one's life.

What is the Program?

The purpose of the Pharmacists Recovery Program is to identify and evaluate the nature and severity of the chemical dependency and/or mental illness, develop a treatment plan contract, monitor participation and provide encouragement and support. In the quickest, most confidential and least stressful manner possible, the individual receives the proper help to face the problem, deal with it and, if possible, return to the profession as a contributing member.

Through this program, the chemically dependent or mentally troubled pharmacist is provided with the hope and assistance required for a successful recovery.

Who Provides the Service?

The California State Board of Pharmacy contracts with Maximus, Inc. to provide confidential assessment, referral, and monitoring services for the Pharmacists Recovery Program. Maximus has a network of professionals throughout California specializing in the treatment of alcohol or other drug abuse and mental illness problems.

Source:
https://www.pharmacy.ca.gov/licensees/personal/pharmacist_recovery.shtml

Who Can Refer to the Program?

This rehabilitation and treatment program accepts referrals on a voluntary basis. Any licensed pharmacist or registered intern in California who is experiencing alcohol or other drug abuse or mental illness can voluntarily seek assistance by contacting a 24-hour toll-free number. ***All voluntary requests for information and assistance are strictly confidential***; this information is not subject to discovery or subpoena. Arrangements will be made for the individual to meet with a licensed professional who will make a confidential evaluation and develop a treatment plan. Pharmacists who use the program are assured that their problem and its nature will remain confidential.

Family, friends, employers, and professional colleagues are also encouraged to contact the program for information and assistance.

An Alternative for the Board of Pharmacy

The Board of Pharmacy also uses the program for pharmacists who are chemically dependent or mentally impaired. Under the Pharmacists Recovery Program, the board may refer a pharmacist to the program in lieu of discipline if there has been no other significant violation of the pharmacy law. In cases that involve a serious violation, the board may refer a pharmacist to the program in addition to discipline.

How to Obtain Services

If you have a problem or live or work with a pharmacist who does, call the Pharmacists Recovery Program toll-free at (800) 522-9198. Your call will be confidential.

Source:
https://www.pharmacy.ca.gov/licensees/personal/pharmacist_recovery.shtml

ATTACHMENT 3

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

a. Community Pharmacy/Hospital Out-Patient Self-Assessment Form (17M-13)

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

COMMUNITY PHARMACY SELF-ASSESSMENT/ HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **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; (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.**

The self-assessment must be completed in its entirety. It may be completed online, printed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial in ink on the self-assessment form. Scanned copies of original signatures and initials may be maintained as file copy for the pharmacy. Do not copy a previous assessment.

Notes: If a hospital pharmacy dispenses prescriptions for outpatient use, this Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment must be completed in addition to the Hospital Pharmacy Self-Assessment (17M-14 Rev. ~~03/19~~1/21). Any pharmacy that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

License #: _____ Exp. Date: _____ Other Permit #: _____ Exp. Date: _____

Licensed Sterile Compounding License# _____ Expiration:

~~Accredited by (if any): _____ From: _____ To: _____~~

Licensed Remote Dispensing Site Pharmacy License # _____ Exp. Date _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____
Website address (if any): _____

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians):
Please use an additional sheet if necessary. APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

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. _____ INT # _____ Exp. Date: _____

7. _____ INT # _____ Exp. Date: _____

8. _____ INT # _____ Exp. Date: _____

9. _____ TCH # _____ Exp. Date: _____

10. _____ TCH # _____ Exp. Date: _____

11. _____ TCH # _____ Exp. Date: _____

COMMUNITY PHARMACY SELF-ASSESSMENT/

HOSPITAL OUTPATIENT PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted.

Please mark the appropriate box for each item. 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.

1. Facility

Yes	No	N/A	
☐	☐	☐	1.1. The pharmacy has an area suitable for confidential patient consultation. (CCR 1764, 1714)
☐	☐	☐	1.2. The pharmacy is secure and only a pharmacist possesses a key. The pharmacy has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, CCR 1714)
☐	☐	☐	1.3. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)
☐	☐	☐	1.4. The pharmacy premises, fixtures, and equipment are maintained in a clean and orderly condition, properly lighted and free from rodents and insects. (CCR 1714)
☐	☐	☐	1.5. The pharmacy sink has hot and cold running water. (CCR 1714)
☐	☐	☐	1.6. The pharmacy has a readily accessible restroom. (CCR 1714)
☐	☐	☐	1.7. Current board-issued "Notice to Consumers" is posted in public view where it can be read by the consumer, or written receipts containing the required information are provided to the consumers. A written receipt that contains the required information on the notice may be provided to consumers as an alternative to posting the notice in the pharmacy. A pharmacy may also or instead display the notice on a video screen in lieu of the poster. Additional "Notice to Consumers" in languages other than English may also be posted. (BPC 4122, CCR 1707.6)
☐	☐	☐	1.8. "Point to Your Language" poster is posted or provided in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6~~[c]~~[b])
☐	☐	☐	1.9. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear nametags, in 18-point type, that contain their name and license status. (BPC 680, BPC 4115.5[e], CCR 1793.7~~[d]~~[c])
☐	☐	☐	1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (BPC 4032, 4058)
☐	☐	☐	1.11. Does the pharmacy compound sterile drugs? (If yes, complete ~~section 27 – "Compounding."~~the current Compounding Self-Assessment Form 17M-39). (CCR 1735.2(k))

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PIC Initials

Yes No N/A

☐☐☐ 1.12. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (BPC 4104[a])

☐☐☐ 1.13. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (BPC 4104[b])

☐☐☐ 1.14. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (BPC 4104[c])

☐☐☐ 1.15. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ 1.16. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____ _____

☐☐☐ 1. 17. The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the customer the lower price. Additionally, the pharmacy submits the claim to the health care service plan or insurer. (BPC 4079, BPC 4079.5)

☐☐☐ 1.18. A pharmacy that dispenses controlled substances shall display safe storage products (a device made with the purpose of storing prescription medications with a locking or secure mechanism for access by the patient i.e. medicine lock box, locking medicine cabinet, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists and owns 4 or less pharmacy. (BPC 4106.5)

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PIC Initials

Yes No N/A

☐☐☐ 1.19. A community pharmacy does not require a pharmacist employee to engage in practice of pharmacy at any time the pharmacy is open to the public unless either another employee at the establishment is made available to assist the pharmacist at all times unless the pharmacy is exempted. (BPC 4113.5)

- ☐ 1.19.1. The pharmacy has designated the name(s) of personnel who will be available to assist the pharmacist (CCR 1714.3 (a)(1));
- ☐ 1.19.2. Designated personnel Is able, at a minimum, to perform the duties of non-licensed pharmacy personnel as specified in section 1793.3, and is qualified to have access to controlled substances (CCR 1714.3 (a)(2)(3));
- ☐ 1.19.3. Designated personnel respond and are able to assist the pharmacist within five minutes after the pharmacist's request (CCR 1714.3(a)(4);
- ☐ 1.19.4. The pharmacy has policies and procedures in compliance with CCR 1714.3 (CCR 1714.3 (b);
- ☐ 1.19.5. All impacted pharmacy employees and designated persons have read and signed a copy of the policies and procedures (CCR 1714.3 (c);

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Delivery of Drugs

Yes No N/A

☐☐☐ 2.1. Dangerous drugs and dangerous devices are only delivered to the licensed premises, and signed for and received by a pharmacist. (BPC 4059.5[a], HSC 11209~~{~~[a]~~}~~)

☐☐☐ 2.2. The pharmacy takes delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty only when all of the following requirements are met: (BPC 4059.5[f]):

- ☐ 2.2.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (BPC 4059.5[f][1]);
- ☐ 2.2.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (BPC 4059.5[f][2]);
- ☐ 2.2.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (BPC 4059.5[f][3]);
- ☐ 2.2.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (BPC 4059.5[f][4]); and

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PIC Initials

☐ 2.2.5. The agent delivering dangerous drugs and dangerous devices leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy is responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy is also ~~be~~ responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. BPC 4059.5[f][5])

☐☐☐ 2.3. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1 [d][1][A][i])

☐☐☐ 2.4. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee- 1[d][1][A][ii])

Yes No N/A

☐☐☐ 2.5. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Drug Stock

Yes No N/A

☐☐☐ 3.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (BPC 4342, HSC 111255, 111335, 22 CCR 70263[q], CCR 1714[b], 21 USC sections 331, 351, 352)

☐☐☐ 3.2. Dangerous drugs or dangerous devices are purchased, traded, sold, warehoused, distributed or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy, or manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169)

☐ 3.2.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.

☐ 3.2.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.

☐ 3.2.3. Are not expired.

☐☐☐ 3.3. If the pharmacy has reasonable cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

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PIC Initials

☐☐☐ 3.4. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

☐☐☐ 3.5. The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023, unit-level traceability. (21 USC 360eee-I(g)~~Drug Supply Chain Security Act~~)

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Voluntary Drug Repository and Distribution Program (HSC 150200)

Yes No N/A

☐☐☐ 4.1. Does the pharmacy donate to or operate a county-approved Voluntary Drug Repository and Distribution Program?

(If yes, complete Section 3~~0~~2 [donate drugs] or Section 3~~1~~3 [operate program] of this Self-Assessment.)

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 5.1. The pharmacy has a PIC that is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 5.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy. (BPC 4113[c], CCR 1709.1[b])

☐☐☐ 5.3. The PIC has completed a biennial pharmacy self-assessment before July 1 of each odd numbered year. An additional self-assessment will be completed within 30 days if a new license is issued or a new PIC employed. Each self-assessment will be maintained in the pharmacy for three years. (CCR 1715)

☐☐☐ 5.4. Is the PIC in charge of another pharmacy?

☐☐☐ 5.5. If yes, are the pharmacies within 50 driving miles of each other? (CCR 1709.1[c])

Name of the other pharmacy _____

☐☐☐ 5.6. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101, 4113)

☐☐☐ 5.7. The PIC is responsible for directing and overseeing the performance of waived clinical laboratory tests, if the pharmacy holds a registration from CDPH to conduct such tests. (~~HSC~~ BPC 1206.5, 1265)

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PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Duties of a Pharmacist

Yes No N/A

☐☐☐ 6.1. Only a pharmacist:

- ☐ transmits a valid prescription to another pharmacist; (BPC 4052[a][2])
- ☐ administers drugs and biological products ordered by the prescriber; (BPC 4052[a][3])
- ☐ manufactures, measures, fits to the patient or sells and repairs dangerous devices or furnishes instructions to the patient or patient representative concerning the use of the dangerous devices; (BPC 4052[a][7])
- ☐ provides consultation, training and education to patients about drug therapy disease management and disease prevention; (BPC 4052[a][8])
- ☐ provides professional information and participates in multidiscipline review of patient progress; (BPC 4052[a][9])
- ☐ furnishes medication including emergency contraception drug therapy, self-administered hormonal contraceptives, nicotine replacement products, naloxone, or prescription medication not requiring a diagnosis recommended by the Centers for Disease Control when traveling outside of the US; administers immunizations, HIV preexposure prophylaxis, HIV postexposure prophylaxis; (BPC 4052 [a][10], 4052[a][11], 4052.01, 4052.02, 4052.03, 4052.3, 4052.8, 4052.9)
- ☐ dispenses aid-in-dying drugs; (HSC 443.5 [b][2]) and
- ☐ orders and interprets tests for monitoring and managing efficacy and toxicity of drug therapies (BPC 4052 [a][12]).

Yes No N/A

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PIC Initials

☐☐☐ 6.2. In addition, ~~O~~ only a pharmacist:

- ☐ receives a new prescription order from the prescriber; (BPC 4070 [a]), CCR 1793.1[a])
- ☐ consults with the patient; (BPC 4052 [a][8], CCR 1707.2, CCR 1793.1[b])
- ☐ identifies, evaluates and interprets a prescription; (CCR 1793.1 [c])
- ☐ interprets the clinical data in a patient medication record; (CCR 1793.1 [d])
- ☐ consults with any prescriber, nurse, health professional or agent thereof; (CCR 1793.1 [e])
- ☐ supervises the packaging of drugs; (CCR 1793.1 [f])
- ☐ checks the packaging procedure and product upon completion; (CCR 1793.1 [f])
- ☐ is responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7 [e]) or
- ☐ performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform and performs all functions which require professional judgment. (BPC 4052, 4052.02, 4052.03, 4052.1, 4052.2, 4052.3, 4052.4, CCR 1793.1 [g])

☐☐☐ 6.3. The pharmacist as part of the care provided by a health care facility, a licensed clinic and a licensed home health agency in which there is physician oversight, or a provider who contracts with a licensed health care service plan with regard to the care or services provided to the enrollees of that health care service plan, is performing the following functions, in accordance with policies, procedures, or protocols of that facility, licensed clinic, or health care service plan that were developed by health professionals, including physicians and surgeons, pharmacists and registered nurses. The functions are: ordering or performing routine drug therapy related patient assessment procedures; ordering drug therapy related laboratory tests; administering drugs or biologicals by injection; initiating and adjusting the drug regimen of a patient; and performing moderate or waived laboratory tests. (BPC 4052, 4052.1, 4052.2, 4052.3, 4052.4)

Yes No N/A

☐☐☐ 6.4. Pharmacists have obtained approval to access the CURES Prescription Drug Monitoring Program (PDMP). (HSC 11165.1)

☐☐☐ 6.5. The pharmacist dispenses emergency contraceptive only pursuant to the statewide protocol found in 16 CCR 1746.

☐☐☐ 6.6. Only a pharmacist performs blood glucose, hemoglobin A1c, or cholesterol tests that are waived under CLIA. (No CDPH registration required.) (BPC 1206.6)

☐☐☐ 6.7. Only a pharmacist performs CLIA waived clinical laboratory tests, where the pharmacy is registered with CDPH to perform such services. (BPC 1206.6)

CDPH (CLIA) Registration #:_____ Expiration: _____

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PIC Initials

☐☐☐ 6.8. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (BPC 4052[b])

☐☐☐ 6.9. All pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 7.1. The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 7.1.1. Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 7.1.2. Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])
- ☐ 7.1.3. Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information in to a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[b])
- ☐ 7.1.4. Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[b])
- ☐ 7.1.5. Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])
- ☐ 7.1.6. Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 8.1. The intern pharmacist performs the functions of a pharmacist only under the direct supervision of a pharmacist. The pharmacist supervises no more than **two interns** at any one time. (BPC 4114, 4023.5, CCR 1726)

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PIC Initials

☐☐☐ 8.2. All prescriptions filled or refilled by an intern are, prior to dispensing, checked for accuracy by a licensed pharmacist and the prescription label initialed by the checking pharmacist. (CCR 1717[b][1], CCR 1712)

☐☐☐ 8.3. The intern hours affidavits are signed by the pharmacist under whom the experience was earned or the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], [c], [d], CCR 1726)

☐☐☐ 8.4. During a temporary absence of a pharmacist or duty-free breaks or meal periods, an intern pharmacist may not perform any discretionary duties nor act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 8.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 9.1. Pharmacy technicians only perform packaging, manipulative, repetitive, or other nondiscretionary tasks, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793, 1793.2, 1793.7)

☐☐☐ 9.2. Pharmacy technician ratio when only one pharmacist is present, is no more than one technician. For each additional pharmacist present, the ratio may not exceed 2 technicians for each additional pharmacist. (BPC 4038, 4115, CCR 1793.7[f])

☐☐☐ 9.3. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type, that identifies himself or herself as a pharmacy technician or pharmacy technician trainee. (BPC 680, BPC 4115.5[e], CCR 1793.7~~[d]~~[c])

☐☐☐ 9.4. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with technician requirements. (CCR 1793.7~~[e]~~[d])

☐☐☐ 9.5. A pharmacy technician trainee participating in an externship may perform packaging, manipulative, repetitive or other nondiscretionary tasks only under the direct supervision and control of a pharmacist; a pharmacist may only supervise one technician trainee. The externship shall be for a period of no fewer than 120 hours and no more than 140 ~~120~~ hours. (BPC 4115.5)

☐☐☐ 9.6. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

10. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 10.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and~~—~~at the direction of a pharmacist~~—~~may request and receive refill authorization. (CCR 1793.3)

☐☐☐ 10.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

11. Consultation/Patient Profile/Review of Drug Therapy

Yes No N/A

☐☐☐ 11.1. Pharmacists provide oral consultation: (BPC 4052[a][8], CCR 1707.2)

- ☐ 11.1.1. whenever the prescription drug has not been previously dispensed to the patient;
- ☐ 11.1.2. whenever a refill prescription drug is dispensed in a different dosage form, strength, or with new written directions;
- ☐ 11.1.3. upon request;
- ☐ 11.1.4. whenever the pharmacist deems it is warranted in the exercise of his or her professional judgment; and
- ☐ 11.1.5. all of the above, unless a patient or patient's agent declines the consultation directly to the pharmacist.

Yes No N/A

☐☐☐ 11.2. The pharmacy 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)

☐☐☐ 11.3. The pharmacist reviews a patient's drug therapy and medication record prior to consultation. (CCR 1707.3)

☐☐☐ 11.4. Consultation is performed in a manner that protects the patient's protected health care information and, in an area, suitable for confidential patient consultation. (Civil Code 56.10, CCR 1714[a], 1764)

☐☐☐ 11.5. Appropriate drug warnings are provided orally or in writing. (BPC 4074, CCR 1744)

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PIC Initials

☐☐☐ 11.6. If prescription medication is mailed or delivered, the pharmacy ensures that: (CCR 1707.2[b][1])

- ☐ 11.6.1. the patient receives written notice of his or her right to request consultation (CCR 1707.2 [b][2][A]);
- ☐ 11.6.2. 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][2][B]);
- ☐ 11.6.3. 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 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: _____

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12. Prescription Requirements

Yes No N/A

☐☐☐ 12.1. Prescriptions are complete with all the required information. (BPC 4040, 4070)

☐☐☐ 12.2. Orally transmitted prescriptions are received and reduced to writing only by a pharmacist or intern pharmacist working under the direct supervision of a pharmacist. (BPC 4070, CCR 1717)

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PIC Initials

Yes No N/A

☐☐☐ 12.3. 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)

☐☐☐ 12.4. 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)

☐☐☐ 12.5. The security and confidentiality of electronically transmitted prescriptions are maintained. (BPC 4070[c], CCR 1717.4[h])

☐☐☐ 12.6. Facsimile prescriptions are received only from a prescriber's office. (BPC 4040[c])

☐☐☐ 12.7. 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])

☐☐☐ 12.8. With the exception of those prescriptions written under HSC 11159.2, 11159.3 and ~~HSC~~ 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)

☐☐☐ 12.9. All controlled substance prescriptions are valid for six months and are signed and dated by the prescriber. (HSC 11164[a][1], 11166)

☐☐☐ 12.10. All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Prescription Labeling, Furnishing and Dispensing

Yes No N/A

☐☐☐ 13.1. The prescription label contains all the required information. (BPC 4076)

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

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

☐☐☐ 13.4. 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])

_____
PIC Initials

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

Yes No N/A

☐☐☐ 13.6. When a biological product is substituted with an alternative biological product, all the requirements of BPC 4073.5 are met. (BPC 4073.5)

☐☐☐ 13.7. If the prescription is filled by a pharmacy technician or a pharmacy technician trainee, 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)

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

☐☐☐ 13.9. 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)

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

~~Yes No N/A~~

☐☐☐ 13.11. The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57[c].

☐☐☐ 13.12. Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])

☐☐☐ 13.13. The pharmacy furnishes dangerous drugs in compliance with:

☐ BPC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to received drugs, or to another pharmacy of common ownership. (BPC 4126.5)

☐ BPC 4119 to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency. (BPC 4119)

☐☐☐ 13.14. 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)

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

☐☐☐ 13.16. 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])

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PIC Initials

☐☐☐ 13.17. The pharmacy dispenses not more than a 90-day supply of a dangerous drug, excluding controlled substances, psychotropic medications and self-administered hormonal contraception, under the following provisions: (BPC 4064.5)

- ☐ 13.17.1 Where the prescription specifies an initial quantity of less than a 90-day supply followed by periodic refills; **and where:** (BPC 4064.5[a])
- ☐ 13.17.1.1 The prescriber has not indicated "no change to quantity" or words of similar meaning; (BPC 4064.5[d])
- ☐ 13.17.1.2. The patient has completed an initial 30-day supply; (BPC 4064.5[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])
- ☐ 13.17.1.3. The total quantity dispensed does not exceed the total quantity authorized on the prescription, including refills; (BPC 4064.5[a][2])
- ☐ 13.17.1.4. 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])
- ☐ 13.17.1.5. The pharmacist is exercising his or her professional judgment. (BPC 4064.5[a][4])
- ☐ 13.17.2. The pharmacist notifies the prescriber of the increase in quantity dispensed. (BPC 4064.5[c])
- ☐ 13.17.3. When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills. (BPC 4064.5)
- ☐ 13.17.4. When a pharmacist furnishes a self-administered hormonal contraceptive pursuant to BPC 4052.3 under protocols developed by the Board of Pharmacy, the pharmacist may furnish, at the patient's request, up to a 12-month supply at one time. (BPC 4064.5)

Yes No N/A

☐☐☐ 13.18. 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])

☐☐☐ 13.19. 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])

☐☐☐ 13.20. Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy 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)

☐☐☐ 13.21. When requested by a patient or patient representative, the pharmacy 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

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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)

☐☐☐ 13.22. When a pharmacist furnishes naloxone pursuant to the board of pharmacy's approved protocol, the pharmacist complies to all the requirements listed in CCR 1746.3.

☐☐☐ 13.23. When the pharmacy furnished naloxone or another opioid antagonist to a school district, county office of education, or charter school pursuant to Section 49414.3 of the Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished. (BPC 4119.8)

☐☐☐ 13.24. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency if the furnished exclusively for use by trained employees of the law enforcement agency and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

☐☐☐ 13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours, provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine (includes informing each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). (CCR 1746.4)

☐☐☐ 13.26. The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197(a), and is furnished exclusively for use by, or in connection with, an authorized entity and an authorized health care provider provides a prescription specifying the quantity of the epinephrine auto-injectors to be furnished to the authorized entity. A new prescription is obtained for any additional epinephrine auto-injector required for use. The pharmacy complies with the requirements for labeling and records maintained pursuant to BPC 4119.4.

☐☐☐ 13.27. When a pharmacist initiates and furnishes HIV preexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.02 and CCR 1747. (BPC 4052.02 and CCR 1747)

☐☐☐ 13.28. When a pharmacist initiates and furnishes HIV postexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.03 and CCR 1747. (BPC 4052.03 and CCR 1747).

☐☐☐ 13.29. Effective January 1, 2022, the pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688).

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14. Refill Authorization

Yes No N/A

☐☐☐ 14.1. Refill authorization from the prescriber is obtained before refilling a prescription. (BPC 4063, ~~4064~~)

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

☐☐☐ 14.3. 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)

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

☐☐☐ 14.5. 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: _____

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15. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 15.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711)

☐☐☐ 15.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 15.3. 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])

☐☐☐ 15.4. 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])

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

☐☐☐ 15.6. The record for quality assurance review for a medication error contains: (CCR 1711[e])

☐ 15.6.1. Date, location, and participants in the quality assurance review;

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☐ 15.6.2. Pertinent data and other information related to the medication error(s) reviewed;

☐ 15.6.3. Findings and determinations; and

☐ 15.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

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

☐☐☐ 15.8. 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: _____

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16. Erroneous or Uncertain Prescriptions / Corresponding Responsibility for Filling Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 16.1. 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])

☐☐☐ 16.2. 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)

☐☐☐ 16.3. 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)

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

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17. Prescription Transfer

Yes	No	N/A	
☐	☐	☐	17.1. Only pharmacists transfer prescriptions from pharmacy to pharmacy, and records of prescription transfers are kept as required. (CCR 1717 [e][1-6])
☐	☐	☐	17.2. Complete and accurate transfer records are kept on each prescription and refill when dispensed by pharmacies sharing a common electronic file. (CCR 1717.1)

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a. Schedule III, IV and V Controlled Substance Prescription Transfers

Yes No N/A

☐☐☐ 17.3. For the **transferring pharmacy**: the prescription hard copy is pulled and "void" is written on its face. The name of the pharmacy to which the prescription is transferred is written on the back of the voided prescription and all other information is recorded as required. The prescription can be transferred only once unless the pharmacies electronically share a real-time, on-line database, in which case the prescription is transferred up to the maximum refills permitted by law and the prescriber's authorization. (CFR 1306.25, CCR 1717[f])

☐☐☐ 17.4. For the **receiving pharmacy**: the prescription is reduced to writing by the pharmacist and "transfer" is written on the face of the transferred prescription and all other information is recorded as required. (CCR 1717[e], CFR 1306.25)

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18. Confidentiality of Prescriptions

Yes No N/A

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

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

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

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

☐☐☐ 18.5. If pharmacy 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)

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

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19. Record Keeping Requirements

Yes No N/A

☐☐☐ 19.1. All completed pharmacy self-~~-~~assessments are on file in the pharmacy and maintained for three years. (CCR 1715)

☐☐☐ 19.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy 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):

- ☐ 19.2.1. Prescription records (BPC 4081[a])
- ☐ 19.2.2. Purchase Invoices for all prescription drugs (BPC 4081[b])
- ☐ 19.2.3. Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription (BPC 4081[d])
- ☐ 19.2.4. Biennial controlled substances inventory (21 CFR 1304.11, CCR 1718)
- ☐ 19.2.5. U.S. Official Order Forms (DEA Form 222) (21 CFR 1305.13)
- ☐ 19.2.6. Power of Attorney for completion of DEA 222 forms (21 CFR ~~1305.07~~1305.05)
- ☐ 19.2.7. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])
- ☐ 19.2.8. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)
- ☐ 19.2.9. Record documenting transfers or sales to other pharmacies, licensees, prescribers, and reverse distributors (BPC 4081, 4105, CCR 1718)
- ☐ 19.2.10. Records of receipt and shipment (BPC 4081)

☐☐☐ 19.3. A pharmacist may sell hypodermic needles and syringes to a person without a prescription is limited to: ~~Hypodermic needle and syringe sales by a pharmacist to a person without a prescription are limited to:~~ (BPC 4145.5)

- ☐ 19.3.1. Persons known to the pharmacist and when the pharmacist has previously been provided with a prescription or other proof of legitimate medical need;
- ☐ 19.3.2. Use on animals, provided the person is known to the pharmacist or the person's identity can be properly established.
- ☐ ~~19.3.3. The sale of hypodermic needles or syringes at any one time to a person 18 or older **only** if the pharmacy is registered in their local county or city with the Disease Prevention Demonstration Project, and complies with the requirements of that project. (HSC 121285, BPC 4145.5)~~
- ☐ 19.3.43. For industrial use, as determined by the board. (BPC 4144.5)
- ☐ 19.3.54. As a public health measure intended to prevent the transmission of HIV, viral hepatitis, and other bloodborne diseases, furnishing of hypodermic needles and syringes for human use to a person 18 years of age or older for personal use. (BPC 4145.5)

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Yes No N/A

☐☐☐ 19.4. When hypodermic needles and syringes are furnished by a pharmacy without a prescription, the pharmacy provides the consumer with written information or verbal counseling on how to access drug treatment, testing and treatment for HIV and hepatitis C and safe disposal of sharps waste; and provide one or more of the following disposal options: (BPC 4145.5[e],[f])

☐ 19.4.1. Onsite, safe, hypodermic needle and syringe collection and disposal program.

☐ 19.4.2. Furnish or make available mail-back sharps containers.

☐ 19.4.3. Furnish or make available sharps containers.

☐☐☐ 19.5. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707, BPC 4105)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

☐☐☐ 19.6. The pharmacy furnishes an epinephrine auto-injector to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code if all of the following are met:

☐ 19.6.1. The epinephrine auto-injectors are furnished for use at a school district site, county office or education, or charter school (BPC 4119.2 [a][1]).

☐ 19.6.2. A physician and surgeon provide a written order that specifies the quantity of epinephrine auto-injectors to be furnished (BPC 4119.2 [a][2]).

☐☐☐ 19.7. The pharmacy furnishes an epinephrine auto-injector to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197a. (BPC 4119.3, 4119.4)

☐ 19.7.1. An authorized healthcare provider provides a written order that specifies the quantity of epinephrine auto-injectors to be dispensed. (BPC 4119.3[a][1], 4119.4[a][2])

☐ 19.7.2. The pharmacy labels each epinephrine auto-injector with the name of the person to whom the prescription was issued, the designation “Section 1797.197a responder” and “First Aid Purposes Only”, the dosage, use and expiration date. (BPC 4119.3[a]~~[1]~~[2], 4119.4[b])

☐ 19.7.3. Each dispensed prescription includes the manufacturer’s product information sheet for epinephrine auto-injectors. (BPC 4119.3[a][2], 4119.4[c])

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20. DEA Controlled Substances Inventory

Inventory:

Yes No N/A

☐☐☐ 20.1. Is completed biennially (every two years).
Date completed: _____ (21 CFR 1304.11[c])

☐☐☐ 20.2. Schedule II inventory is separate from Schedule III, IV and V. See also Section 21. (21 CFR 1304.04[h][1], ~~1304.04[h][2])~~

☐☐☐ 20.3. All completed inventories are available for inspection for three years. (CCR 1718)

☐☐☐ 20.4. 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])

☐☐☐ 20.5. Separate Schedule II records are maintained. This includes Schedule II prescriptions, invoices, US official order forms, and inventory records. (21 CFR 1304.04[h])

☐☐☐ 20.6. 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 pharmacy 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][~~2~~1])

☐☐☐ 20.7. 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)

☐☐☐ 20.8. 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 pharmacy, 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[g])

☐☐☐ 20.9. When a pharmacy distributes schedule II controlled substances to a DEA registrant (pharmacies, wholesales, manufacturers, prescribers) a DEA Form222 is prepared by the purchasing registrant and provided to the pharmacy selling the schedule II controlled substances. (21 CFR 1305.12)

☐☐☐ 20.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, such as those listed above, Copy 2 of the DEA Form222, is properly completed by the pharmacy selling the controlled substances and that copy is submitted at the end of each month to the DEA regional office. (21 CFR 1305.13)

☐☐☐ 20.11. Sales of controlled substances to other pharmacies or prescribers do not exceed five percent of the total number of controlled substances dosage units dispensed per calendar year; otherwise a wholesaler registration is obtained from DEA and from the board. (21 CFR 1307.11 [a][b], Drug Supply Chain Security Act. BPC 4160)

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Yes No N/A

☐☐☐ 20.12. 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 pharmacy 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])

☐☐☐ 20.13. The pharmacy generates a controlled substance printout for refills of Schedule III-V prescriptions at least every three days (72 hours) which contains the signature of the dispensing pharmacist, or the pharmacy maintains an alternate system to document the refilling of controlled substance prescriptions that complies with 21 CFR 1306.22.

☐☐☐ 20.14. 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)

☐☐☐ 20.15. Do pharmacy staff hand initial prescription records or prescription labels, or

☐☐☐ 20.16. Does the pharmacy 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 pharmacy. (CCR 1712, 1717[b][1], 1717[f])

☐☐☐ 20.17.

<u>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. [HSC 11165(d)])</u>

☐☐☐ 20.18. Furnishing of dangerous drugs and controlled substances for physician office use is done under sales and purchase records that correctly give the date, names and addresses of supplier and buyer, the drug or device and its quantity. The prescription may not be used for obtaining dangerous drugs or controlled substances for supplying a practitioner for the purpose of dispensing to patients. (21 CFR 1306.04[b], HSC 11250)

☐☐☐ <u>20.19. The pharmacy 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).</u>

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21. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 21.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 21.2. The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

☐☐☐ 21.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This report requires: (CCR 1715.65 [c])

- ☐ 21.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 21.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 21.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 21.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 21.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

Yes No N/A

☐☐☐ 21.4. The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

☐☐☐ 21.5. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

☐☐☐ 21.6. A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

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22. Oral/Electronic Transmission and Partial Fill of Schedule II Controlled Substance Prescriptions

Yes No N/A

☐☐☐ 22.1. A faxed prescription for a Schedule II controlled substance is dispensed only **after** the original written prescription is received from the prescriber. (21 CFR 1306.11[a], HSC 11164)

☐☐☐ 22.2. An oral or electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or a licensed hospice care is dispensed only **after** the pharmacist has reduced the prescription to writing on a pharmacy-generated prescription form, and: (21 CFR 1306.11, 21 CFR 1306.11[f], HSC 11167.5)

- ☐ 22.2.1. The licensed facility provides the pharmacy with a copy of the prescriber's signed order, when available.
- ☐ 22.2.2. The prescription is endorsed by the pharmacist with the pharmacy's name, license, and address.
- ☐ 22.2.3. The physician has signed the original prescription or provides a facsimile signature on the prescription.
- ☐ 22.2.4. The signature of the person who received the controlled substance for the licensed skilled nursing facility, licensed intermediate care facility, licensed home health agency or licensed hospice. (21 CFR 1306.11[f], HSC 11167.5)

Yes No N/A

☐☐☐ 22.3. If unable to supply the full quantity, the pharmacist partially fills a Schedule II prescription and is aware that if the remaining portion of the prescription is to be filled, it must be filled within 72 hours. The pharmacist shall notify the prescriber if the remaining portion of the prescription is not filled within 72 hours. (21 CFR 1306.13[a], CCR 1745[d])

☐☐☐ 22.4. The pharmacist maintains records (in a readily retrievable form or on the original prescription) of each partial filling (filled within 60 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance written for a patient of a skilled nursing facility or a patient diagnosed as "terminally ill." (21 CFR 1306.13[b], CCR 1745)

☐☐☐ 22.5. The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance when a partial fill is requested by the patient or practitioner. The pharmacist shall report to CURES only the actual amounts of drug dispensed. The total dispensed shall not exceed the prescribed quantity. (21 USC 829[f], BPC 4052.10)

☐☐☐ 22.6. Controlled substances written with the "11159.2 exemption" for the terminally ill are only dispensed when the original prescription is received, is tendered and partially filled within 60 days and no portion is dispensed more than 60 days from the date issued. (HSC 11159.2, 21 CFR 1306.11[a], CCR 1745)

☐☐☐ 22.7. The pharmacist, in a true emergency dispenses a Schedule II controlled substance from a prescription transmitted orally or electronically by a prescriber. If the order is written by the

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prescriber, the prescription is in ink, signed and dated by the prescriber. If the prescription is orally or electronically transmitted, it must be reduced to hard copy. The prescriber provides a written prescription on a controlled substance form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order. (21 CFR 1306.11[d], HSC 11167)

☐☐☐ 22.8. All prescriptions received, maintained or transmitted by the pharmacy, whether new or refill, received orally, in writing or electronically, are handled to ensure their security, integrity, authenticity and confidentiality. (CCR 1717.4)

☐☐☐ 22.9. Electronic image transmission prescriptions are either received in hard copy or the pharmacy has the capacity to retrieve a hard copy facsimile of the prescription from the pharmacy's computer memory. (CCR 1717.4[e])

☐☐☐ 22.10. All electronically transmitted prescriptions include the name & address of the prescriber, a telephone number for oral confirmation, date of transmission and the name of identity of the recipient. (CCR 1717.4[c])

☐☐☐ 22.11. Prescriptions received into an interim storage device, in addition to the prescription information, record and maintain the date the prescription is entered into the device, the date the prescription is transmitted out of the device and the recipient of the outgoing transmission. (CCR 1717.4[d])

☐☐☐ 22.12. A computer generated prescription that is not an e-script and is printed out or faxed by the practitioner to the pharmacy must be manually signed. (21 CFR 1306.05)

☐☐☐ 22.13. Electronic prescriptions (e-scripts) for controlled substances that are received from the prescriber meet federal requirements. (21 CFR 1306.08, 21 CFR 1311)

☐☐☐ 22.14. Controlled substance prescriptions with the 11159.3 exemption during a declared local, state, or federal emergency, noticed by the Board, may be dispensed if the following are met:

☐ The prescription contains the information specified in HSC 11164(a), indicates that the patient is affected by a declared emergency with the words "11159.3 exemption" or a similar statement, and is written and dispensed within the first two weeks of notice issued by the board.

☐ When the pharmacist fills the prescription, the pharmacist exercises appropriate professional judgment, including reviewing the patient's activity report from the CURE PDMP before dispensing the medication.

☐ If the prescription is a Schedule II controlled substance, dispenses no greater than the amount needed for a seven-day supply.

☐ The patient first demonstrates, to the satisfaction of the pharmacist, their inability to access medications, which may include, but not limited to, verification of residency within an evacuation area.

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23. Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 23.1. Does the pharmacy use an automated drug delivery system, automated patient dispensing system and/or automated unit dose system? (BPC 4427.7 ~~CCR 1713~~)

If yes, complete the annual self-assessment for automated drug delivery systems.

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Repackaging by the Pharmacy

Yes No N/A

☐☐☐ 24.1. Drugs are repackaged (pre-counted or poured) in quantities suitable for dispensing to patients of the pharmacy. Such repackaging is performed according to the Current Good Manufacturing Practice (CGMP), and the drugs are properly labeled with at least the following information: name of drug, strength, dosage form, manufacturer's name and lot number, expiration date, and quantity per repackaged unit. (21 CFR Part 210, 211 [CGMP], BPC 4342, HSC 110105, 111430~~, USP 1178, 1136~~)

☐☐☐ 24.2. A log is maintained for drugs pre-packed for future dispensing. (BPC 4342, CCR 1735.3, 1751.1, 21 CFR Parts 210, 211)

Yes No N/A

☐☐☐ 24.3. Drugs previously dispensed by another pharmacy are re-packaged at the patient's request and includes the name and address of both pharmacies and complies with the other requirements of BPC 4052.7.

☐☐☐ 24.4. The pharmacy only repackages and furnishes a reasonable quantity of dangerous drugs and devices for prescriber office use. (BPC 4119.5 [b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Policies and Procedures

Yes No N/A

☐☐☐ 25.1. There are written policies and procedures in place for:

☐ 25.1.1. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it affects his or her ability to practice the profession or occupation authorized by his or her license, including the reporting to the board within 14 days of receipt or development; (BPC 4104[a],[c])

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☐ 25.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy, including the reporting to the board within 14 days of receipt or development; (BPC 4104[b],[c])

☐ 25.1.3. Oral consultation for discharge medications to an inpatient of a health care facility licensed pursuant to HSC 1250, or to an inmate of an adult correctional facility or juvenile detention facility; (BPC 4074, CCR 1707.2[b][3])

☐ 25.1.4. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy; (CCR 1714.1[f])

☐ 25.1.5. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file; (CCR 1717.1[e])

☐ 25.1.6. The delivery of dangerous drugs and dangerous devices to a secure storage facility, if the pharmacy accepts deliveries when the pharmacy is closed and there is no pharmacist present; (BPC 4059.5[f][1])

☐ 25.1.7. Compliance with Title VII of Public Law 109-177 – Combat Methamphetamine Epidemic Act of 2005;

☐ ~~25.1.8. Reporting requirements to protect the public; (BPC 4104)~~

☐ 25.1.~~9~~8. A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection. (BPC 733)

☐ 25.1.~~10~~9. Preventing the dispensing of a prescription when the pharmacist determines that the prescribed drug or device would cause a harmful drug interaction or would otherwise adversely affect the patient's medical condition; and (BPC 733)

☐ 25.1.~~11~~10. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5(d))

☐ 25.1.11~~2~~. Inventory reconciliation reporting requirements. (CCR 1715.65[b])

☐ 25.1.12~~2~~. Community pharmacy staffing (CCR 1714.3 [b])

Yes No N/A

☐☐☐ 25.2. Does your pharmacy employ the use of a common electronic file?

☐ 25.2.1. If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1(e))

☐☐☐ 25.3. Does your pharmacy furnish emergency contraceptives pursuant to BPC 4052[a][10][A][1], BPC 4052, CCR 1746? If yes, does the pharmacy:

☐ 25.3.1. Follow the protocol for pharmacists furnishing Emergency Contraception (EC) approved by the California State Board of Pharmacy and the Medical Board of California? (CCR 1746)

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☐ 25.3.2. Provide the patient with a copy of the current EC Fact Sheet approved by the Board of Pharmacy? (CCR 1746)

☐ 25.3.3. Maintain in the pharmacy EC medications and adjunctive medications (for nausea and vomiting when taken with EC containing estrogens) as listed in the protocol? (CCR 1746)

☐ 25.3.4. Prior to furnishing EC, the pharmacist has completed a minimum of one hour of continuing education specific to emergency contraception. (CCR 1746)

☐ 25.3.5. If no, EC services are not immediately available or any pharmacist declines to furnish pursuant to a conscience clause, does the pharmacist refer the patient to another emergency contraception provider? (CCR 1746, CCR 1746.1[b][9])

☐ 25.3.6. Does the pharmacy have a protocol that ensures a patient has timely access to a prescribed drug or device despite a pharmacist's refusal to dispense a prescription or order? (BPC 733[b])

☐ 25.3.7. If a pharmacist declines to dispense a prescription drug or device pursuant to an order or prescription, the pharmacist has previously notified his or her employer in writing? (BPC 733[b], BPC 4052.3)

☐☐☐ 25.4. Furnishes naloxone hydrochloride in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.01[a], CCR 1746.3)

☐ 25.4.1. Procedures to ensure education of the person to whom the drug is furnished, not limited to opioid prevention, recognition and response, safe administration, potential side effects, or adverse events and the imperative to seek emergency medical care for the patient.

☐ 25.4.2. Procedures for the notification of the patient's primary care provider with patient consent of any drug or device furnished to the patient or entry of appropriate information in a patient record system.

☐ 25.4.3. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency if the furnished exclusively for use by trained employees of the law enforcement agency and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)

Yes No N/A

☐☐☐ 25.5. Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.9, CCR 1746.2)

☐☐☐ 25.6. Furnishes Self-Administered hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. A pharmacist may furnish at the patient's request up to a 12month supply at one time. (BPC 4052.3, BPC 4064.5[f][2], CCR 1746.1)

☐☐☐ 25.7. Furnishes travel medications not requiring a diagnosis that are recommended by the federal Center for Disease Control and Prevention (CDC) for individuals traveling outside the 50

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states and the District of Columbia pursuant to section BPC 4052(a)(10)(A)(3) in compliance with CCR 1746.5. (BPC 4052 (a)(10) and CCR 1746.5[a][c])

☐☐☐ 25.8. Pharmacist initiates and furnishes HIV preexposure prophylaxis in accordance with BPC 4052.02 and CCR 1747 (BPC 4052.02 and CCR 1747).

☐☐☐ 25.8. Pharmacist initiates and furnishes HIV postexposure prophylaxis in accordance with BPC 4052.03 and CCR 1747 (BPC 4052.02 and CCR 1747).

CORRECTIVE ACTION OR ACTION PLAN: _____

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26. Refill Pharmacy

Yes No N/A

☐☐☐ 26.1. Pharmacy processes refills for another pharmacy within this state (CCR 1707.4[a])

If the answer is "yes", name the pharmacy or pharmacies _____

☐☐☐ 26.2. Does the pharmacy employ the use of a common electronic file? If yes, are there policies and procedures in place to prevent unauthorized disclosures? (CCR 1717.1)

☐☐☐ 26.3. Some or all pharmacy refill orders are processed by another California licensed pharmacy. (CCR 1707.4[a])

If the answer is "yes," name of refilling pharmacy(s) _____

If the answer to both questions above is “no” or “not applicable” go to section 26.

☐☐☐ 26.4. Originating pharmacy and refill pharmacy have a contract outlining the refill arrangement, or the pharmacies have the same owner. (CCR 1707.4[a][1])

☐☐☐ 26.5. Refill prescription label meets requirements of BPC 4076 and CCR 1707.5 and shows the name and address of the refilling and or originating pharmacy. (CCR 1707.4[a][2])

☐☐☐ 26.6. Patient is provided with written information, either on the prescription label or prescription container that describes which pharmacy to contact for questions. (CCR 1707.4[a][3])

☐☐☐ 26.7. Both pharmacies maintain complete and accurate records of refill. (CCR 1707.4[a][4])

☐☐☐ 26.8. Both pharmacies are responsible for accuracy of the refilled prescription. (CCR 1707.4[a][5])

☐☐☐ 26.9. Originating pharmacy is responsible for consultation, maintenance of a medication profile and reviewing the patient's drug therapy before delivery of each prescription. (CCR 1707.4[a][6])

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CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Compounding

Yes No N/A

☐☐☐ 27.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the current "Compounding Self-Assessment" Form 17M-39 ~~(Rev. 02/12)~~ (CCR 1735.2[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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28. Nuclear Pharmacy

Yes No N/A

☐☐☐ 28.1. All pharmacists handling radioactive drugs are competent in the preparation, handling, storage, receiving, dispensing, disposition and pharmacology of radioactive drugs. (CCR 1708.4)

☐☐☐ 28.2. A pharmacist qualified under CCR 1708.4 to furnish radioactive drugs is in the pharmacy whenever the furnishing of radioactive drugs occurs. All personnel involved in the furnishing of radioactive drugs are under the immediate and direct supervision of such a qualified pharmacist. (CCR 1708.5)

☐☐☐ 28.3. The pharmacy possesses a current Sterile Compounding Permit (BPC 4127) and is compliant with CCR 1751. (Must also complete the current Compounding Self-Assessment, 17M-39 ~~Rev. 02/12.~~) (CCR 1735.2 ~~et al.~~[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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29. Telepharmacy Systems and Remote Dispensing Site Pharmacies

Yes No N/A

☐☐☐ 29.1. Pharmacy provides tele-pharmacy services and acts as a supervising pharmacy for only **one** remote dispensing site pharmacy and has obtained a remote dispensing site pharmacy license from the board. (BPC 4130 [b][e], BPC 4044.6, BPC 4044.3[a])

If the answer is "yes", name the remote dispensing site pharmacy and license number:

Name:_____ License No.:_____

List the names of all qualified remote dispensing site pharmacy technician:

TCH Name:_____ License No._____

_____
PIC Initials

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

TCH Name: _____ License No. _____

If the answer to the question above is “no” or “not applicable” go to section ~~26~~30.

☐☐☐ 29.2. The supervising pharmacy uses a telepharmacy system for the dispensing of prescription drugs and providing related drug regimen review and patient counseling services at the remote dispensing site pharmacy. (BPC ~~4031[a]~~4130, BPC 4044.7)

☐☐☐ 29.3. The remote dispensing site pharmacy is located in a medically underserved area unless otherwise approved by the board. (BPC 4130 [c])

☐☐☐ 29.4. The remote dispensing site pharmacy ~~is staffed by pharmacists or pharmacy technicians, or both, but~~ does not employ any unlicensed personnel. (BPC 4130 [d])

☐☐☐ 29.5. The supervising pharmacy has only obtained one remote dispensing site pharmacy license. (BPC 4130 [e])

☐☐☐ 29.6. The remote dispensing site pharmacy is not operated by the state and is not located in any state facility, including, but not limited to, correctional facilities, state hospitals, or developmental centers. (BPC 4130 [f])

☐☐☐ 29.7. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and will become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130 [h])

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Yes No N/A

☐☐☐ 29.8. The supervising pharmacy provides telepharmacy services for only one remote dispensing site pharmacy. (BPC 4131[a])

☐☐☐ 29.9. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131 [b])

☐☐☐ 29.10. The supervising pharmacy and the remote dispensing site pharmacy are under common ownership. (BPC 4131 [c])

☐☐☐ 29.11. The remote dispensing site pharmacy is staffed by a pharmacist, or at least one registered pharmacy technician meeting the qualifications of Section 4132 (BPC 4131[d]).

☐☐☐ 29.12. Pharmacy technicians working at a remote dispensing site pharmacy remain under the direct supervision and control of a pharmacist at the supervising pharmacy at all times that the remote dispensing site pharmacy is operational. (BPC 4131[d])

☐☐☐ 29.13. The supervising pharmacists utilizes a telepharmacy system to supervise operations through audio and visual technology from the supervising pharmacy. (BPC 4131[d])

☐☐☐ 29.14. The designated pharmacist-in-charge of the supervising pharmacy is also the pharmacist-in-charge at the remote dispensing site pharmacy. (BPC 4131[e])

☐☐☐ 29.15. The pharmacist -in-charge of the remote dispensing site pharmacy and the pharmacist-on-duty at the supervising pharmacy are responsible to ensure that both the supervising pharmacy and the remote dispensing site pharmacy are sufficiently staffed to allow for appropriate supervision, which is supervision that would not be reasonably expected to result in an unreasonable risk of harm to public health, safety, or welfare. (BPC 4131[f])

☐☐☐ 29.16. In addition to the requirements of BPC 42024204, a pharmacy technician ~~at least one pharmacy technician~~ working at the remote dispensing site pharmacy has met the qualifications promulgated by the board as required by BPC 4132. (BPC 4132[a]). The regulations developed by the board only apply to pharmacy technicians working at remote dispensing sites. BPC 4132(a)

- ☐ Possess a pharmacy technician license that is in good standing.
- ☐ Possess and maintain a certification issued by the board-approved pharmacy technician certification program.
- ☐ Possess one of the following: a minimum of an associated degree in pharmacy technology, a minimum of a bachelor's degree in any subject, or a certification of completion from a course of training specified by regulations adopted by the board pursuant to BPC 4202.
- ☐ Complete a minimum of 2,000 hours of experience working as a pharmacy technician within the two years preceding first commencing work in the remote dispensing site pharmacy.

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Yes No N/A

☐☐☐ 29.17. Registered pharmacy technicians may perform order entry, packaging, manipulative, repetitive, and other nondiscretionary tasks at the remote dispensing site pharmacy under the supervision of a pharmacist at the supervising pharmacy using a telepharmacy system. (BPC 4132[b])

☐☐☐ 29.18. Pharmacy technicians at the remote dispensing site pharmacy do not do any of the following:

- ☐ 29.18.1. Receive a new prescription order orally from a prescriber or other person authorized to prescribe by law. (BPC 4132[c][1])
- ☐ 29.18.2. Consult with a patient or ~~his or her~~ their agent regarding a prescription, either prior to or after dispensing, or regarding any medical information contained in a patient medication record system or patient chart. (BPC 4132[c][2])
- ☐ 29.18.3. Identify, evaluate, or interpret a prescription. (BPC 4132[c][3])
- ☐ 29.18.4. Interpret the clinical data in a patient medication record system or patient chart. (BPC 4132[c][4])
- ☐ 29.18.5. Consult with any prescriber, nurse, or other health care professional or authorized agent thereof. (BPC 4132[c][5])
- ☐ 29.18.6. Supervise the packaging of drugs and check the packaging procedures and product upon completion. (BPC 4132[c][6])
- ☐ 29.18.7. Perform any function that requires the professional judgment of a licensed pharmacist. (BPC 4132[c][7])
- ☐ 29.18.8. Compound drug preparations. (BPC 4132[c][8])

☐☐☐ 29.19. A pharmacist at the supervising pharmacy supervises no more than two pharmacy technicians at each remote dispensing site pharmacy. The pharmacist may also supervise pharmacy technicians at the supervising pharmacy. (BPC 4132[d])

☐☐☐ 29.20. The supervising pharmacy's telepharmacy system maintains a video and audio communication system that provides for effective communication between the supervising pharmacy and the remote dispensing site pharmacy's personnel and patients. (BPC 4133[a])

☐☐☐ 29.21. The telepharmacy system facilitates adequate pharmacist supervision and allows the appropriate exchange of visual verbal, and written communications for patient counseling and other matters involved in the lawful dispensing of drugs. (BPC 4133[b])

☐☐☐ 29.22. Patient counseling is provided using audio-visual communication prior to all prescriptions being dispensed from the remote dispensing site pharmacy. (BPC 4133[c])

☐☐☐ 29.23. The telepharmacy system is able to do all of the following:

- ☐ 29.23.1. Identify and record the pharmacy technician preparing each prescription and the supervising pharmacist who reviewed and authorized the dispensing of the prescription. (BPC 4133[d][1])

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☐ 29.23.2. Require a pharmacist to review and compare the electronic image of any new prescription presented at the remote dispensing site pharmacy with the data entry record of the prescription. (BPC 4133[d][2])

☐ 29.23.3. Require the pharmacy technician to use barcode technology to verify the accuracy of the drug to be dispensed. (BPC 4133[d][3])

☐ 29.23.4. Require remote visual confirmation by a pharmacist at the supervising pharmacy of the drug stock bottle and the drug to be dispensed prior to dispensing. (BPC 4133[d][4])

☐ 29.23.5. Ensure that a prescription is not sold or delivered to a patient prior to a pharmacist performing final verification of the accuracy of the prescription and releasing the prescription for sale and delivery. (BPC 4133[d][5])

Yes No N/A

☐☐☐ 29.24. The video and audio communication system used to counsel and interact with each patient or patient's caregiver shall be secure and compliant with the federal Health Insurance Portability and Accountability Act. (Public Law 104-191). (BPC 4133[e])

☐☐☐ 29.25. All records of prescriptions dispensed including the records of the actions performed through the telepharmacy system shall be maintained at the remote dispensing site pharmacy and shall be maintained for three years after the filling of the prescription. (BPC 4133[f])

☐☐☐ 29.26. A pharmacist from the supervising pharmacy completes a monthly in-person, self-inspection of each remote dispensing site pharmacy using the form designated by the board and retains all inspection reports. (BPC 4134[a])

☐☐☐ 29.27. A perpetual inventory is kept for all controlled substances stored at the remote dispensing site pharmacy. (BPC 4134[b])

☐☐☐ 29.28. All controlled substances stored at the remote dispensing site pharmacy are stored in a secure cabinet or safe that is locked. (BPC 4134[c])

☐☐☐ 29.29. A pharmacist from the supervising pharmacy performs inventory and inventory reconciliation functions at the remote dispensing site pharmacy to detect and prevent the loss of any controlled substances. (BPC 4134[d])

☐☐☐ 29.30. The pharmacist-in-charge of the remote dispensing site pharmacy reviews all inventory and inventory reconciliation reports taken and establishes and maintains secure methods to prevent losses of any controlled substances. (BPC 4134[e])

☐☐☐ 29.31. A pharmacist from the supervising pharmacy compiles an inventory reconciliation report of all Schedule II controlled substances at the remote dispensing site pharmacy at least once every three months. This compilation shall include the following:

☐ 29.31.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (BPC 4134[f][1])

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☐ 29.31.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (BPC 4134[f][2])

☐ 29.31.3. A comparison of the two above-mentioned items to determine if there are any variances; (BPC 4134[f][3])

☐ 29.31.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; ~~and~~ (BPC 4134[f][4])

Yes No N/A

☐☐☐ 29.32. The remote dispensing site pharmacy reports in writing, any identified losses of controlled substances and possible causes of losses to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the remote dispensing site pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (BPC 4134[g])

☐☐☐ 29.33. Possible causes of overages are identified in writing and incorporated into the inventory reconciliation report. (BPC 4134[h])

☐☐☐ 29.34. The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge of the remote dispensing site pharmacy, and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (BPC 4134 [i])

☐☐☐ 29.35. While closed, the remote dispensing site pharmacy utilizes an alarm or other comparable monitoring system. (BPC 4135[a])

☐☐☐ 29.36. The remote dispensing site pharmacy is not open or its employees are not allowed access at times when the supervising pharmacy is closed. (BPC 4135[b])

☐☐☐ 29.37. The remote dispensing site pharmacy's security system tracks entries into the remote dispensing site pharmacy and the pharmacist-in-charge periodically review the record of entries. (BPC 4135[b])

☐☐☐ 29.38. Pharmacy services are not provided at the remote dispensing site pharmacy if the telepharmacy system is unavailable. (BPC 4135[b])

☐☐☐ 29.39. The remote dispensing site pharmacy retains a recording of facility surveillance excluding patient communications, for a minimum of 120 days. (BPC 4135[c])

☐☐☐ 29.40. Dangerous drugs and devices and controlled substances ordered by the remote dispensing site pharmacy are signed for and received by a pharmacist or a registered pharmacy technician, who meets the qualifications of Section 4132. (BPC 4059.5[~~d~~g])

☐☐☐ 29.41. A controlled substance signed for by a pharmacy technician under this section is stored separately from existing inventory until the time the controlled substance is reviewed and countersigned by a pharmacist. (BPC 4059.5[~~d~~g])

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Yes No N/A

☐☐☐ 29.42. Any receipt and storage of a controlled substance by a pharmacy technician pursuant to this section is captured on video, and the video is accessible to the supervising pharmacy and maintained by the remote dispensing site pharmacy for 120 days. (BPC 4059.5[~~g~~g])

CORRECTIVE ACTION OR ACTION PLAN: _____

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30. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 30.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to the federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that applies to the type of program(s):

☐ Mail back envelopes or package service. (CCR 1776.2)

☐ Collection receptacles in the pharmacy. (CCR 1776.3)

☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[~~e~~f])

☐☐☐ 30.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) is not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

☐☐☐ 30.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 30.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 30.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 30.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

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Yes No N/A

☐☐☐ 30.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 30.9. The preaddressed envelope and package contains a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 30.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number: _____ Expiration Date: _____

☐☐☐ 30.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], [g])

Pharmacies with Collection Receptacles in the Pharmacy (CCR 1776.1, 1776.3)

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 30.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i])

Date the board was notified: _____

☐☐☐ 30.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 30.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported: _____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

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Yes No N/A

☐☐☐ 30.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 30.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[d])

☐☐☐ 30.19. The collection receptacle is securely fastened to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter. (CCR 1776.3[b])

☐☐☐ 30.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner~~,~~ but does not allow for an individual to reach into the receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

☐☐☐ 30.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

- ☐ 30.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle.
- ☐ 30.23.2. The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 30.23.3. The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 30.23.4. The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 30.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[d],[e],[g])

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR ~~1707.31776~~ 1776.3[h])

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PIC Initials

Yes No N/A

☐☐☐ 30.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 30.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 30.28. The pharmacy maintains records for collected unwanted drugs from consumers for three years, including the following records for each liner: (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premise. (CCR 1776.3[l])

☐☐☐ 30.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) is not to be deposited, (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 30.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 30.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 30.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs. (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

_____

☐☐☐ 30.34. Was the board notified in writing within 30 days of establishing a collection receptacle? (CCR 1776.4[b][2])

_____

PIC Initials

Yes No N/A

☐☐☐ 30.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4], [5])

☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 30.36. When the pharmacy license was renewed, did the pharmacy provide ~~the list~~ a current list of collection receptacles? (CCR 1776.4[b][6])

☐☐☐ 30.37. The skilled nursing facility places patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

☐☐☐ 30.38. Is the collection receptacle located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, have a small opening that allows deposit of drugs into the inside of the collection receptacle and directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner? (CCR 1776.4[e][f][g])

☐☐☐ 30.39. The liner certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 30.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 30.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 30.42. The rigid container is either disposable, reusable, or recyclable. The rigid container is leak resistant, have sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 30.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) cannot be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

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PIC Initials

Yes No N/A

☐☐☐ 30.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 30.45. The installation, removal, transfer, and storage of inner liners is performed only by (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 30.46. Sealed inner liners placed in a container is stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

☐☐☐ 30.47. Liners housed in a rigid container is delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

☐☐☐ 30.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 30.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

- ☐ 30.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])
- ☐ 30.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])
- ☐ 30.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])
- ☐ 30.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])
- ☐ 30.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

_____

PIC Initials

CORRECTIVE ACTION OR ACTION PLAN: _____

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31. Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

Yes No N/A

☐☐☐ 31.1. The pharmacy is a provider of blood clotting products for home use. (HSC 125286.20)

- ☐ 31.1.1. Health system pharmacy. (HSC 125286.20[j][1][B])
- ☐ 31.1.2. Pharmacy affiliated with hemophilia treatment centers. (HSC 125286.20[j][1][C])
- ☐ 31.1.3. Specialty home care pharmacy. (HSC 125286.20[j][1][D])
- ☐ 31.1.4. Retail pharmacy. (HSC 125286.20[j][1][E])

☐☐☐ 31.2. The pharmacy meets the current requirements of HSC 125286.25 including knowledge of bleeding disorders, access to providers with clinical clotting factor experience, maintaining 24 hour 7 day a week on call service with knowledgeable pharmacy staffing, ability to obtain all FDA approved brands of blood clotting products, supplying all necessary infusion equipment and supplies with each prescription, storing and shipping or delivering blood clotting products in conformity with state and federal standards (and per the product's package insert), shipping authorized nonemergency prescription blood clotting products and equipment within two business days, shipping authorized emergency prescription blood clotting products and supplies within 12 hours for patient living within 100 miles (from major metropolitan airport) and within one day if the patient lives more than 100 miles (from a major metropolitan airport), providing patients a designated contact telephone number for reporting delivery problems and responding to calls within a reasonable time period, notifying patients of Class 1 and 2 recalls and withdrawals of blood clotting products or equipment within 24 hours of receiving such notice, participating in National Patient Notification System for blood clotting recalls, providing language interpretive services and has a detailed disaster plan for the requirements of Standards of Service for Providers of Blood Clotting Products for Home Use Act or other disruptions of normal business operation.

32. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 32.1. The pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202.5, 150204, BPC 4169.5)

- ☐ 32.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (HSC 150202.5)
- ☐ 32.1.2. The pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)

☐☐☐ 32.2. If the pharmacy utilizes a surplus medication collection and distribution intermediary, the pharmacy ensures that the intermediary is licensed by the California State Board of Pharmacy. (BPC 4169.5)

_____
PIC Initials

Yes No N/A

☐☐☐ 32.3. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☐ 32.4. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])

- ☐ 32.4.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 32.4.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 32.4.3. Were returned from a health facility to which the drugs were originally issued, in a manner consistent with state and federal law, and where the drugs were centrally stored; were under the control of a health facility staff member; and that were never in the possession of a patient or individual member of the public. (H~~&~~C 150202.5[b], 150204[c][3])
- ☐ 32.4.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 32.4.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

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33. Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 33.1. The pharmacy conducts a county-approved drug repository and distribution program. (HSC 150201, 150204)

- ☐ 33.1.1. The pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and:** (HSC 150201[a][1])
  - ☐ 33.1.1.1. Is county owned (HSC 150201[b][1]) or
  - ☐ 33.1.1.2. Contracts with the county to establish a voluntary drug repository and distribution program. (HSC 150201[b][1], 150200)
- ☐ 33.1.2. The pharmacy is owned and operated by a primary care clinic licensed by the California Department of Public Health, and is not on probation with the California State Board of Pharmacy. (HSC 150201[a][2])

☐☐☐ 33.2. The pharmacy has been prohibited by the county board of supervisors, the county public health officer, or the California State Board of Pharmacy from participating in the program because it does not comply with the provisions of the program. (HSC 150204[a][5])

Issued By: _____ Date: _____

_____
PIC Initials

Yes No N/A

☐☐☐ 33.3. Date that the county health department confirmed receipt of the pharmacy's "notice of intent" to participate in the program: _____ (HSC 150204[a][3])

☐☐☐ 33.4. The pharmacy provides the county health department on a quarterly basis the name and location of all sources of donated medication it receives. (HSC 150204[a][4][A])

Date last quarterly report was submitted: _____

☐☐☐ 33.5. The pharmacy complies with the county's established written procedures. (HSC 150204[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Drugs and Maintenance of Drug Stock

Yes No N/A

☐☐☐ 33.6. Donated medications are segregated from the participating entity's other drug stock by physical means, for purposes that include inventory, accounting and inspection. (HSC 150204[j])

☐☐☐ 33.7. Records of acquisition and disposition of donated medications are kept separate from the participating entity's other drug acquisition and disposition records. (HSC 150204[k])

☐☐☐ 33.8. The participating entity follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])

☐☐☐ 33.9. Donated medications received are unused, unexpired and meet the following requirements: (HSC 150202, 150202.5, 150204[c])

- ☐ 33.9.1. Are received from authorized sources. (HSC 150202, 150203)
- ☐ 33.9.2. No controlled substances are received. (HSC 150204[c][1])
- ☐ 33.9.3. Are not adulterated, misbranded, or stored under conditions contrary to USP standards or the product manufacturer. (HSC 150204[c][2])
- ☐ 33.9.4. Medications received from a health care facility were centrally stored and under the control of a licensed health care professional or trained staff member of facility, and were never in the possession of a patient or member of the public. (HSC 150204[c][3])
- ☐ 33.9.5. Are received in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 150204[d])
- ☐ 33.9.6. Are maintained in the donated packaging until dispensed to an eligible patient under the program, who presents a valid prescription. (HSC 150204[i])
- ☐ 33.9.7. For donated medications that require refrigeration, there are specific procedures to ensure that the medications are packaged, transported, stored, and dispensed at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

_____
PIC Initials

Yes No N/A

☐☐☐ 33.10. The pharmacy exists solely to operate the repository and distribution program. (HSC 150204(i). If yes:

☐ 33.10.1. The pharmacy repackages a reasonable quantity of donated medicine in anticipation of dispensing the medicine to its patient population.

☐ 33.10.2. The pharmacy has policies and procedures in place for identifying and recalling medications.

☐ 33.10.3. Repackaged medications are repackaged with the earliest expiration date.

☐☐☐ 33.11. Donated medication received in open containers is not dispensed under the program or transferred to another participating entity; and once identified, is quarantined immediately and disposed of in accordance with the Medical Waste Management Act. (HSC 150204[d], 150204[h])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Transferring Donated Drugs From One Participating Entity to Another

Yes No N/A

☐☐☐ 33.12. The pharmacy transfers donated medications to another participating county-owned pharmacy within an adjacent county. (HSC 150204[g][4])

☐☐☐ 33.13. The pharmacy has a written agreement outlining the protocols and procedures for the transfer of donated medications. (HSC 150204[g][4][A])

Adjacent counties to which donated medications are transferred:

_____

☐☐☐ 33.14. Donated medication is not transferred by any participating entity more than once. (HSC 150204[g][4][B])

☐☐☐ 33.15. When transferring donated medications, documentation accompanies the medication that identifies the drug name, strength, quantity of medication, and the donating facility from where the medication originated. (HSC 150204[g][4][C])

☐☐☐ 33.16. When transferring donated medication, documentation includes a statement that the medication may not be transferred to another participating entity. (HSC 150204[g][4][C])

Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program: Dispensing to Eligible Patients

☐☐☐ 33.17. Donated medications that are dispensed to an eligible patient that presents a valid prescription are dispensed in a new and properly labeled container, specific to the eligible patient. (HSC 150204[i])

_____

PIC Initials

Yes No N/A

☐☐☐ 33.18. The pharmacist adheres to standard pharmacy practices, as required by state and federal law, when dispensing donated medications under this program. (HSC 150204[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

34. Emergency Medical Services Automated Drug Delivery Systems

Yes No N/A

☐☐☐ 34.1 The pharmacy restocks dangerous drugs and dangerous devices into emergency medical services automated drug delivery systems (EMSADDS) in compliance with section BPC 4119.01, BPC 4034.5

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected by _____. 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 _____ _____
(Pharmacist-in-Charge) Date

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

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 Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____
Date

_____
PIC 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 (BPC), Division 1, Chapter 1 – General Provisions
BPC, Division 2, Chapter 1 – General Provisions
BPC, Division 2, Chapter 3 – Clinical Laboratory Technology
BPC, Division 2, Chapter 9 – Pharmacy
California Code of Regulation (CCR), 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 (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
CFR, Title 21, Chapter I, Subchapter C, Part 210 – Current Good Manufacturing Practice in Manufacturing, Processing, Packaging, or Holding of Drugs; General
CFR, Title 21, Chapter I, Subchapter C, Part 211 – Current Good Manufacturing Practice for Finished Pharmaceuticals
CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice Combat Methamphetamine Epidemic Act of 2005. Pub. L. 109-177. 120 Stat. 256.9 Mar. 2006
Health and Safety Code (HSC), Division 2, Chapter 1 – Licensing Provisions
HSC, Division 10 – Uniform Controlled Substances Act
HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
HSC, Division 106, Part 5, Chapter 2 – Genetic Disease Services
HSC, Division 116 – Surplus Medication Collection and Distribution
United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)
USC, Title 21, Chapter 13 – Drug Abuse Prevention and Control

ATTACHMENT 3

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

b. Compounding Self-Assessment (17M-39)

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

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **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.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

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

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

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

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

Hours: Weekdays _____ Sat _____ Sun. _____ 24 Hours _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
7. _____ RPH # _____ Exp. Date: _____
   APH # _____ 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: _____

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PIC Initials

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. 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.

ALL COMPOUNDING Complete Sections 1 through 10.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐☐☐ 1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounding Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐☐☐ 2.1 The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐☐☐ 2.2 The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐☐☐ 2.3 The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- 2.3.1 Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- 2.3.2 Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- 2.3.3 Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- 2.3.4 The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**
- 2.3.5 Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**
- 2.3.6 Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

☐☐☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

- 2.4.1 Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

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2.4.2 Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

2.4.3 Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

Yes No N/A

☐☐☐ 2.5 The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

- 2.5.1 Active ingredients used.
- 2.5.2 Equipment to be used.
- 2.5.3 Beyond use date (BUD).
- 2.5.4 Inactive ingredients used.
- 2.5.5 Specific and essential compounding steps.
- 2.5.6 Quality reviews required at each step.
- 2.5.7 Post-compounding process or procedures, if required.
- 2.5.8 Instructions for storage and handling.

☐☐☐ 2.6 The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐☐☐ 2.7 The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐☐☐ 2.8 All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐☐☐ 2.9 Every compounded drug preparation is given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

2.9.1 For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])

- 2.9.1.1 The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
- 2.9.1.2 The chemical stability of any one ingredient in the compounded drug preparation;
- 2.9.1.3 The chemical stability of the combination of all ingredients in the compounded drug preparation,
- 2.9.1.4 for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
- 2.9.1.5 for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
- 2.9.1.6 for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
- 2.9.1.7 The pharmacist, using his or her professional judgment establishes an extended date as provided in (D), (E), and (F), if the pharmacist researched(s) by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors pharmacist analyzed included: i) the nature of the drug and its degradation mechanism, (ii) the dosage form and its components, (iii) the potential for microbial proliferation in the preparation, (iv)the container in which it is packaged, (v) the expected storage conditions,

and (vi) the intended duration of therapy. Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

2.9.2 For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])

2.9.2.1 The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,

2.9.2.2 The chemical stability of any one ingredient in the sterile compounded drug preparation,

2.9.2.3 The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

2.9.2.4 The beyond use date assigned for sterility in CCR 1751.8.

2.9.3 For sterile compounded drug preparations, extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])

2.9.3.1 Method Suitability Test,

2.9.3.2 Container Closure Integrity Test, and

2.9.3.3 Stability Studies.

2.9.4 The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

2.9.5 Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

☐☐☐ 2.10 The pharmacist performing, or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation. (CCR 1735.2[j])

☐☐☐ 2.11 Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐☐☐ 2.12 Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

2.12.1 Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

2.12.2 Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐☐☐ 3.1 The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

3.1.1 The master formula document.

3.1.2 A compounding log consisting of a single document containing all of the following:

3.1.2.1 The name and strength of the compounded drug preparation.

3.1.2.2 The date the drug preparation was compounded.

3.1.2.3 The identity of the pharmacy personnel who compounded the drug preparation.

3.1.2.4 The identity of the pharmacist reviewing the final drug preparation.

3.1.2.5 The quantity of each component used in compounding the drug preparation.

3.1.2.6 The manufacturer or supplier, expiration date and lot number of each component.

3.1.2.7 The pharmacy assigned reference or lot number for the compounded drug preparation.

3.1.2.8 The beyond use date or beyond use date and time of the final compounded drug preparation.
3.1.2.9 The final quantity or amount of drug preparation compounded.
3.1.2.10 Documentation of quality reviews and required post-compounding process and procedures.

☐☐☐ 3.2 The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐☐☐ 3.3 Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐☐☐ 3.5 The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐☐☐ 4.1 Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])
- 4.1.1 Name of the compounding pharmacy and dispensing pharmacy (if different);
- 4.1.2 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- 4.1.3 Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- 4.1.4 The beyond use date for the drug preparation;
- 4.1.5 The date compounded; and
- 4.1.6 The lot number or pharmacy reference number.

☐☐☐ 4.2 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐☐☐ 4.3 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

☐☐☐ 4.4 Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and beyond use date. (CCR 1735.4[d])

☐☐☐ 4.5 All hazardous agents bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains written policies and procedure for compounding which establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

☐☐☐ 5.2 The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐☐☐ 5.3 The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- 5.3.1 Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- 5.3.2 A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
- 5.3.3 Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- 5.3.4 Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- 5.3.5 Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
- 5.3.6 Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
- 5.3.7 Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- 5.3.8 Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- 5.3.9 Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- 5.3.10 Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- 5.3.11 Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐☐☐ 6.1 The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐☐☐ 6.2 All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐☐☐ 6.3 All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

6.3.1 Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐☐☐ 6.4 When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐☐☐ 6.5 Hazardous drug compounding is completed in an externally exhausted physically separate room with the following requirements: (CCR 1735.6[e])

6.5.1 Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when preparations are assigned a BUD of 12 hours or less or when nonsterile products are compounded; and

6.5.2 Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

6.5.3 For sterile compounding, each PEC BSC or CACI in the room shall also be externally exhausted.

6.5.3 For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted,

6.5.4 All surfaces within the room are smooth, seamless, impervious, and non-shedding.

CORRECTIVE ACTION OR ACTION PLAN:

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐☐☐ 7.1 The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

☐☐☐ 7.2 The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

☐☐☐ 7.3 Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ 8.1 The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

☐☐☐ 8.2 The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

- 8.2.1 Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])
- 8.2.2 Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- 8.2.3 Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- 8.2.4 Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- 8.2.5 Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

9. Compounding Consistent with United States Pharmacopeia – National Formulary (B&PC 4126.8)

☐☐☐ 9.1 The compounding of drug preparation is consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.

10. Duties of a Pharmacy Issuing a Compounded Drug Recall (B&PC 4126.9)

Yes No N/A

☐☐☐ 10.1 When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (B&PC 4126.9[a][1-2])

- 10.1.1 Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- 10.1.2 The recalled drug was dispensed, or is intended for use, in this state.

☐☐☐ 10.2 A recall notice issued pursuant to subdivision (a) is made as follows: (B&PC 4126.9[b][1-3])

- 10.2.1 If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.
- 10.2.2 If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.
- 10.2.3 If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐☐☐ 10.3 If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (B&PC 4126.9[c])

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COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (B&PC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 11 through 27.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

11. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐☐☐ 11.1 Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (B&PC 4123)

11.1.1 The contractual arrangement is reported to the board within 30 days of commencing that compounding.

12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ 12.1 The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

Yes No N/A

☐☐☐ 12.2 The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

12.2.1 The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

12.2.2 The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.

12.2.3 The environments within the pharmacy meet at least the following standards: (CCR 1751[b])

12.2.3.1 Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.

12.2.3.1.1Certification records must be retained in the pharmacy.

12.2.3.2 Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.

12.2.3.3 A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.

12.3.3.4 There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐☐☐ 13.1 The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- 13.1.1 In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])
- 13.1.2 Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])
- 13.1.3 The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])
- 13.1.4 A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])
- 13.1.5 The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])
  - 13.1.5.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
  - 13.1.5.2 An ISO Class 5 cleanroom.
  - 13.1.5.3 A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐☐☐ 13.2 The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

- 13.2.1 Be ventilated in a manner not interfering with laminar air flow.

Yes No N/A

☐☐☐ 13.3 Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ 14.1 In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

- 14.1.1 Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

14.1.2 Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
14.1.3 Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
14.1.4 Results of viable air and surface sampling.
14.1.5 Biannual video of smoke studies in all ISO Class 5 certified spaces.
14.1.6 Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
14.1.6.1 Controlled room temperature.
14.1.6.2 Controlled cold temperature.
14.1.6.3 Controlled freezer temperature.
14.1.7 Certification(s) of the sterile compounding environment(s).
14.1.8 Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.
14.1.9 Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).
14.1.10 Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.
14.1.11 Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

☐☐☐ 14.2 The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

☐☐☐ 14.3 The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ 15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy label each compounded sterile drug preparation with at least the following information: (CCR 1751.2[a-c])
15.1.1 The telephone number of the pharmacy.
15.1.2 Instructions for storage, handling, and administration.
15.1.3 All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

☐☐☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. CCR 1751.3[a])

16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- 16.2.1 Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- 16.2.2 Airflow considerations and pressure differential monitoring.
- 16.2.3 An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- 16.2.4 Cleaning and maintenance of ISO environments and segregated compounding areas.
- 16.2.5 Compounded sterile drug preparation stability and beyond use dating.
- 16.2.6 Compounding, filling, and labeling of sterile drug preparations.
- 16.2.7 Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- 16.2.8 Depyrogenation of glassware (if applicable)
- 16.2.9 Facility management including certification and maintenance of controlled environments and related equipment.
- 16.2.10 For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- 16.2.11 Hand hygiene and garbing.
- 16.2.12 Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- 16.2.13 Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- 16.2.14 Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- 16.2.15 Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- 16.2.16 Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.17 Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.18 Proper use of equipment and supplies.
- 16.2.19 Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- 16.2.20 Record keeping requirements.
- 16.2.21 Temperature monitoring in compounding and controlled storage areas.
- 16.2.22 The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- 16.2.23 Use of automated compounding devices (if applicable).

16.2.24 Visual inspection and other final quality checks of sterile drug preparations.

☐☐☐ 16.3 For lot compounding, the pharmacy maintains ~~a~~ written policies and procedures which include~~s~~ at least the following: (CCR 1751.3[b][1-3])
- 16.3.1 Use of master formula documents and compounding logs.
- 16.3.2 Appropriate documentation.
- 16.3.3 Appropriate sterility and potency testing.

☐☐☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.2[c][1-2])
- 16.4.1 Process validation for chosen sterilization methods.
- 16.4.2 End-product evaluation, quantitative, and qualitative testing.

☐☐☐ 16.5 All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ 17.1 No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations (CCR 1751.4[a])

☐☐☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐☐☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐☐☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])
- 17.4.1 All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- 17.4.2 Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- 17.4.3 Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- 17.4.4 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

☐☐☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])
- 17.5.1 At the beginning of each shift;
- 17.5.2 At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- 17.5.3 After each spill; and
- 17.5.4 When surface contamination is known or suspected.

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☐☐☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

17.6.1 Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.

17.6.2 Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.6.2.1 Certification records are retained for at least 3 years.

17.6.3 Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])

17.6.3.1 Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

17.6.3.2 Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

17.6.3.3 Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

17.6.4 Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

☐☐☐ 17.7 Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

17.7.1 Additionally, each PEC used to compound hazardous agents shall be externally vented.

17.7.2 The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.7.3 Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

17.7.4 During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

☐☐☐ 17.8 If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

☐☐☐ 17.9 Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

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☐☐☐ 17.10 Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CCR 1751.4[j])

17.10.1 Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and is done at least once every six months.

17.10.2 Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling.

17.10.3 Viable air sampling is performed under dynamic conditions which simulate actual production.

17.10.3 Viable surface sampling is performed under dynamic conditions of actual compounding.

17.10.5 When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation includes, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐☐☐ 17.11 The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which typically includes a room temperature of 20-24 degrees Celsius (68-75 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

CORRECTIVE ACTION OR ACTION PLAN: _____

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐☐☐ 18.1. When compounding sterile drug preparations, the following standards are met: (CCR 1751.5[a][1-6])

- 18.1.1 Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.
- 18.1.2 Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.
- 18.1.3 Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.
- 18.1.4 Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic devices.
- 18.1.5 Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn.
- 18.1.6 Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.
- 18.1.7 Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.
- 10.1.8 Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.
- 18.1.9 Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐☐☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐☐☐ 19.1 Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐☐☐ 19.2 The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])

☐☐☐ 19.3 Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐☐☐ 19.4 The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐☐☐ 19.5 The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

19.5.1 The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following: (CCR 1751.6[e][1][A-J])

19.5.1.1 Aseptic technique.
19.5.1.2 Pharmaceutical calculations and terminology.
19.5.1.3 Sterile preparation compounding documentation.
19.5.1.4 Quality assurance procedures.
19.5.1.5 Aseptic preparation procedures.
19.5.1.6 Proper hand hygiene, gowning and gloving technique.
19.5.1.7 General conduct in the controlled area (aseptic area practices).
19.5.1.8 Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
19.5.1.9 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
19.5.1.10 Container, equipment, and closure system selection.

19.5.2 Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. (CCR 1751.6[e][2])

19.5.2.1 Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.
19.5.2.2 Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
19.5.2.3 Each person's proficiency and continuing training needs must be reassessed at least every 12 months.
19.5.2.3 Results of these assessments must be documented and retained in the pharmacy for three years.

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ 20.1 There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

20.1.1 The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])

20.1.1.1 Procedures for cleaning and sanitization of the sterile preparation area.

20.1.1.2 Actions to be taken in the event of a drug recall.

20.1.1.3 Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

☐☐☐ 20.2.1 The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

20.2.2 Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])

20.2.3 The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])

20.2.3.1 The quality assurance program yields an unacceptable result.

20.2.3.2 There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

20.2.4 The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

☐☐☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])

☐☐☐ 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])

☐☐☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

20.5.1 The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B)

20.5.1.1 Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

20.5.1.2 Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐☐☐ 21.1 Every sterile compounded drug preparation is given and labeled with a beyond use date incompliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations:

☐☐☐ 21.2 The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- 21.2.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; **and**
- 21.2.2 The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; **and**
- 21.2.3 Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

☐☐☐ 21.3 The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

- 21.3.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
- 21.3.2 The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- 21.3.3 The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐☐☐ 21.4 The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile

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ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])

21.4.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

☐☐☐ 21.5 The beyond use date states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])

21.5.1 The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

21.5.2 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

21.5.3 The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

☐☐☐ 21.6 Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

21.6.1 Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

21.6.2 If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.

21.6.3 "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.

21.6.4 Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

☐☐☐ 21.7 The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐☐☐ 22.1 Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐☐☐ 22.2 Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

22.2.1 When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.

22.2.2 When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

22.2.3 If the puncture time is not noted on the container, the container is immediately discarded.

☐☐☐ 22.3 Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty-eight (28) days from initial opening or puncture. (CCR 1751.9[c])

22.3.1 Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance.

22.3.2 If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded.

23. Sterile Compounding Reference Materials (CCR 1751.10)

☐☐☐ 23.1 The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

24. Sterile Compounding License Renewal (B&PC 4127.1, 4127.15, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (B&PC 4127.1, 4127.15 4127.2)

Yes No N/A

☐☐☐ 24.1 The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐☐☐ 24.2 The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐☐☐ 24.3 The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.4 The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.5 The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐☐☐ 24.6 A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (B&PC 4127.2[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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25. Hospital Satellite Compounding Pharmacy (B&PC 4127.15)

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☐☐☐ 25.1 A hospital satellite compounding pharmacy compounds sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

25.2 The services provided shall be directly related to the services or treatment plan administered in the physical plant.

26. Nonresident Pharmacy (B&PC 4127.2)

☐☐☐ 26.1 Pharmacy notifying the board within 10 days of the suspension of any accreditation held by the pharmacy.

26.2 Pharmacy provides to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

26.3 Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (B&PC 4127.9)

Yes No N/A

☐☐☐ 27.1 The pharmacy contacts the recipient pharmacy, prescriber or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (B&PC 4127.9[a] B&PC 4127.1 and 4127.2)

☐☐☐ 27.2 A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (B&PC 4127.9[b][1])

Yes No N/A

☐☐☐ 27.3 A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (B&PC 4127.9[b][2])

☐☐☐ 27.4 A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (B&PC 4127.9[b][3])

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PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. 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 I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

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 could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ Date _____

_____
PIC Initials

ATTACHMENT 3

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

c. Hospital Pharmacy Self-Assessment (17M-14)

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

HOSPITAL PHARMACY SELF-ASSESSMENT

Title 16 of the California Code of Regulations section 1715 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **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. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety. It may be completed online, printed, signed, and readily available in the pharmacy. Signatures and initials shall be an original handwritten signature or initial in ink on the self-assessment form. Scanned copies of original signatures and initials may be maintained as file copy for the pharmacy. Do not copy a previous assessment.

Notes: If dispensing prescriptions for outpatient use, a Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (17M-13, Rev. ~~03/19~~1/2021) must be completed also. A hospital that compounds drug products must also complete the Compounding Self-Assessment (17M-39 Rev. 02/12).

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

Pharmacy Name: _____

Address: _____ Phone: _____

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

License #: _____ Exp. Date: _____ Other License #: _____ Exp. Date: _____

Licensed Sterile Compounding License #_____ Expiration: _____

~~Accredited by (optional): _____ From: _____ To: _____~~

Centralized Hospital Packaging#: _____ Exp. Date: _____

DEA Registration #: _____ Exp. Date: _____ Date of DEA Inventory: _____

Hours: *Weekdays* _____ *Sat.* _____ *Sun.* _____ *24 Hours* _____

PIC: _____ RPH # _____ Exp. Date: _____

Website address (if any): _____

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PIC Initials

Pharmacy staff (pharmacists, interns, technicians):
APH=Advanced Practice Pharmacist, DEA =Drug Enforcement Administration.

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. _____	RPH # _____	Exp. Date: _____
	APH # _____ _	Exp. Date: _____
	DEA # _____	Exp. Date: _____
9. _____	INT # _____	Exp. Date: _____
10. _____	INT # _____	Exp. Date: _____
11. _____	INT # _____	Exp. Date: _____
12. _____	INT # _____	Exp. Date: _____
13. _____	TCH # _____	Exp. Date: _____
14. _____	TCH # _____	Exp. Date: _____
15. _____	TCH # _____	Exp. Date: _____
16. _____	TCH # _____	Exp. Date: _____

HOSPITAL PHARMACY SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are Title 16 unless otherwise noted.

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

1. Pharmacy

Yes No N/A

☐☐☐ 1.1. The pharmacy is secure and has provisions for effective control against the theft of dangerous drugs and devices. (BPC 4116, 4117, CCR 1714)

☐☐☐ 1.2. The pharmacy has procedures in place to take action to protect the public when a licensed individual employed by or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the profession or occupation authorized by his or her license, or is discovered or known to have engaged in the theft, diversion, or self-use of dangerous drugs. (BPC 4104[a])

☐☐☐ 1.3. The pharmacy has written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individual employed by or with the pharmacy. (BPC 4104[b])

☐☐☐ 1.4. The pharmacy reports to the board within 14 days of the receipt or development of the following information with regard to any licensed individual employed by or with the pharmacy: (1) any admission by a licensed individual of chemical, mental, or physical impairment affecting his or her ability to practice; (2) Any admission by a licensed individual of theft, diversion, or self-use of dangerous drugs; (3) Any video or documentary evidence demonstrating chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (4) Any video or documentary evidence demonstrating theft, diversion, or self-use of dangerous drugs by a licensed individual; (5) Any termination based on chemical, mental, or physical impairment of a licensed individual to the extent it affects his or her ability to practice; (6) Any termination of a licensed individual based on theft, diversion, or self-use of dangerous drugs. (BPC 4104[c])

☐☐☐ 1.5. The pharmacy maintains a supply of ~~"night stock"~~ medications which are accessible without entering the pharmacy during hours when the pharmacy is closed, and the pharmacist is not available. Access is limited to designated registered nurses. (22 CCR 70263[n])

☐☐☐ 1.6. The pharmacy is of sufficient size and has an unobstructed area to accommodate the safe practice of pharmacy. (CCR 1714)

☐☐☐ 1.7. The pharmacy premises**,** fixtures**,** and equipment are maintained in a clean and orderly condition. (CCR 1714)

☐☐☐ 1.8. The pharmacy sink has hot and cold running water. (CCR 1714)

☐☐☐ 1.9. The pharmacy has a readily accessible restroom. (CCR 1714)

Yes No N/A

☐☐☐ 1.10. The original board-issued pharmacy license and the current renewal are posted where they may be clearly read by the purchasing public. (BPC 4032, 4058)

☐☐☐ 1.11. Pharmacists, interns, pharmacy technicians, and pharmacy technician trainees wear name tags, in 18-point type, that contain their name and license status. (BPC 680, BPC 4115.5[e], CCR 1793.7[c])

☐☐☐ 1.12. Does the pharmacy compound sterile drugs?
(If yes, complete the current Compounding Self-Assessment Form 17M-39~~, Rev. 10/12~~12/16~~~~)

☐☐☐ 1.13. The pharmacy is subscribed to the board's e-mail notifications. (BPC 4013)
Date Last Notification Received: _____

E-mail address registered with the board: _____

☐☐☐ 1.14. For a pharmacy whose owner owns two or more pharmacies, the pharmacy receives the board's e-mail notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

E-mail address registered with the board:_____

CORRECTIVE ACTION OR ACTION PLAN: _____

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2. Nursing Stations

Yes No N/A

☐☐☐ 2.1. Adequate space is available at ward or nursing station for the storage of drugs and preparation of medication doses. All such spaces and areas can be locked and are accessible to authorized personnel only. (22 CCR 70269)

☐☐☐ 2.2. The pharmacist, intern pharmacist, or pharmacy technician completes the monthly inspections of all floor stock and drugs maintained in nursing stations. Any irregularities are reported to the director of nursing services, and as required by hospital policy. (BPC 4119.7[c], 4115[i~~-j~~], 22 CCR 70263[q][10])

☐ 2.2.1. An intern pharmacist shall report any irregularities to the pharmacist. (BPC 4119.7[c])

☐ 2.2.2. A pharmacy technician shall report any irregularities to the pharmacist-in-charge and to the director of the health care facility within 24 hours. (BPC 4115[i][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Delivery of Drugs

Yes No N/A

☐☐☐ 3.1. Delivery to the pharmacy of dangerous drugs and dangerous devices are only delivered to the licensed premise and signed for and received by a pharmacist. (BPC 4059.5[a])

☐☐☐ 3.2. Deliveries to a hospital pharmacy may be made to a central receiving location within the hospital. However, the dangerous drugs or dangerous devices shall be delivered to the licensed pharmacy premise within one working day following receipt by the hospital, and the pharmacist on duty at that time shall immediately inventory the drugs or devices. (BPC 4059.5[c])

☐☐☐ 3.3. A pharmacy may take delivery of dangerous drugs and dangerous devices when the pharmacy is closed and no pharmacist is on duty if all of the following requirements are met (BPC 4059.5[f]):

- ☐ 3.3.1. The drugs are placed in a secure storage facility in the same building as the pharmacy (BPC 4059.5[f][1]);
- ☐ 3.3.2. Only the pharmacist-in-charge or a pharmacist designated by the pharmacist-in-charge has access to the secure storage facility after dangerous drugs or dangerous devices have been delivered (BPC 4059.5[f][2]);
- ☐ 3.3.3. The secure storage facility has a means of indicating whether it has been entered after dangerous drugs or dangerous devices have been delivered (BPC 4059.5[f][3]);
- ☐ 3.3.4. The pharmacy maintains written policies and procedures for the delivery of dangerous drugs and dangerous devices to a secure storage facility (BPC 4059.5[f][4]); and
- ☐ 3.3.5. The agent delivering dangerous drugs and dangerous devices pursuant to this subdivision leaves documents indicating the name and amount of each dangerous drug or dangerous device delivered in the secure storage facility. The pharmacy shall be responsible for the dangerous drugs and dangerous devices delivered to the secure storage facility. The pharmacy shall also be responsible for obtaining and maintaining records relating to the delivery of dangerous drugs and dangerous devices to a secure storage facility. (BPC 4059.5[f][5])

☐☐☐ 3.4. Prior to, or at the time of, accepting ownership of a product included in the Drug Supply Chain Security Act from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1[d][1][A][i])

☐☐☐ 3.5. Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. Note: This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])

☐☐☐ 3.6. The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])

☐☐☐ 3.7. The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023 unit-level traceability. (21 USC 360eee-1[g]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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4. Drug Stock

Yes No N/A

☐☐☐ 4.1. The drug stock is clean, orderly, properly stored, properly labeled and in-date. (BPC 4342, HSC 111255, 111335, CCR 1714 (b), 22 CCR 70263[q], 21 USC sections 331, 351, 352)

☐☐☐ 4.2. All ward/floor drug stock and drug supplies that are maintained for access when the pharmacist is not available are properly labeled and stored. Records of drugs taken from the drug stock or drug supplies must be maintained and the pharmacist must be notified. (22 CCR 70263[n])

☐☐☐ 4.3. Preferentially priced drugs are furnished solely or predominately to inpatients in accordance with provisions of the Nonprofit Institutions Act (15 USC 13c). Such drugs also may be dispensed pursuant to prescriptions for inpatients at the time of discharge, for employees of the hospital, ~~or on an emergency basis for~~ to a walk-in customer (provided that sales to walk-ins do not exceed one percent of the pharmacy's total prescription sales) or to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need. (BPC 4380, CCR 1710[a])

☐☐☐ 4.4. All unit-dose drugs received from a centralized hospital packaging pharmacy are correctly labeled, are barcoded, and the barcode is readable at the patient's bedside. (BPC 4128.4, 4128.5)

☐☐☐ 4.5. All drugs are maintained in accordance with national standards regarding the storage area and refrigerator or freezer temperature and manufacturer's guidelines. (BPC 4119.7[b]

☐☐☐ 4.6. Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices: (BPC 4059.5, 4169)

- ☐ 4.6.1. Are not known or reasonably should not be known to the pharmacy as being adulterated.
- ☐ 4.6.2. Are not known or reasonably should not be known to the pharmacy as being misbranded.
- ☐ 4.6.3. Are not expired.

☐☐☐ 4.7. If the pharmacy reasonably has cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge. (BPC 4107.5)

☐☐☐ 4.8. The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person. (BPC 4163)

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Pharmacies That Donate Drugs to a Voluntary County-Approved Drug Repository and Distribution Program

Yes No N/A

☐☐☐ 5.1. The hospital pharmacy donates medications to a county-approved drug repository and distribution program, and meets the following requirements: (HSC 150202, 150202.5, 150204)

- ☐ 5.1.1. The hospital pharmacy is licensed by and is not on probation with the California State Board of Pharmacy, **and** (HSC 150202.5)
- ☐ 5.1.2. The hospital pharmacy's primary or sole type of pharmacy practice is limited to skilled nursing facility, home health care, board and care, or mail order. (HSC 150202.5)

☐☐☐ 5.2. No controlled substances shall be donated. (HSC 150204[c][1])

☐☐☐ 5.3. Drugs that are donated are unused, unexpired and meet the following requirements: (HSC 150202.5, 150204[c])

- ☐ 5.3.1. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer. (HSC 150204[c][2])
- ☐ 5.3.2. Were received directly from a manufacturer or wholesaler. (HSC 150202.5[a])
- ☐ 5.3.3. Were centrally stored and under the control of a health facility staff member, and were never in the possession of a patient or individual member of the public. (HSC 150202.5[b], 150204[c][3])
- ☐ 5.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed. (HSC 105204[d])
- ☐ 5.3.5. For donated medications that require refrigeration, are medications that are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150204[m])

☐☐☐ 5.4. The hospital pharmacy follows the same procedural drug pedigree requirements for donated drugs as it does for drugs purchased from a wholesaler or directly from a drug manufacturer. (HSC 150204[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Pharmacist-in-Charge (PIC)

Yes No N/A

☐☐☐ 6.1. The pharmacy has a PIC who is responsible for the daily operation of the pharmacy. (BPC 4101, 4113, 4305, 4330, CCR 1709, 1709.1)

☐☐☐ 6.2. The PIC has adequate authority to assure the pharmacy's compliance with laws governing the operation of a pharmacy (CCR 1709.1[b])

☐☐☐ 6.3. Is the PIC in charge of another pharmacy?

If yes, the pharmacies are within 50 driving distance miles of each other. (CCR 1709.1[c])

If yes, name of other pharmacy _____

Yes No N/A

☐☐☐ 6.4. Any change of PIC is reported by the pharmacy and the departing PIC to the board in writing within 30 days. (BPC 4101, 4330)

☐☐☐ 6.5. The PIC is not concurrently serving as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailer. (CCR 1709.1[d])

CORRECTIVE ACTION OR ACTION PLAN: _____

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7. Duties of a Pharmacist

Yes No N/A

☐☐☐ 7.1. Only a pharmacist: (BPC 4019, BPC 4051, BPC 4052, BPC 4052.2, CCR 1717[c], CCR 1793.1, CCR 1793.7)

- ☐ 7.1.1. ~~The pharmacist r~~ Receives a chart order for an inpatient; (BPC 4019, BPC 4051 [b], BPC 4052, BPC 4052.2, CCR 1717, CCR 1793.1[a])
- ☐ 7.1.2. Identifies, evaluates and interprets the chart order; (CCR 1717[c], CCR 1793.1[c])
- ☐ 7.1.3. Reviews patient's drug regimen and interprets the clinical data in the patient's medication record; (BPC 4052.1[a][4], BPC 4052.2[a][4], CCR 1793.1[d])
- ☐ 7.1.4. Consults with any prescriber, nurse or health care professional; (CCR 1793.1[e])
- ☐ 7.1.5. Calculates drug doses; (BPC 4052 [a][3], BPC 4052.2 [a][3], BPC 4052.2 [a][4])
- ☐ 7.1.6. Supervises the packaging of drugs and checks the packaging procedures and products upon completion; (CCR 1793.1[f])
- ☐ 7.1.7. Is responsible for all activities of pharmacy technicians, interns and clerks related to the furnishing of drugs to ensure that all such activities are performed completely, safely and without risk of harm to patients; (CCR 1793.7[e])
- ☐ 7.1.8. Performs any other duty which federal or state law or regulation authorizes only a registered pharmacist to perform; and performs all functions which require professional judgment. (BPC 4052, BPC 4052.2, CCR 1793.1[g])

☐☐☐ 7.2 Pharmacists in a licensed health care facility who are performing the following functions are doing so in accordance with the hospital's policies, procedures and protocols which have been developed by health professionals including physicians, pharmacists, and registered nurses, with the concurrence of the facility administrator: (BPC 4027, 4051, 4052, 4052.1, 4052.2)

- ☐ 7.2.1. Ordering or performing routine drug therapy-related patient assessment procedures; (BPC 4052.1[a][1]; 4052.2[a][1])
- ☐ 7.2.2. Ordering drug therapy-related laboratory tests; administering drugs or biologicals by injection; (BPC 4052[a][3], 4052.1[a][2], [3]; 4052.2[a][2], [3])
- ☐ 7.2.3. Initiating or adjusting the drug regimen of a patient; (BPC 4052.1[a][4], BPC 4052.2[a][4])
- ☐ 7.2.4. Performing moderate or waived laboratory tests. (Prior to performing any of these functions, the pharmacist must have either (1) successfully completed clinical residency

training, or (2) demonstrated clinical experience in direct patient care delivery as specified in BPC section 4052.2[d]. (BPC 4052.4)

Yes No N/A

☐☐☐ 7.3. The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration. (BPC 4052[b])

☐☐☐ 7.4. All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. (HSC 11165.1)

☐☐☐ 7.5. All pharmacists have joined the board's email notification list. (BPC 4013)

☐☐☐ 7.6 The hospital pharmacist (or pharmacy technician or an intern pharmacist if both requirements of BPC 4118.5 (b) 1 and 2 are met) shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patients if the hospital has more than 100 beds, the accurate medication profile is acquired during hospital pharmacy's hours of operation. (BPC 4118.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Duties of an Advanced Practice Pharmacist

Yes No N/A

☐☐☐ 8.1 The advanced practice pharmacist has received an advanced practice pharmacist license from the board and may do the following: (BPC 4016.5, 4210)

- ☐ 8.1.1 Perform patient assessments, order and interpret drug therapy-related tests, and refer patients to other health care providers; (BPC 4052.6[a])
- ☐ 8.1.2 Participate in the evaluation and management of diseases and health conditions in collaboration with other health care providers; (BPC 4052.6[a])
- ☐ 8.1.3 Initiate drug therapy and promptly transmit written notification to, or enter the appropriate information into a patient record system shared with the patient's primary care provider or diagnosing provider; (BPC 4052.6[b])
- ☐ 8.1.4 Adjust or discontinue drug therapy and promptly transmit written notification to the patient's diagnosing prescriber or enters the appropriate information in a patient's record system shared with the prescriber; (BPC 4052.6[b])
- ☐ 8.1.5 Prior to initiating or adjusting a controlled substance therapy, the advance practice pharmacist is personally registered with the federal Drug Enforcement Administration; (BPC 4052.6[d])
- ☐ 8.1.6 Ordering of tests is done in coordination with the patient's primary care provider or diagnosing prescriber, including promptly transmitting written notification to the prescriber or entering information in a patient record system shared with the prescriber. (BPC 4052.6[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Duties of an Intern Pharmacist

Yes No N/A

☐☐☐ 9.1. Intern pharmacists are performing all the functions of a pharmacist only under the direct supervision of a pharmacist, and the pharmacist is supervising no more than **two interns** at any one time. (BPC 4023.5, 4030, 4114, 4119.6, 4119.7, CCR 1726)

- ☐ 9.1.1 Stock, replenish and inspect the emergency pharmaceutical supply container and the emergency medical system supplies. (BPC 4119.6)
- ☐ 9.1.2. Inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐☐☐ 9.2. All prescriptions filled or refilled by an intern are initialed or documented by secure computer entry by a pharmacist prior to dispensing. (CCR 1712[a], 1717[b][1])

☐☐☐ 9.3. During a temporary absence of a pharmacist for a meal period or duty free break, an intern pharmacist does not perform any discretionary duties or act as a pharmacist. (CCR 1714.1[d])

☐☐☐ 9.4. The intern hours affidavits are signed by the pharmacist under whom the experience was earned~~,~~ or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience, when applicable. (BPC 4209[b], [c], [d]; CCR 1726)

☐☐☐ 9.5. All intern pharmacists have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Duties of a Pharmacy Technician

Yes No N/A

☐☐☐ 10.1. Registered pharmacy technicians are performing packaging, manipulative, repetitive, or other nondiscretionary tasks related to the furnishing of drugs, while assisting and under the direct supervision and control of a pharmacist. The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision. (BPC 4023.5, 4038, 4115, CCR 1793.2, CCR 1793.7)

☐☐☐ 10.2. The ratio is no less than one pharmacist to two technicians. (BPC 4115[f], CCR 1793.7[f])

☐☐☐ 10.3. When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[f], CCR 1793.7[f])

☐☐☐ 10.4. Any function performed by a technician in connection with the dispensing of a prescription or chart order, including repackaging from bulk and storage of pharmaceuticals is verified and

documented in writing by a pharmacist or documented by a pharmacist using secure computer entry. (CCR 1712, 1793.7)

Yes No N/A

☐☐☐ 10.5. A pharmacy technician or pharmacy technician trainee wears identification, in 18-point type that identifies himself or herself as a pharmacy technician or pharmacy technician trainee. (BPC 680, BPC 4115.5[e], CCR 1793.7[d])

☐☐☐ 10.6. The pharmacy has a job description for the pharmacy technician and written policies and procedures to ensure compliance with the technician requirements. (CCR 1793.7)

☐☐☐ 10.7. During a temporary absence of a pharmacist for a meal period or duty free break, a pharmacy technician may, at the discretion of the pharmacist, remain in the pharmacy but may only perform nondiscretionary tasks. Any task performed by the pharmacy technician during the pharmacist's temporary absence is reviewed by the pharmacist. (BPC 4115[g], CCR 1714.1[c])

☐☐☐ 10.8. The general acute-care hospital has an ongoing clinical pharmacy program and allows specially trained pharmacy technicians to check the work of other pharmacy technicians when the following conditions are met: (CCR 1793.8)

- ☐ 10.8.1. Pharmacists are deployed to the inpatient care setting to provide clinical services.
- ☐ 10.8.2. Compounded or repackaged products are previously checked by a pharmacist, then used by the technician to fill unit dose distribution and floor and ward stock.
- ☐ 10.8.3. The overall operations are the responsibility of the pharmacist-in-charge.
- ☐ 10.8.4. The pharmacy technician checking technician program is under the direct supervision of the Pharmacist as specified in the policies and procedures.
- ☐ 10.8.5. There is an ongoing evaluation of the program that uses specialized and advanced trained pharmacy technicians to check the work of other pharmacy technicians.

☐☐☐ 10.9. Pharmacy technician duties include the following:

- ☐ 10.9.1. Package emergency supplies for use in the health care facility and the hospital's emergency medical system. (BPC 4119, 4115[i])
- ☐ 10.9.2. Seal emergency containers for use in the health care facility. (BPC 4115[i])
- ☐ 10.9.3. Perform monthly checks of the drug supplies stored throughout the health care facility and report any irregularities within 24 hours to the pharmacist-in-charge and to the director or chief executive officer. (BPC 4115[i])

☐☐☐ 10.10. All pharmacy technicians have joined the board's email notification list. (BPC 4013)

CORRECTIVE ACTION OR ACTION PLAN: _____

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11. Duties of Non-Licensed Personnel

Yes No N/A

☐☐☐ 11.1. A non-licensed person (clerk/typist) is permitted to type a prescription label or otherwise enter prescription information into a computer record system, and at the direction of a pharmacist, may request and receive refill authorization. (BPC 4007, CCR 1793.3)

☐☐☐ 11.2. The number of non-licensed personnel supervised by each pharmacist does not interfere with the effective performance of the pharmacist's responsibilities under the Pharmacy Law. (CCR 1793.3[b])

CORRECTIVE ACTION OR ACTION PLAN: _____

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PHARMACY PRACTICE

12. Pharmaceutical Service Requirements

Yes No N/A

☐☐☐ 12.1. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas in written policies and procedures:

- ☐ 12.1.1. Basic information concerning investigational drugs and adverse drug reactions;
- ☐ 12.1.2. Repackaging and compounding records;
- ☐ 12.1.3. Physician orders;
- ☐ 12.1.4. Wards, nursing stations and night stock medications;
- ☐ 12.1.5. Drugs brought into the facility by patients for storage or use;
- ☐ 12.1.6. Bedside medications;
- ☐ 12.1.7. Emergency drug supply;
- ☐ 12.1.8. Pass medications;
- ☐ 12.1.9. Inspection of ward stock, nursing stations and night lockers no less frequently than every 30-days\\Outdated drugs;
- ☐ 12.1.10. Routine distribution of inpatient medications;
- ☐ 12.1.11. Preparation, labeling and distribution of IV admixtures and cytotoxic agents;
- ☐ 12.1.12. Handling of medication when pharmacist not on duty; and
- ☐ 12.1.13. Use of electronic image and data order transmissions.

☐☐☐ 12.2. The pharmacy complies with the requirements of 22 CCR 70263, addressing the following areas:

- ☐ 12.2.1. Destruction of controlled substances; and
- ☐ 12.2.2. Development and maintenance of the hospital's formulary. (22 CCR 70263, ~~CCR 1751, CCR 1751.8~~)

CORRECTIVE ACTION OR ACTION PLAN: _____

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13. Medication/Chart Order

Yes No N/A

☐☐☐ 13.1. The pharmacy receives the original, the electronic transmission, or a copy of the medication order. Faxed copies, tele-autograph copies, or transmissions between computers are permissible. (BPC 4019, 4040, CCR 1717.4)

☐☐☐ 13.2. The chart or medical record of the patient contains all of the information required by BPC 4040 and the chart order is signed by the practitioner authorized by law to prescribe drugs if present or, if not present, within a specified time frame not exceeding 48 hours. (BPC 4019, 4040, 22 CCR 70263[g])

☐☐☐ 13.3. A copy of the chart order is maintained on the premises for three years. (BPC 4081, 4105, 4333)

☐☐☐ 13.4. The pharmacy furnishes dangerous drugs or dangerous devices pursuant to preprinted or electronic standing orders, order sets and protocols established under policies and procedures. (BPC 4119.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Labeling and Distribution

Yes No N/A

☐☐☐ 14.1. Unit dose medication are properly labeled and include the information as required by BPC 4076, or the information is otherwise readily available at the time of drug administration. (BPC 4076[b])

☐☐☐ 14.2. The pharmacist is responsible for the proper labeling, storage and distribution of investigational drugs pursuant to the written order of the investigator. (22 CCR 70263[o]).

☐☐☐ 14.3. This pharmacy furnishes dangerous drugs in compliance with BPC 4126.5 only to a patient pursuant to a prescription, a wholesaler from whom the dangerous drugs were purchased, a manufacturer from whom the drugs were purchased, a licensed wholesaler acting as a reverse distributor, another pharmacy to alleviate a temporary shortage with a quantity sufficient to alleviate the temporary shortage, a health care provider authorized to receive drugs, to another pharmacy of common ownership, or to a patient or to another pharmacy pursuant to a prescription. (BPC 4126.5)

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Duration of Drug Therapy

Yes No N/A

☐☐☐ 15.1. The hospital has policies limiting the duration of drug therapy in the absence of the prescriber's specific indication of duration of drug therapy or under other circumstances recommended by the pharmacy and therapeutics committee or its equivalent and approved by the executive committee of the medical staff. Limitations are established for classes of drugs and/or individual drug entities. (22 CCR 70263[j])

CORRECTIVE ACTION OR ACTION PLAN: _____

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16. Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

Yes No N/A

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

☐☐☐ 16.2. Patient medical information, all prescriptions (chart orders, patient discharge and employee prescriptions) are confidential and are not disclosed unless authorized by law. (BPC 4040, CCR 1764, Civil Code 56 et seq.)

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

☐☐☐ 16.4. The pharmacy ensures electronically transmitted prescriptions (chart orders, discharge patient or employee prescriptions) are received, maintained and transmitted in a secure and confidential manner. (CCR 1717.4)

☐☐☐ 16.5. Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within three business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (BPC 4105, CCR 1707)

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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17. Quality Assurance and Medication Errors

Yes No N/A

☐☐☐ 17.1. Pharmacy has established quality assurance program that documents medication errors attributable, in whole or in part, to the pharmacy or its personnel. (BPC 4125, CCR 1711)

☐☐☐ 17.2. Pharmacy quality assurance policies and procedures are maintained in the pharmacy and are immediately retrievable. (CCR 1711[c])

☐☐☐ 17.3. 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 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])

☐☐☐ 17.4. 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])

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

☐☐☐ 17.6. The record for quality assurance review for a medication error contains: (CCR 1711[e]);

- ☐ 17.6.1. Date, location, and participants in the quality assurance review;
- ☐ 17.6.2. Pertinent data and other information related to the medication error(s) reviewed;
- ☐ 17.6.3. Findings and determinations;
- ☐ 17.6.4. Recommended changes to pharmacy policy, procedure, systems or processes, if any.

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

☐☐☐ 17.8. 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: _____

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18. Record Keeping Requirements

Yes No N/A

☐☐☐ 18.1. All completed pharmacy self-assessments are on file in the pharmacy and are maintained for three years. (CCR 1715)

☐☐☐ 18.2. All drug acquisition and disposition records (complete accountability) are maintained for at least three years. Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. These records include:

- ☐ 18.2.1. Prescription records (BPC 4081[a])

☐ 18.2.2. Purchase Invoices and sales records for all prescription drugs (BPC 4081~~[b]~~)

☐ 18.2.3. Biennial controlled substances inventory (21 CFR 1304.11)

☐ 18.2.4. U.S. Official Order Forms (DEA Form~~-~~ 222) (21 CFR 1305.13, 21 CFR 1305.22)

☐ 18.2.5. Power of Attorney for completion of DEA 222 forms (21 CFR 1305.~~07~~ 05)

☐ 18.2.6. Theft and Loss Reports (DEA Form 106) (21 CFR 1301.74[c])

☐ 18.2.7. Record documenting return of drugs to wholesaler or manufacturer (BPC 4081)

☐ 18.2.8. Record documenting transfers or sales to other pharmacies, prescribers, and reverse distributors. (BPC 4059, 4081, 4105, 4332, CCR 1718)

☐ 18.2.9. Centrally stored unused medications donated to a drug repository and distribution program. (HSC 150200, 150202[a][1]), 150204[k], BPC 4105[c].

Yes No N/A

☐☐☐ 18.3. Transfers or sales to other pharmacies and prescribers do not exceed five percent of the pharmacy's total annual purchases of dangerous drugs or devices. If more than five percent, registration with the board as a wholesaler has been obtained. (21 CFR 1307.11, Drug Supply Chain Security Act (DSCSA), BPC 4160)

☐☐☐ 18.4. If sales or distributions of controlled substances to other hospitals, pharmacies, or prescribers exceed five percent of the total number of controlled substances dosage units (that are furnished to the inpatients or dispensed on prescriptions to discharge patients or employees) per calendar year, the following have been obtained: a separate DEA distributor registration and a wholesaler's permit from the board. (21 CFR 1307.11, DSCSA, BPC 4160)

☐☐☐ 18.5. A controlled substances inventory is completed biennially (every two years).

Date completed: _____ (21 CFR 1304.11)

☐☐☐ 18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)

☐☐☐ 18.7. Separate Schedule II records are maintained. This includes triplicate prescriptions, invoices, US official order forms and inventory records. (21 CFR 1304.04)

☐☐☐ 18.8. Inventories and records for Schedule III-V controlled substances are filed separately or maintained in a readily retrievable manner that distinguishes them from other ordinary business records. (21 CFR 1304.04)

☐☐☐ 18.9. DEA Forms 222 are properly executed. (21 CFR 1305.12)

☐☐☐ 18.10. When the pharmacy distributes Schedule II controlled substances to other DEA registrants, Copy 2 of the DEA Form 222, properly completed, are submitted at the end of each month to the DEA Regional Office. (21 CFR 1305.13)

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

☐☐☐ 18.12. Records stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within two business days. Records for non-controlled substances are maintained on the licensed premises for at least one year from

the date of dispensing. Controlled substances are maintained on the licensed premises for at least two years from the date of dispensing. (CCR 1707)

Yes No N/A

☐☐☐ 18.13. Do pharmacy staff hand initial prescription records and prescription labels, OR does the pharmacy 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 pharmacy. (CCR 1712, CCR 1717)

CORRECTIVE ACTION OR ACTION PLAN: _____

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19. Inventory Reconciliation Report of Controlled Substances

Yes No N/A

☐☐☐ 19.1. The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])

☐☐☐ 19.2 The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])

☐☐☐ 19.3 A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This compilation shall require: (CCR 1715.65 [c])

- ☐ 19.3.1 A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2 A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])
- ☐ 19.3.3 A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])
- ☐ 19.3.4 All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])
- ☐ 19.3.5 Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])

☐☐☐ 19.4 The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])

☐☐☐ 19.5 The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy

for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])

Yes No N/A

☐☐☐ 19.6 A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])

☐☐☐ 19.7 A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])

☐☐☐ 19.8 The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that (CCR 1715.65[h]):

- 19.8.1 All controlled substances added to an automated drug delivery system are accounted for;
- 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel;
- 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- 19.8.4 Confirmed losses of controlled substances are reported to the board.

CORRECTIVE ACTION OR ACTION PLAN: _____

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20. After-Hours Supply of Medication

Yes No N/A

☐☐☐ 20.1 The pharmacy has a system assuring the prescribed medications are available in the hospital 24 hours a day. (22 CCR 70263[e])

☐☐☐ 20.2. The pharmacy maintains a record of the drugs taken from the after-hours supply of medications and the pharmacist is notified of such use. The record includes the name and strength of the drug, the amount taken, the date and time, the name of the patient to whom the drug was administered and the signature of the registered nurse. (22 CCR 70263[n])

CORRECTIVE ACTION OR ACTION PLAN: _____

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21. Drug Supplies for Use in Medical Emergencies

Yes No N/A

☐☐☐ 21.1. A supply of drugs for use in medical emergencies only is immediately available at each nursing unit or service area as required. (22 CCR 70263[f])

Yes No N/A

☐☐☐ 21.2. Written policies and procedures have been developed that establish the contents of the supply, procedures for use, restocking and sealing of the emergency drug supply. (22 CCR 70263[f][1], BPC 4115[i][3], BPC 4119.6)

☐☐☐ 21.3. The emergency drug supply is stored in a clearly marked portable container which is sealed by the pharmacist in such a manner that a seal must be broken to gain access to the drugs. The contents of the container are listed on the outside cover and include the earliest expiration date of any drugs within. (22 CCR 70263[f][2])

☐☐☐ 21.4. The pharmacist is responsible for inspection of the drug supply at periodic intervals (no less frequently than every 30 days) specified in the writ-ten policies. Records of the inspection are kept for at least three years. The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy's written inspection policies and procedures. (22 CCR 70263[f][3], BPC 4115[i][3], BPC 4119.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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22. Schedule II-V Controlled Substances Floor Stock Distribution Records

Yes No N/A

☐☐☐ 22.1. Records for the distribution of Schedule II-V controlled substances floor stock are open to inspection by authorized officers of the law and are preserved for at least three years from the date of making. (BPC 4081)

CORRECTIVE ACTION OR ACTION PLAN: _____

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23. Emergency Room Dispensing

Yes No N/A

☐☐☐ 23.1. A prescriber may dispense a dangerous drug, including a controlled substance, to an emergency room patient if all of the following apply: (BPC 4068[a])

- ☐ 23.1.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital;
- ☐ 23.1.2. The dangerous drug is acquired by the hospital pharmacy;
- ☐ 23.1.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens;
- ☐ 23.1.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, III, IV or V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is release to the patient. (HSC 11165[d]).
- ☐ 23.1.5. The prescriber determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonably

believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient; and

☐ 23.1.6. The quantity of drugs dispensed to any patient pursuant to this section are limited to that amount necessary to maintain uninterrupted therapy during the period when pharmacy services outside the hospital are not readily available or accessible, but shall not exceed a 72-hour supply;

Yes No N/A

☐☐☐ 23.2. ~~The prescriber shall ensure that the label on the drug contains all the information required by Section 4076. (BPC 4068[a][7])~~ The prescription label contains all the required information in BPC 4076 and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the 4 required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 23.3. The prescriber shall be responsible for any error or omission related to the drugs dispensed. (BPC 4068[b])

☐☐☐ 23.4. The brand name or generic name and manufacturer of the prescription drug is accurately identified on the label and prescription record. (BPC 4076, CCR 1717)

☐☐☐ 23.5. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 23.6. Prescriptions are dispensed in new, senior-adult ease –of-opening tested, and child-resistant containers or in a noncomplying package, only pursuant to the prescription or when requested by the purchaser. (15 USC 1473 ~~section 4~~[b], 16 CFR 1700.15, CCR 1717)

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

☐☐☐ 23.8. The pharmacy provides patients with required Black Box Warning Information. (21 CFR 201.57[c])

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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24. Discharge Medication/Consultation Services

Yes No N/A

☐☐☐ 24.1. Patients receive information regarding each medication given at the time of discharge. The information includes the use and storage of each medication, the precautions and relevant warnings and the importance of compliance with directions. A written policy has been developed in collaboration with a physician and surgeon, a pharmacist, and a registered nurse and approved

by the medical staff that ensures that each patient receives the medication consultation. (BPC 4074, CCR 1707.2)

Yes No N/A

☐☐☐ 24.2. Prescriptions are transmitted to another pharmacy as required by law. (BPC 4072, CCR 1717[c], [f], 1717.4)

☐☐☐ 24.3. The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the 4 required items in the required order. (BPC 4076, CCR 1707.5)

☐☐☐ 24.4. 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~~ (BPC 4074 [a][b], CCR 1744[a])~~, BPC 4076.7~~

☐☐☐ 24.5 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]).

☐☐☐ 24.6. The trade name or generic name and manufacturer of the prescription drug is accurately identified in the prescription record. (CCR 1717)

☐☐☐ 24.7. Generic substitution for discharge medications is communicated to the patient, and the name of the dispensed drug product is indicated on the prescription label. (BPC 4073)

☐☐☐ 24.8. If the prescription is filled by a pharmacy technician, the pharmacist's initials are on the prescription label to document the pharmacist's verification of the product or can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means and is immediately retrievable in the pharmacy. (~~BPC 4115[f],~~ CCR 1793.7, CCR 1712)

☐☐☐ 24.9. Controlled substances are dispensed in prescription containers bearing a federal warning label prohibiting transfer of the drugs. (21 CFR 290.5)

☐☐☐ 24.10. 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, 16 CFR 1700.15, CCR 1717)

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

☐☐☐ 24.12. The pharmacy provides patients with required Black Box Warning. (21 CFR 201.57[c])

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

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

☐☐☐ 24.15. Effective January 1, 2022, the pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients. (BPC 688).

CORRECTIVE ACTION OR ACTION PLAN: _____

25. Central Filling of Patient Cassettes For Other Hospital Pharmacies

Yes No N/A

☐☐☐ 25.1. Pharmacy processes orders for the filling of patient cassettes for another hospital or Pharmacy within this state receives filled medication orders or patient cassettes from another hospital. (CCR 1710[b])

If the answer is "yes," name of hospital: _____

☐☐☐ 25.2. Pharmacy receives filled medication containers or cassettes from another pharmacy. (CCR 1710[b])

If the answer is "yes," name of supplying pharmacy: _____

If the answer to this and the previous question is "no" or "not applicable" go to Section 26.

Yes No N/A

☐☐☐ 25.3. Prescription information is electronically transferred between the two pharmacies. (CCR 1710[b][6])

☐☐☐ 25.4. Pharmacy has a contract with the ordering hospital pharmacy or has the same owner. (CCR 1710[b][1])

☐☐☐ 25.5. Filled cassettes are delivered directly to the ordering hospital pharmacy. (CCR 1710[b][2])

☐☐☐ 25.6. Each cassette or container meets the requirements of Business and Professions Code section 4076. (CCR 1710[b][3], BPC 4076[b], BPC 4076[c], BPC 4076[d])

☐☐☐ 25.7. Complete and accurate records are maintained of each cassette fill transaction, including the name of the pharmacist checking the cassettes at each pharmacy. (CCR 1710[b][5])

26. Centralized Hospital Packaging Pharmacy

Yes No N/A

☐☐☐ 26.1 Prior to engaging in centralized hospital packaging, the pharmacy in addition to the hospital pharmacy license, has obtained a Centralized Hospital Packaging specialty license from the Board (BPC 4128.2a)

License Number: _____

CORRECTIVE ACTION OR ACTION PLAN: _____

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☐☐☐ 26.2. The pharmacy prepares medications, by performing the following specialize functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located within a 75-mile radius: (BPC 4128)

Hospitals to which central packaged unit dose medications are provided:

- ☐ 26.2.1. _____ Distance (miles): _____
- ☐ 26.2.2. _____ Distance (miles): _____

- ☐ 26.2.3. _____ Distance (miles): _____
- ☐ 26.2.4. _____ Distance (miles): _____
- ☐ 26.2.5 Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.6 Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to BPC 4128.4.
- ☐ 26.2.7 Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to BPC 4128.4.

Yes No N/A

☐☐☐ 26.3. The pharmacy prepares and stores limited quantities of unit-dose drugs in advance of a patient-specific prescription in amounts necessary to ensure continuity of care. (BPC 4128.3)

☐☐☐ 26.4. Any unit dose medications produced by a centralized hospital packaging pharmacy are barcoded to be machine readable at the inpatient's bedside using barcode medication administrative software. (BPC 4128.4[a])

- ☐ The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software verifies that the medication satisfies these criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient. (BPC 4128[b])

☐☐☐ 26.5. Any label for each unit dose medication produced by a centralized hospital packaging pharmacy displays a human-readable label that contains the following: (BPC 4128.5[a])

- ☐ 26.5.1 The date the medication was prepared.
- ☐ 26.5.2 The beyond-use date
- ☐ 26.5.3 The established name of the drug.
- ☐ 26.5.4 The quantity of each active ingredient.
- ☐ 26.5.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.
- ☐ 26.5.6 Special storage or handling requirements.
- ☐ 26.5.7 The name of the centralized hospital packaging pharmacy.

☐☐☐ 26.6. The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5[b])

- ☐ 26.6.1 The components used in the drug product.
- ☐ 26.6.2 The expiration date of each of the drug's components.
- ☐ 26.6.3 The National Drug Code Directory number.

☐☐☐ 26.7. The centralized hospital packaging pharmacy and the pharmacists working in the pharmacy are responsible for the integrity, potency, quality, and labeled strength of any unit dose drug product prepared by the centralized hospital packaging pharmacy. (BPC 4128.7)

CORRECTIVE ACTION OR ACTION PLAN: _____

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27. Policies and Procedures

Yes No N/A

☐☐☐ 27.1. There are written policies and procedures in place for:

☐ 27.1.1. Oral consultation for discharge medication to an inpatient of a health care facility licensed pursuant to HSC 1250. The assurance that each patient received information regarding each medication given at the time of discharge. (BPC 4074[e], CCR 1707.2 [b][3])

☐ 27.1.2. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to be chemically, mentally, or physically impaired to the extent that it effects his or her ability to practice the profession or occupation authorized by his or her license. (BPC 4104[a])

☐ 27.1.3. Action to be taken to protect the public when a licensed individual employed by or with the pharmacy is known to have engaged in the theft or diversion or self-use of prescription drugs belonging to the pharmacy. (BPC 4104[b])

☐ 27.1.4. Addressing chemical, mental, or physical impairment, as well as, theft, diversion, or self-use of dangerous drugs, among licensed individual employees by or with the pharmacy. (BPC 4104[b])

☐ 27.1.5. Reporting to the board within 14 days of the receipt or development of information as specified in BPC 4104[c][1-6].

☐ 27.1.6. Operation of the pharmacy during the temporary absence of the pharmacist for breaks and meal periods including authorized duties of personnel, pharmacist's responsibilities for checking all work performed by ancillary staff, and pharmacist's responsibility for maintaining the security of the pharmacy. (CCR 1714.1[f])

☐ 27.1.7. Assuring confidentiality of medical information if your pharmacy maintains the required dispensing information for prescriptions, other than controlled substances, in a shared common electronic file. (CCR 1717.1[e])

☐ 27.1.8. Helping patients with limited or no English proficiency understand the information on the prescription container label in the patient's language, including the selected means to identify the patient's language and providing interpretive services in the patient's language. (CCR 1707.5)

☐ 27.1.9. Inventory reconciliation reporting requirements. (CCR 1715.65)

☐ 27.1.10. Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility. (BPC 4115[i][3])

☐ 27.1.11. Intern pharmacist under the direct supervision and control of a pharmacist may inspect the drugs maintained in the health care facility at least once per month. (BPC 4119.7[c])

☐ 27.1.12. Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided. (BPC 4119.7[a~~c~~])

☐ 27.1.13. Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer's guidelines. (BPC 4119.7[b], 22 CCR 70263[c][1], [q] Part 6)

☐ 27.1.14. Written policies and procedures for establishing the supply contents, procedure for use, restocking and sealing of emergency drug supply. (CCR 70263[f][1])

☐ 27.1.15. If applicable, written policies and procedures addressing for dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside. (CCR 70262[l])

☐ 27.1.16. Policies regarding the use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator's written orders. (CCR 70263[o]).

CORRECTIVE ACTION OR ACTION PLAN: _____

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28. Compounding

Yes No N/A

☐☐☐ 28.1. Prior to allowing any drug product to be compounded in a pharmacy, the pharmacist-in-charge must complete the current "Compounding Self-Assessment" Form 17M-39 (Rev. ~~02/~~12/16). (CCR 1735.2)

CORRECTIVE ACTION OR ACTION PLAN: _____

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29. Automated Drug Delivery Systems

Yes No N/A

~~☐☐☐ 29.1. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery systems (ADDS) for doses administered at the facility and approved services listed on the hospital's license and is exempt from registration with the Board. (BPC 4105.5[e])~~

~~☐☐☐ 29.2. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery system (ADDS) for doses dispensed to patients that are registered with the Board. (BPC 4105.5[b])~~

~~☐☐☐ 29.3. Prior to July 1, 2019: The hospital pharmacy operates automated drug delivery system (ADDS) for doses dispensed to patients that are registered with the Board. (BPC 4105.5[b])~~

~~☐☐☐ 29.4. Prior to July 1, 2019: The hospital pharmacy is in compliance with the following:~~

~~☐ 29.4.1. The ADDS is consistent with legal requirements. (BPC 4105.5[c][1])~~

~~☐ 29.4.2. The pharmacy has policies and procedures related to the ADDS including appropriate security measures and monitoring of the inventory to prevent theft and diversion. (BPC 4105.5[c][2])~~

~~☐ 29.4.3. Reports drug losses from the ADDS to the board as required by law. (BPC 4105.5[c][3])~~

~~☐ 29.4.4. The pharmacy license is unexpired and not subject to disciplinary conditions. (BPC 4105.5[c][4]~~

Yes No N/A

☐☐☐ 29.5~~1~~. ~~July 1, 2019 and thereafter:~~ The hospital pharmacy operates automated drug delivery systems (ADDS) that are automated unit dose systems (AUDS) for doses administered at the facility and approved services listed on the hospital's license and the ADDS is/are exempt from licensure with the Board. (BPC 4427.2[i])

☐☐☐ 29.6~~2~~. ~~July 1, 2019 and thereafter:~~ The hospital pharmacy operates automated drug delivery system (ADDS) that are automated patient delivery dispensing systems (APDS) for doses dispensed to patients at the facility and approved services listed on the hospital's license and the ADDS is/are licensed with the Board. (BPC 4427.2[a])

☐☐☐ 29.3. If the pharmacy operated an automated drug delivery systems, the pharmacist-in-charge has completed the annual self-assessment for automated drug delivery systems. (BPC 4427.7)

~~Effective July 1, 2019, all pharmacies, including hospital pharmacies are required to complete the Automated Drug Delivery System Self-Assessment by July 1st annually and within 30 days whenever a new pharmacy permit is issued, there is a change in the pharmacist-in-charge and he/she becomes the new pharmacist-in-charge of the pharmacy, and there is a change in the licensed location of the pharmacy to a new address. (BPC 4427.7, CCR 1715)~~

CORRECTIVE ACTION OR ACTION PLAN: _____

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30. Prescription Drug Take-Back Services

Yes No N/A

☐☐☐ 30.1. Does the pharmacy participate in a Prescription Drug Take-Back Program and adheres to The federal, state and local requirements governing the collection and destruction of dangerous drugs? (CCR 1776, 1776.1)

If yes, check off below the type of prescription drug take-back program the pharmacy offers and complete the sections that applies to the type of program(s):

☐ Mail back envelopes or package service. (CCR 1776.2)

☐ Collection receptacles in the pharmacy. (CCR 1776.3)

☐ Drug take-back services in the Skilled Nursing Facilities. (CCR 1776.4, HSC 1250[c])

Yes No N/A

☐☐☐ 30.2. Only prescription drugs that have been dispensed by any pharmacy or practitioner to a consumer are eligible for collection as part of drug take-back services maintained by the pharmacy. (CCR 1776.1[f ~~e~~])

☐☐☐ 30.3. Dangerous drugs that have not been dispensed to consumers for use (such as outdated drug stock, drug samples provided to medical practitioners or medical waste) is not collected as part of the pharmacy's drug take-back service. (CCR 1776.1[f])

☐☐☐ 30.4. The pharmacy does not accept or possess prescription drugs from skilled nursing facilities, residential care homes, health care practitioners or any other entity as part of its drug take-back services. (CCR 1776.1[g][2])

☐☐☐ 30.5. Quarantined, recalled or outdated prescription drugs from the pharmacy stock are not disposed as part of the pharmacy's drug take-back services. (CCR 1776.1[g][3])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies Offering Mail Back Envelopes or Package Services (CCR 1776.1, 1776.2)

Yes No N/A

☐☐☐ 30.6. The pharmacy provides prescription drug take-back preaddressed mailing envelopes or packages to consumers to return prescription drugs to an authorized destruction location. (CCR 1776.2[a])

☐☐☐ 30.7. All drug take-back envelopes and packages made available to the public are preaddressed to a location registered with the DEA as a collector. (CCR 1776.2[b])

☐☐☐ 30.8. The preaddressed envelopes and packages are water and spill proof, tamper evident, tear resistant and sealable. The exterior is nondescript and has no markings indicating the envelope or package contains prescription drugs. Postage is prepaid on each envelope or package. (CCR 1776.2[c])

☐☐☐ 30.9. The preaddressed envelope and package contains a unique identification number for each envelope and package, and the instructions for users indicates the process to mail back the drugs. (CCR 1776.2[d])

☐☐☐ 30.10. The pharmacy does not accept any mail back packages or envelopes containing drugs unless the pharmacy is registered as a collector and has an onsite method of destruction that complies with DEA requirements. The consumer is directed to mail the envelopes or packages. (CCR 1776.2[e])

If the answer is no and the pharmacy is registered with DEA as a collector with an onsite method of destruction that complies with DEA requirements, list the following (21 CFR 1317.40):

DEA Collector Registration Number:_____

Expiration Date:_____

☐☐☐ 30.11. Once drugs are deposited into a mail back envelope or package by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d],[g])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Pharmacies with Collection Receptacles in the Pharmacy/Hospital (CCR 1776.1, 1776.3)

Yes No N/A

☐☐☐ 30.12. The pharmacy is registered with DEA as a collector for purposes of maintaining a prescription drug take-back collection receptacle. (21 CFR 1317.30, 1317.40, CCR 1776)

☐☐☐ 30.13. The pharmacy notified the board in writing within 30 days of establishing the collection program. (CCR 1776.1[i])

Date the board was notified:_____

☐☐☐ 30.14. When the pharmacy renewed its pharmacy license, the pharmacy identified and disclosed to the board all the locations where its collection receptacles are located. (CCR 1776.1[i][2])

☐☐☐ 30.15. The pharmacy is aware, any tampering with a collection receptacle or theft of deposited drugs and any tampering, damage or theft of the removed liner are reported to the board in writing within 14 days. (CCR 1776.1[i][3][4])

List the dates the board was notified of any tampering or theft from the collection receptacle and/or tampering, damage or theft of the removed liner:

Date reported:_____

☐☐☐ 30.16. The pharmacy is not on probation with the board. (CCR 1776.1[l])

If answered NO, meaning the pharmacy is on probation, the pharmacy cannot maintain a drug take back collection receptacle and must cease and notify the board in writing within 30 days and notify the DEA within 30 days.

☐☐☐ 30.17. Once drugs are deposited into a collection receptacle by the consumer, the pharmacy does not remove, count, sort or individually handle any prescription drugs from the consumer. (CCR 1776.1[d], 1776.3[e])

☐☐☐ 30.18. The collection receptacle is substantially constructed with a permanent outer container, removable inner liner, and is locked at all times to prevent access to the inner liner. (CCR 1776.3[a],[d])

☐☐☐ 30.19. The collection receptacle is securely fasten to a permanent structure so it cannot be removed and is installed in an inside location. (CCR 1776.3[b])

☐☐☐ 30.20. The receptacle is visible to the pharmacy and DEA registrant employees, but not located in or near emergency areas, nor behind the pharmacy's counter or is located in an area that is regularly monitored by pharmacy or DEA registrant employees and not in the proximity of any emergency or urgent care areas. When no pharmacy or DEA registrant employees are present, the collection receptacle is locked so that drugs are not deposited into the collection receptacle. (CCR 1776.3[b],[c])

☐☐☐ 30.21. The receptacle includes a small opening that allows deposit of drugs into the inside of the receptacle directly into the inner liner, but does not allow for an individual to reach into the

receptacle's contents. When the pharmacy is closed, the collection receptacle is not accessible to the public for deposit of drugs. The pharmacy locks the deposit opening on the collection receptacle. (CCR 1776.3[d])

Yes No N/A

☐☐☐ 30.22. The pharmacy directs consumers to directly deposit the drugs into the collection receptacle. (CCR 1776.3[e])

☐☐☐ 30.23. The inner liner used is made of material that is certified by the manufacturer to meet the ASTM D179 standard test for impact resistance of 165 grams (drop dart test) and the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes. (CCR 1776.3[f])

- ☐ 30.23.1 The liner is waterproof, tamper evident, tear resistant, and opaque to prevent viewing or removal of any contents once the liner has been removed from the collection receptacle. (CCR 1776.3[f])
- ☐ 30.23.2 The liner is clearly marked to display the maximum contents (for example, in gallons). (CCR 1776.3[f][2]
- ☐ 30.23.3 The liner bears a permanent, unique identification number established by the pharmacy or pre-entered onto the liner by the liner's manufacturer or distributor. (CCR 1776.3[f][2])
- ☐ 30.23.4 The liner is removable as specified pursuant to CCR 1776.3.

☐☐☐ 30.24. The receptacle allows the public to deposit prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once the prescription drugs or any other item is placed in the collection receptacle, the prescription drug or item cannot be removed, counted, sorted, or otherwise individually handled. (CCR 1776.3[d],[e],[g])

☐☐☐ 30.25. If the liner is not already itself rigid or already inside of a rigid container when it is removed from the collection receptacle, the liner is immediately, without interruption, placed in a rigid container for storage, handling and transport. (CCR 1776.3~~1707.3~~[h])

☐☐☐ 30.26. The liner is removed from a locked collection receptacle only by or under the supervision of two employees of the pharmacy. Upon removal, the liner is immediately, without interruption, sealed and the pharmacy employees record, in a log, their participation in the removal of each liner from the collection receptacle. Liners and their rigid containers are not opened, x-rayed, analyzed, or penetrated at any time by the pharmacy or pharmacy personnel. (CCR 1776.3[i])

☐☐☐ 30.27. Liners and their rigid containers that are filled and removed from the collection receptacle is stored in a secured, locked location in the pharmacy no longer than 14 days. (CCR 1776.3[j])

☐☐☐ 30.28. The pharmacy maintain records for collected unwanted drugs from consumers for three years, including the following records for each liner: (CCR 1776.3[k], 1776.6[a])

☐☐☐ 30.29. The pharmacy seals the inner liners and their contents are shipped to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX, USPS) or by a licensed reverse distributor pick up at the licensed pharmacy's premise. (CCR 1776.3[l])

☐☐☐ 30.30. The collection receptacle has a signage that includes: (1) the name and phone number of the responsible pharmacy, (2) medical sharps and needles (e.g. insulin syringes) is not to be

deposited, (3) consumers may deposit prescription drugs including Schedule II-V controlled substance. (CCR 1776.1[e], 1776.3[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Onsite Pharmacies with Drug Take-Back Services in Skilled Nursing Facilities

Yes No N/A

☐☐☐ 30.31. The pharmacy provides mail back envelopes or packages to skilled nursing facility employees or person lawfully entitled to dispose of resident decedent's property of unwanted or unused prescription drugs. (CCR 1776.4[a])

☐☐☐ 30.32. If the pharmacy provides mail back envelopes or packages to skilled nursing facilities, the skilled nursing facility employees keeps a record noting the specific quantity of each prescription drug mailed back, the unique identification number of the mail back package and the preaddressed location to which the mail back envelope is sent. (CCR 1776.4[a])

☐☐☐ 30.33. If the pharmacy is onsite at a skilled nursing facility, has the pharmacy established a collection receptacle in the skilled nursing facility for the collection and ultimate disposal of unwanted prescription drugs. (CCR 1776.4[b])

If no, answer N/A to the remaining questions in this section.

If yes, continue answering the questions in this section.

List the location(s) of the collection receptacle:

_____

_____

☐☐☐ 30.34. Was the board notified in writing within 30 days of establishing a collection receptacle? (CCR 1776.4[b][2])

☐☐☐ 30.35. Has there been any tampering of the collection receptacle, theft of the deposited drugs and/or tampering, damage or theft of the removed liner? (CCR 1776.4[b][4],[5])

☐ If yes, was the board notified in writing within 14 days of any tampering of the collection receptacles and/or liner?

☐☐☐ 30.36. When the pharmacy license was renewed, did the pharmacy provide ~~the list~~ a current list of collection receptacles? (CCR 1776.4[b][6])

☐☐☐ 30.37. The skilled nursing facility places patient's unneeded prescription drugs into a collection receptacle within three business days after the permanent discontinuance of use of a medication by a prescriber, as a result of the resident's transfer to another facility or as a result of death. Records of such deposit is made in the patient's records, with the name and signature of the employee discarding the drugs. (CCR 1776.4[d])

☐☐☐ 30.38. Is the collection receptacle located in a secured area regularly monitored by the skilled nursing facility employees, securely fastened to a permanent structure so it cannot be removed, have a small opening that allows deposit of drugs into the inside of the collection receptacle and

directly into the inner liner, but does not allow for an individual to reach into the receptacle's contents, securely locked and substantially constructed with a permanent outer container and a removable inner liner? (CCR 1776.4[e][f][g])

Yes No N/A

☐☐☐ 30.39. The liner certified by the manufacturer to meet the American Society for Testing Materials (ASTM) D1709 standard test for impact resistance of 165 grams (drop dart test), the ASTM D1922 standards for tear resistance of 480 grams in both parallel and perpendicular planes, waterproof, tamper evident, tear resistant, opaque to prevent viewing and discourage removal of any contents once the liner is removed from the collection receptacle, marked to display the maximum contents, and bear a permanent, unique identification number. (CCR 1776.4[h])

☐☐☐ 30.40. The receptacle allows the deposit of prescription drugs into the receptacle for containment into the inner liner, without permitting access to or removal of prescription drugs already deposited into the collection receptacle and liner. Once a prescription drug or item is placed in the collection receptacle, the prescription drug or item cannot be removed, sorted, counted, or otherwise individually handled. (CCR 1776.4[g][1])

☐☐☐ 30.41. If the liner is not already itself rigid or already inside a rigid container when it is removed from the collection receptacle, the liner is immediately placed in a rigid container for storage, handling and transport. (CCR 1776.4[g][2])

☐☐☐ 30.42. The rigid container is either disposable, reusable, or recyclable. The rigid container is leak resistant, have sealable tight fitting covers and kept clean and in good repair. (CCR 1776.4[g][2])

☐☐☐ 30.43. The collection receptacle contains signage with (1) the name and phone number of the pharmacy, (2) medical sharps and needles (e.g. insulin syringes) can not be deposited, and (3) consumers may deposit prescription drugs including Schedule II-V controlled substances. (CCR 1776.4[i])

☐☐☐ 30.44. Once deposited, the prescription drugs are not counted, sorted, or otherwise individually handled. (CCR 1776.4[j])

☐☐☐ 30.45. The installation, removal, transfer, and storage of inner liners is performed only by (1) one employee of the authorized collector pharmacy and one supervisory level employee of the long-term care facility (e.g. charge nurse or supervisor) designated by the authorized collector or (2) by or under the supervision of two employees of the authorized collector pharmacy. (CCR 1776.4[k])

☐☐☐ 30.46. Sealed inner liners placed in a container is stored at the skilled nursing facility up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer to a reverse distributor for destruction. (CCR 1776.4[l])

☐☐☐ 30.47. Liners housed in a rigid container is delivered to a reverse distributor for destruction by a common or contract carrier or by a reverse distributor picked up at the skilled nursing facility. (CCR 1776.4[m])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

Record Keeping Requirements for Board Licensees Providing Drug Take Back Services

Yes No N/A

☐☐☐ 30.48. Records required for drug take back services are maintained for three years. (CCR 1776.6)

☐☐☐ 30.49. The pharmacy makes and keeps the following records for each liner: (CCR 1776.6[a])

☐ 30.49.1. The date each unused liner is acquired, its unique identification number and size (e.g. 5 gallon, 10 gallon). If the liner does not already contain a unique identification number, the pharmacy assigns the unique identification number. (CCR 1776.6[a][1])

☐ 30.49.2. The date each liner is installed in a collection receptacle, the address of the location where each liner is installed, the unique identification number and size (e.g., 5 gallon, 10 gallon), the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed each installation. (CCR 1776.6[a][2])

☐ 30.49.3. The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size (e.g. 5 gallon, 10 gallon) of each inner liner removed, the registration number of the collector pharmacy, and the names and signatures of the two employees that witnessed the removal and sealing. (CCR 1776.6[a][3])

☐ 30.49.4. The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage. (CCR 1776.6[a][4])

☐ 30.49.5. The date each sealed inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealer inner liner was transferred, the unique identification number and size (e.g., 5 gallon, 10 gallon) of each liner transferred, and the names and signatures of the two employees who transferred each sealed inner liner to the reverse distributor or distributor, or the common carrier who delivered it, the company used, and any related paperwork (invoice, bill of lading). (CCR 1776.6[a][5])

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected by _____. 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 _____ _____
(Pharmacist-in-Charge) Date

ACKNOWLEDGEMENT BY HOSPITAL ADMINISTRATOR:

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 Pharmacist-in-Charge Certification above could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____ _____
Date

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 (BPC), Division 2, Chapter 1 – General Provisions
BPC, Division 2, Chapter 9 – Pharmacy
California Code of Regulation (CCR), Title 16, Division 17 – California State Board of Pharmacy
CCR, Title 22, Division 5, Chapter 1 – General Acute Care Hospitals
Civil Code, Division 1, Part 2.6, Chapter 2 – Disclosure of Medical Information by Providers
Code of Federal Regulations (CFR), Title 16, Chapter II, Subchapter E, Part 1700 – Poison Prevention Packaging
CFR, Title 21, Chapter I, Subchapter C, Part 201, Subpart B – Labeling Requirements for Prescription Drugs and/or Insulin
CFR, Title 21, Chapter I, Subchapter C, Part 208 – Medication Guides for Prescription Drug Products
CFR, Title 21, Chapter I, Subchapter C, Part 290 – Controlled Drugs
CFR, Title 21, Chapter I, Subchapter D, Part 310, Subpart E – Requirements for Specific New Drugs and Devices
CFR, Title 21, Chapter II - Drug Enforcement Administration, Department of Justice
Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act
HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law), Chapter 2 – Administration
HSC, Division 116 – Surplus Medication Collection and Distribution
United States Code (USC), Title 15, Chapter 39A – Special Packaging of Household Substances for Protection of Children
USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

ATTACHMENT 3

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

d. Wholesaler Dangerous Drugs & Devices Self-Assessment (17M-26)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, California 95833
(916) 574-7900 FAX (916) 574-8618

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR GAVIN NEWSOM

WHOLESALER/THIRD-PARTY LOGISTICS PROVIDER SELF-ASSESSMENT

All legal references used throughout this self-assessment form are explained on page 27.

All references to "drugs" throughout this self-assessment form refer to dangerous drugs and dangerous devices as defined in Business & Professions Code (BPC) section 4022. (http://www.pharmacy.ca.gov/laws_regs/lawbook.pdf).

In addition, the following terms have the following meanings:

- "Dispose" means to dispose of drugs or return them to the supplier for disposal.
- "Distribute" means to distribute, ship, transfer, deliver, or otherwise relocate drugs.
- "Store" means to store, warehouse, or otherwise hold drugs.
- "Purchase" means to purchase, order, trade, or otherwise acquire ownership of drugs.
- "Sell" means, as the drugs' owner, to sell, trade, or otherwise transfer ownership of the drugs to a new owner.
- "Suspect product" and "illegitimate product" mean drugs subject to the Drug Supply Chain Security Act that are a suspect or illegitimate product as defined in that act.

For purposes of completing this assessment, the following abbreviations refer to specified licensing categories:

- WLS= Wholesaler
- 3PL= Third-Party Logistics Provider, Reverse Third-Party Logistics Provider
- DRIC = Designated Representative-in-Charge
- RM = Responsible Manager
- DR =
    - For WLS: Designated Representative, or Pharmacist Fulfilling the Duties of that Role
        - *If the WLS Facility Is Exclusively a Reverse Distributor Facility: Designated Representative, Designated Representative-Reverse Distributor, or Pharmacist Fulfilling the Duties of Either Role*
    - For 3PL: Designated Representative-3PL

WLS/3PL Name:_____

Licensed Premises/Place of Business/Facility Being Assessed:

Address: _____

Phone: _____

Email address: _____

Ownership: Please mark one

○ sole owner ◉ partnership ○ corporation ○ LLC

○ non- licensed owner ○ Other (please specify)

WLS/3PL License #_____ Expiration Date _____

Other License # _____ Expiration Date _____
(Use additional sheets if needed.)

DEA Registration # _____ Expiration Date _____

VAWD Accreditation # _____ Expiration Date _____

Date of most recent DEA Inventory _____

Hours: Weekdays _____ Sat _____ Sun _____ 24 Hours ○

DRIC/RM _____

DRIC/RM License # _____ Expiration Date _____

Website Address (optional):

Other Licensed Staff (DR):

1. _____ DR#/RPH#_____ Exp. Date _____

2. _____ DR#/RPH#_____ Exp. Date _____

3. _____ DR#/RPH#_____ Exp. Date _____

4. _____ DR#/RPH#_____ Exp. Date _____

5. _____ DR#/RPH#_____ Exp. Date _____

6. _____ DR#/RPH#_____ Exp. Date _____

7. _____ DR#/RPH#_____ Exp. Date _____

8. _____ DR#/RPH#_____ Exp. Date _____

9. _____ DR#/RPH#_____ Exp. Date _____

10._____ DR#/RPH#_____ Exp. Date _____

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

1. Ownership/Location

Yes No N/A

☐ ☐ ☐ 1.1. Review the current WLS/3PL license for this place of business. Are the listed owners correct and is the listed address correct? If not, please indicate discrepancy. If either is incorrect, notify the board in writing immediately. (BPC 4160[a],[c]) **Attach a copy of the notification letter to the board to this document.**

☐ ☐ ☐ 1.2. Has the WLS/3PL established and does it maintain a list of officers, directors, managers and other persons in charge of drug distribution, handling and storage at this place of business? The list must contain a summary of the duties and qualifications for each job listed. (CCR 1780[f][3], BPC 4082, CFR 205.50[h]) **Please attach a copy of the list to this document.** (This list should be dated.)

Note: Upon request, the owner must provide the board with the names of the owners, managers and employees of this place of business and a brief statement of the capacity in which they are employed. (BPC 4082)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

2. Facility

2.1. Premises, fixtures and equipment:

Yes No N/A

☐ ☐ ☐ 2.1.1. Are clean and orderly
☐ ☐ ☐ 2.1.2. Are well ventilated
☐ ☐ ☐ 2.1.3. Are free from rodents, insects, birds, or vermin of any kind
☐ ☐ ☐ 2.1.4. Are adequately lit
☐ ☐ ☐ 2.1.5. Have plumbing in good repair
☐ ☐ ☐ 2.1.6. Have temperature & humidity monitoring to assure compliance with USP Standards (The USP standards for various drugs may differ (CCR 1780[b], BPC 4053.1[b][3][A][iv], HSC 111255, 111295, 111305, CFR 205.50[a],[c], 211.42-211.58, 211.142[b])

☐ ☐ ☐ 2.2. Is there a quarantine area for outdated, damaged, deteriorated, adulterated, or misbranded drugs, drugs with the outer or secondary seal broken, partially used containers, drugs returned under conditions that cast doubt on the drugs' safety, identity, strength, quality or purity, or drugs that are a suspect

or illegitimate product? (CCR 1780[e], 17 CCR 10377.4[e], CFR 205.50[a][3],[e], 211.142[a], USC 360eee–1[c][4], 360eee–3[d][2][C][i])

Yes No N/A

☐ ☐ ☐ 2.3. Are dangerous drugs and devices stored in a secured and locked area? (BPC 4167, CCR 1780[a], 17 CCR 10377.4[a], CFR 205.50[a][2],[b])

☐ ☐ ☐ 2.4. Is access to areas where dangerous drugs and devices are stored limited to authorized personnel? (CCR 1780[c], 17 CCR 10377.4[a][3], CFR 205.50[b][1][iii])

List personnel with keys to the area(s) where dangerous drugs or devices are stored (list by name or job title):

_____

_____

_____

☐ ☐ ☐ 2.5. Does this place of business operate only when a is on the premises? (BPC 4053.1[c], 4053.2[c], 4160[c][1], CCR 1781)

2.6. The licensed premises is equipped with the following specific security features:

☐ ☐ ☐ 2.6.1. There is an alarm to detect after-hours entry.
☐ ☐ ☐ 2.6.2. The outside perimeter of the building is well lit.
☐ ☐ ☐ 2.6.3. The security system provides protection against theft and diversion including tampering with computers and or electronic records. (CCR 1780[c], 17 CCR 10377.4[a],[b],[c], CFR 205.50[b])

Explain how your security system complies with these requirements.

_____

_____

☐ ☐ ☐ 2.7. Is this business a "reverse distributor", that is, does the business act as an agent for a pharmacy, WLS, 3PL, manufacturer, or others, by receiving, inventorying, warehousing, or managing the disposition of outdated or non-saleable drugs? (BPC 4040.5)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Yes No N/A

☐ ☐ ☐ 2.8. The facility has obtained approval from the board if acting as a reverse distributor which acquires dangerous drugs or dangerous devices from an unlicensed source that was previously licensed with the board for the sole purpose of destruction of the dangerous drugs or dangerous devices (BPC 4163(c))

Date of approval from the board: _____

☐ ☐ ☐ 2.9. The facility is subscribed to the board's email notifications. (BPC 4013)

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

☐ ☐ ☐ 2.10. The facility receives the board's email notifications through the owner's electronic notice system. (BPC 4013[c])

Date Last Notification Received: _____

Email address registered with the board: _____

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

3. Designated Representative-in-Charge/ Responsible Manager / Designated Representative-Reverse Distributor / Owner Responsibilities

Yes No N/A

☐ ☐ ☐ 3.1. The owner and the DRIC/RM are both equally responsible for maintenance of the records and inventory of this facility. (BPC 4081[b])

☐ ☐ ☐ 3.2. Is the DRIC/RM at least 18 years of age and responsible for the WLS/3PL's compliance with all state and federal laws for the wholesale distribution of drugs

(in the case of a WLS) or all state and federal laws for 3PLs and the 3PL's customer specifications (in the case of a 3PL), respectively? The DRIC may be a DR or a pharmacist, subject to approval by the board. (BPC 4053.1[b], 4053.2[b], 4101[b], 4160[d],[e], 4200[a][1])

Yes No N/A

☐ ☐ ☐ 3.3. The owner must notify the board within 30 days of termination of the DRIC/RM. (BPC 4305.5[a])

☐ ☐ ☐ 3.4. The owner must DRIC/RM in its 30-day notice to the board regarding the termination of the former DRIC/RM. (BPC 4160[f],[g]) The appropriate form for this notification is available on the board's website.

☐ ☐ ☐ 3.5. A DRIC/RM who ends their employment as DRIC/RM for this place of business must notify the board within 30 days. (BPC 4101[b],[c], 4305.5[c]) This notification is in addition to that required of the owner.

CORRECTIVE ACTION OR ACTION PLAN _____

_____

4. Ordering Drugs by this Business for Future Sale

4.1. If you are a WLS, do you only order drugs from a supplier if the supplier is one of the following?

Yes No N/A

☐ ☐ ☐ 4.1.1. A WLS licensed by the board. If the drugs are subject to the Drug Supply Chain Security Act, the WLS must also be in the FDA Wholesale Distributor and Third-Party Logistics Provider Reporting Database or otherwise confirmed to be in compliance with the FDA reporting requirements described in Section 16.3.

☐ ☐ ☐ 4.1.2. A licensed manufacturer.

☐ ☐ ☐ 4.1.3. A pharmacy licensed by the board, nonresident pharmacy registered with the board, or nonresident pharmacy acting through a WLS or 3PL licensed by the board, only under a circumstance described in Section 7.5.

☐ ☐ ☐ 4.1.4. A clinic listed in Section 4180 of the Business and Professions Code, only under a circumstance described in Section 7.6. (A WLS may not purchase drugs from a clinic at wholesale or for sale at wholesale.) (BPC 4120[a], 4163[b], 4169[a][1],[d], 4180[a],[b], USC 360eee–1[c][3])

4.2. If you are a WLS, when drugs are returned to your ownership by a business that originally purchased the drugs from you:

☐ ☐ ☐ 4.2.1. Do you document the drugs' return with an acquisition record for your business and a disposition record for the business returning the drugs?

Yes No N/A

☐ ☐ ☐ 4.2.2. If the drugs are returned by a hospital, clinic, other health care entity (not including a retail pharmacy or wholesale distributor), or charitable institution (if sold at a discount or donated to that institution), are you provided written documentation that the drugs were kept under proper conditions for storage, handling, and shipping? (BPC 4081, 4105, 4169[a][5], 4332, CFR 203.23[c], 205.3[h], 205.50[f])

In addition, if the drugs are subject to the Drug Supply Chain Security Act:

☐ ☐ ☐ 4.2.3. Do you only accept the drugs if you can associate them with their transaction information and transaction statement?

☐ ☐ ☐ 4.2.4. Beginning November 27, 2020, do you only redistribute the drugs after you verify the product identifier on each sealed homogenous case or each package of the drugs, as applicable? (USC 360eee–1[c][1][B][i][II], FDA Final Guidance, September 23, 2019)

☐ ☐ ☐ 4.3. For license verification of a trading partner, the WLS may use the licensing information displayed on the board's internet website. (BPC 4106)

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

5. Receipt of Drugs by this Business

Yes No N/A

☐ ☐ ☐ 5.1. When drugs are received by this place of business, are they received at the licensed premises, and received by and signed for only by a DR? (BPC 4059.5[a])

☐ ☐ ☐ 5.2. When drugs are received by this place of business, is the outside of each shipping container visually inspected to identify the drugs and prevent acceptance of contaminated drugs by detecting container damage? (CCR 1780[d][1], HSC 111255, 111305, CFR 205.50[d], USC 331[c], 351[a][2][A])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

6. Drug Stock

Yes No N/A

☐ ☐ ☐ 6.1. Is all drug stock open for inspection during regular business hours? (BPC 4080)

☐ ☐ ☐ 6.2. Are all drugs you receive at the licensed premises maintained on the premises in a secure manner? You cannot obtain or receive drugs, by purchase or other arrangement, for storage on the licensed premises that you are not able to securely store on the premises. (BPC 4167, CFR 205.50[b])

6.3. Are all drugs sold at wholesale that are stored or warehoused off-site:

☐ ☐ ☐ 6.3.1. Maintained at a premises licensed by the board?

☐ ☐ ☐ 6.3.2. If another business or person stores or warehouses the drugs on your behalf, is the business or person licensed by the board as a WLS or 3PL? (BPC 4043, 4169[a][1])

☐ ☐ ☐ 6.4. Do all drugs you purchase, receive, sell, store, deliver, or offer to deliver conform to the standards and tests for strength, quality, and purity provided in the latest edition of United States Pharmacopoeia or the National Formulary? (BPC 4169[a][2],[3], 4342[a], HSC 111280, 111295, 111305, USC 331[a],[c], 351[b])

☐ ☐ ☐ 6.5. Do all drug containers you store on your premises have a manufacturer's expiration date? Any drug without an expiration date is considered expired. An expired drug may not be sold, held for sale, or distributed. (CCR 1718.1, BPC 4169[a][4], CFR 205.50[e][1], USC 360eee–3[d][2][C][iii][VI])

☐ ☐ ☐ 6.6. Are outdated, damaged, deteriorated ~~or~~, misbranded, or adulterated drugs held in a quarantine area physically separated from other drugs until disposal? If the drugs are a suspect or illegitimate product, you must also follow the procedures specified in Section 6.8. (CCR 1780[e], 17 CCR 10377.4(e), BPC 4169[a][2],[3],[4], HSC 111295, 111305, 111440, 111450, CFR 205.50[e][1], USC 331[a],[c], 351, 360eee–3[d][2][C][iii][VI])

☐ ☐ ☐ 6.7. Are drugs with the outer or secondary seal broken, or partially used drugs held in a quarantine area and physically separated from other drugs until disposal? If the drugs are a suspect or illegitimate product, you must also follow the procedures specified in Section 6.8. (CCR 1780[e][2], CFR 205.50[e][2], HSC 111255, 111295, 111305, USC 331[a],[c], 351[a])

Yes No N/A

☐ ☐ ☐ 6.8. When the conditions under which drugs are returned to your ownership or premises (including conditions under which they were held, stored, or shipped before being received) cast doubt on the drugs' safety, identity, strength, quality or purity, are the drugs quarantined and disposed of, unless testing or investigation proves the drugs meet USP standards? If the drugs are a suspect or illegitimate product, you must also clear the drugs with the FDA as described in Section 6.8 before the drugs may be returned to normal stock. (CCR 1780[e], HSC 111280, 111295, 111305, CFR 205.50[e][3], USC 331[a],[c], 351[b])

6.9. If you are a WLS, when either drugs are a suspect product, or you are notified that drugs are an illegitimate product:

☐ ☐ ☐ 6.9.1. Are the drugs quarantined?

☐ ☐ ☐ 6.9.2. Do you promptly conduct an investigation in coordination with applicable trading partners to determine whether the drugs are an illegitimate product? (USC 360eee–1[c][4][A][i],[c][4][B][iii])

If you conclude the drugs are an illegitimate product:

☐ ☐ ☐ 6.9.3. Within 24 hours, do you notify the FDA and immediate trading partners that may have received the drugs?

☐ ☐ ☐ 6.9.4. Do you dispose of the drugs?

☐ ☐ ☐ 6.9.5. Do you take reasonable and appropriate steps to assist a trading partner in destroying the drugs? (USC 360eee–1[c][4][B])

If you conclude the drugs are not an illegitimate product:

☐ ☐ ☐ 6.9.6. Do you clear the product with the FDA by promptly notifying the FDA of your determination? (USC 360eee–1[c][4][A][ii],[c][4][B][iii])

CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

7. Sale or Distribution of Drugs by this Business

7.1. Are drugs sold or distributed within the state only to the following recipients?

If the drugs **are not** sold or distributed for sale at wholesale, to any of the following:

Yes No N/A

☐ ☐ ☐ 7.1.1. A WLS or (in the case of distribution only) 3PL licensed by the board. If the drugs are subject to the Drug Supply Chain Security Act, the WLS or 3PL must also be in the FDA Wholesale Distributor and Third-Party Logistics Provider Reporting Database or otherwise confirmed to be in compliance with the FDA reporting requirements described in Section 16.3.

☐ ☐ ☐ 7.1.2. A pharmacy or hospital pharmacy licensed by the board.

☐ ☐ ☐ 7.1.3. A person or business licensed by a prescriber board.

☐ ☐ ☐ 7.1.4. A licensed manufacturer.

☐ ☐ ☐ 7.1.5. A laboratory authorized to receive drugs.

☐ ☐ ☐ 7.1.6. A hospital, clinic, or other health care entity authorized to receive drugs.

☐ ☐ ☐ 7.1.7. The master or first officer of an ocean vessel, as provided in Section 7.14. (CCR 1783[a],[b], BPC 4059[b], 4059.5[a],[b],[d], 4066, 4163[a], USC 360eee[2][B],[C], 360eee–1[c][3])

If the drugs **are** sold or distributed for sale at wholesale, only to one of the following:

☐ ☐ ☐ 7.1.8. A WLS, 3PL, pharmacy, hospital pharmacy, or licensed manufacturer described above.

☐ ☐ ☐ 7.1.9. A hospital or clinic licensed by the board to purchase drugs at wholesale. (BPC 4056[a], 4169[a][1], 4180, 4190)

7.2. Describe how you verify a business or person is appropriately licensed.

_____

_____

7.3. List any businesses or persons that order or receive drugs from you that are not licensed according to the list above:

_____

_____

☐ ☐ ☐ 7.4. If you are a WLS, do you only purchase or sell drugs that are subject to the Drug Supply Chain Security Act if they are encoded with a product identifier? (USC 360eee–1(c)(2))

☐ ☐ ☐ 7.4. Are drugs only furnished by your business to an authorized person? (CCR 1783[a],[b], BPC 4163[a]) Note: An authorized person can be a business or natural person.

7.5. Does your business only receive drugs from a pharmacy if:

If you are a WLS, either:

Yes No N/A

☐ ☐ ☐ 7.5.1. the pharmacy originally purchased the drugs from you?

☐ ☐ ☐ 7.5.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.5.3. the drugs are needed to alleviate a shortage? (and only a quantity sufficient to alleviate a specific shortage). (BPC 4126.5[a], USC 360eee–1[d][1][C])

If you are a 3PL, either:

☐ ☐ ☐ 7.5.4. you are storing the drugs for the pharmacy or otherwise acting on the pharmacy's behalf?

☐ ☐ ☐ 7.5.5. you are a reverse 3PL?

☐ ☐ ☐ 7.5.6. you are acting on behalf of a WLS in a circumstance described in Section 7.5.1., 7.5.2., or 7.5.3., above?

☐ ☐ ☐ 7.5.6. you are acting on behalf of another pharmacy in a circumstance described in Section 7.5.2., above?

☐ ☐ ☐ 7.5.7. you are acting on behalf of a manufacturer, and the pharmacy is returning the drugs to the manufacturer? (BPC 4126.5[a], USC 360eee–1[d][1][C])

7.6. Does your business only receive drugs from a clinic if:

If you are a WLS, either:

☐ ☐ ☐ 7.6.1. the clinic originally purchased the drugs from you?

☐ ☐ ☐ 7.6.2. your business is a "reverse distributor"?

☐ ☐ ☐ 7.6.3. The clinic is listed in Section 4180 of the Business and Professions Code, there is a proclaimed state of emergency, and the drugs are needed to alleviate a temporary shortage that could result in the denial of health care. (CCR 1776.5, 1780[e], BPC 4040.5, 4126.5[b][1])

If you are a 3PL, either:

☐ ☐ ☐ 7.6.4. you are storing the drugs for the clinic or otherwise acting on the clinic's behalf?

☐ ☐ ☐ 7.5.5. you are a reverse 3PL?

☐ ☐ ☐ 7.6.5. you are acting on behalf of a WLS in a circumstance described in Section 7.6.1., 7.6.2., or 7.6.3., above?

☐ ☐ ☐ 7.6.5. you are acting on behalf of another clinic in a circumstance described in Section 7.6.3., above?

☐ ☐ ☐ 7.6.6. you are acting on behalf of a manufacturer or pharmacy, and the clinic is returning the drugs to the manufacturer or pharmacy? (BPC 4126.5[a], HSC 10377.8, 21 CFR 211.204, USC 360eee–1[d][1][C])

7.6. Are all drugs that are purchased, sold, or distributed by your business:

Yes No N/A

☐ ☐ ☐ 7.6.1. free of adulteration as defined by the CA Health & Safety Code section 111250 et seq.?

☐ ☐ ☐ 7.6.2. free of misbranding as defined by CA Health & Safety Code section 111335?

☐ ☐ ☐ 7.6.3. **confirmed** to not be past their beyond use date (expired drugs)? (BPC 4169, HSC 111295, 111305, 111440, 111450, USC 360eee–1[c][2])

7.7. List any incidents where adulterated, misbranded or expired drugs were purchased, sold, distributed by this business in the past 2 years.

_____

_____

7.8. If your business sells or distributes dangerous drugs or devices outside of California, either to another state within the United States or a foreign country, do you:

Yes No N/A

☐ ☐ ☐ 7.8.1. comply with all CA pharmacy laws related to the distribution of dangerous drugs or devices?

☐ ☐ ☐ 7.8.2. comply with the pharmacy law of the receiving state within the United States?

☐ ☐ ☐ 7.8.3. comply with the statues and regulations of the Federal Food and Drug Administration and the Drug Enforcement Administration relating to the wholesale distribution of dangerous drugs or devices?

☐ ☐ ☐ 7.8.4. comply with all laws of the receiving foreign country related to the wholesale distribution of dangerous drugs or devices?

☐ ☐ ☐ 7.8.5. comply with all applicable federal regulations regarding the exportation of dangerous drugs or devices? (CCR 1783[a],[b], BPC 4059.5[e], CFR 205.50[i])

7.9. Describe how you determine a business in a foreign country is authorized to receive dangerous drugs or devices.

_____

_____

Yes No N/A

☐ ☐ ☐ 7.10. If preferentially priced drugs are sold by your business, that sale complies with CA Pharmacy Law. (BPC 4380)

Yes No N/A

☐ ☐ ☐ 7.11. Do your business' advertisements for dangerous drugs or devices contain false, fraudulent, misleading or deceptive claims? (BPC 4341, BPC 651, CCR 1766)

☐ ☐ ☐ 7.12. Do you offer or receive any rebates, refunds, commissions or preferences, discounts or other considerations for referring patients or customers? If your business has any of these arrangements, please list with whom. (BPC 650)

_____

_____

☐ ☐ ☐ 7.13. Does your business sell dangerous drugs or devices to the master or first officer of an ocean vessel, after your business has received a written prescription? If so, describe how you comply with the ordering, delivery and record keeping requirements for drugs including controlled substances, and the requirement to notify the board of these sales. (BPC 4066, CFR 1301.25)

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CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

8. Donations of Medication to Voluntary Drug Repository and Distribution Programs

Yes No N/A

☐ ☐ ☐ 8.1. The wholesaler donates medications to a county-approved drug repository and distribution program, provided the following requirements are met: (HSC 150203, 150204)

☐ ☐ ☐ 8.2. No controlled substances shall be donated. (HSC 150204[c][1])

8.3. Drugs that are donated: (HSC 150204[c])

☐ ☐ ☐ 8.3.1. Are unused and unexpired.

Yes No N/A

☐ ☐ ☐ 8.3.2. Have not been adulterated, misbranded, or stored under conditions contrary to standards set by the USP or the product manufacturer.

☐ ☐ ☐ 8.3.3. Have never been in the possession of a patient or individual member of the public.

☐ ☐ ☐ 8.3.4. Are in unopened, tamper-evident packaging or modified unit dose containers with lot numbers and expiration dates affixed.

☐ ☐ ☐ 8.3.5. For donated medications that require refrigeration, are stored, packaged and transported at appropriate temperatures and in accordance with USP standards and pharmacy law. (HSC 150200, 150202[b], 150204[c][2],[3],[d],[i][1],[m])

9. Outgoing Shipments of Drugs

Yes No N/A

☐ ☐ ☐ 9.1. Do you inspect each outgoing shipment to confirm the identity of the drugs and assure the drugs were not damaged while stored by your business? (CCR 1780[d][2], 17 CCR 10377.4[d])

☐ ☐ ☐ 9.2. Does your business use a common carrier (a shipping or delivery company — UPS, US Mail, FedEx, DHL) for delivery of drug orders to your customers? (BPC 4166[a])

9.3. List the common carriers (shipping or delivery companies) you use.

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CORRECTIVE ACTION OR ACTION PLAN _____

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Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

10. Delivery of Drugs

Yes No N/A

☐ ☐ ☐ 10.1. Are all drugs ordered by a pharmacy or another wholesaler delivered by the seller, or on the seller's behalf, to the address of the buyer's licensed premises and signed for and received by a pharmacist or DR where allowed? (BPC 4059.5[a])

Yes No N/A

☐ ☐ ☐ 10.2. Are all drugs ordered by a manufacturer or prescriber delivered by the seller, or on the seller's behalf, to the manufacturer's or prescriber's licensed business address and signed for by a person duly authorized by the manufacturer or prescriber? (BPC 4059.5[d])

☐ ☐ ☐ 10.3. Are all drugs ordered by a hospital ~~are~~ delivered by the seller, or on the seller's behalf, either to the pharmacy premises or to a central receiving area within the hospital? (BPC 4059.5[c])

☐ ☐ ☐ 10.4. If drugs are delivered to a pharmacy when the pharmacy is closed and a pharmacist is not on duty, documents are left with the delivery in the secure storage facility by the seller, or on the seller's behalf, indicating the name and amount of each dangerous drug delivered. (BPC 4059.5[f])

CORRECTIVE ACTION OR ACTION PLAN _____

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11. Controlled Substances

Yes No N/A

☐ ☐ ☐ 11.1. Are there effective controls to prevent theft or diversion of controlled substances? (CFR 1301.71)

☐ ☐ ☐ 11.2. Are DEA requirements for storage of Schedule II controlled substances being met? (Specific requirements are listed in CFR 1301.71-1301.76)

☐ ☐ ☐ 11.3. Are DEA requirements for storage of Schedule III, IV and V controlled substances being met? (Specific requirements are listed in CFR 1301.71-1301.76)

☐ ☐ ☐ 11.4. Is a DEA inventory completed by your business every 2 years for all schedules (II - V) of controlled substances? (CFR 1304.11[a],[c],[e], USC 827)

☐ ☐ ☐ 11.5. Is the biennial record of the DEA inventory required for Schedule II – V controlled substances conducted every 2 years, retained for 3 years? (CFR 1304.11, CCR 1718, 1780[f][2])

☐ ☐ ☐ 11.6. Does the biennial inventory record document that the inventory of controlled substances was taken at the "close of business" or "opening of business." (CFR 1304.11)

☐ ☐ ☐ 11.7. Has the person within your business who signed the original DEA registration, or the last DEA registration renewal, created a power of attorney for each person allowed to order Schedule II controlled substances for this business? (CFR 1305.05)

11.7.1. List the individuals at this location authorized by power of attorney to order controlled substances. (USC 822[a][1], 957[a], CFR 1301.12[b][1], 1301.35[c], 1309.21[a], 1309.23[b][1], 1309.42[b])

_____

_____

Yes No N/A

☐ ☐ ☐ 11.8. Does your business follow employee-screening procedures required by DEA to assure the security of controlled substances? (CFR 1301.76[a], 1301.90, CCR 1776.5[d])

☐ ☐ ☐ 11.9. If any employee of this business possesses, sells, uses or diverts controlled substances, in addition to the criminal liability you must evaluate the circumstances of the illegal activity and determine what action you should take against the employee. (CFR 1301.92)

☐ ☐ ☐ 11.10. Are all controlled substances purchased, sold or transferred by your business, done so for legitimate medical purposes? (HSC 11153.5[a],[b],[c])

☐ ☐ ☐ 11.11. If your business distributes controlled substances through an agent (i.e. detail person), do you have adequate security measures in place to prevent theft or diversion of those controlled substances? (CFR 1301.74[f])

☐ ☐ ☐ 11.12. If a person attempts to purchase controlled substances from your business and the person is unknown to you, you make a good faith effort to determine the person (individual or business) is appropriately licensed to purchase controlled substances. (CFR 1301.74[a])

11.13. Explain how your business determines an unknown business or individual is appropriately licensed to purchase controlled substances.

_____

_____

☐ ☐ ☐ 11.14. If your business uses a common carrier to deliver controlled substances, your business determines the common carrier has adequate security to prevent the theft or diversion of controlled substances. (BPC 4166, CFR 1301.74[f])

☐ ☐ ☐ 11.15. If your business uses a common carrier to deliver controlled substances, are the shipping containers free of any outward indication that there are controlled substances within, to guard against storage or in-transit theft? (CFR 1301.74[e])

Yes No N/A

☐ ☐ ☐ 11.16. Are all Schedule II controlled substances ordered from your business using a fully completed DEA 222 order form? (CFR 1305.03, 1305.06)

☐ ☐ ☐ 11.17. When your business fills orders for Schedule II controlled substances, is the date filled and the number of containers filled recorded on copies 1 and 2 of DEA 222 form? Is copy 1 retained and copy 2 sent to DEA at the close of the month the controlled substance order was filled? (CFR 1305.13[b])

☐ ☐ ☐ 11.18. If a Schedule II controlled substance order cannot be filled, does your business return copy 1 and 2 of the DEA 222 order form to the buyer with a letter indicating why the order could not be filled? (CFR 1305.15)

☐ ☐ ☐ 11.19. When your business partially fills Schedule II controlled substances, is the balance provided within 60 days of the date of the order form? After the final partial filling, is copy 1 retained in your files and copy 2 of the completed DEA 222 order form sent to DEA by the close of that month? (CFR 1305.13[b])

☐ ☐ ☐ 11.20. For all Schedule II controlled substances received by your business, is copy 3 of the DEA 222 order form completed by writing in for each item received, the date received and the number of containers received? (CFR 1305.13[e])

☐ ☐ ☐ 11.21. Does your business use the online CSOS secure transmission system offered by the Drug Enforcement Administration in place of a paper DEA 222 Form for Schedule II controlled substances? (CFR 1305.21, 1305.22)

☐ ☐ ☐ 11.22. Does your business follow the procedure outlined by DEA to obtain Schedule II controlled substances when the original DEA 222 order form is lost or stolen? (CFR 1305.16(a))

☐ ☐ ☐ 11.23. Are all records of purchase and sale for all schedules of controlled substances for your place of business kept on your licensed premises for 3 years from the making? (BPC 4081, CCR 1718, CFR 1304.03, 1305.17[c], 1305.17[a],[b], and HSC 11252, 11253)

☐ ☐ ☐ 11.24. Are records of Schedule II controlled substances stored separate from all others? (CFR 1304.04[f][1])

☐ ☐ ☐ 11.25. Are records for Schedule III-V controlled substances stored so that they are easily retrievable? (CFR 1304.04[f][2])

☐ ☐ ☐ 11.26. Before your business distributes thiafentanil, carfentanil, etorphine HCl, and/or diprenorphine, do you contact the DEA to determine the person (individual or business) is authorized to receive these drugs? (CFR 1301.74(g))

Yes No N/A

☐ ☐ ☐ 11.27. Do you separate records for the sale of thiafentanil, carfentanil, etorphine HCl, and/or diprenorphine from all other records? (CFR 1305.17[d])

☐ ☐ ☐ 11.28. Does the owner of your business notify the DEA, on a DEA 106 form, of any theft or significant loss of controlled substances upon discovery of the theft? (CFR 1301.74[c])

☐ ☐ ☐ 11.29. Does the owner of your business notify the board of any loss of controlled substances within 30 days of discovering the loss? (CCR 1715.6)

☐ ☐ ☐ 11.30. Do you report suspicious orders to the Suspicious Orders Report System (SORS)? Suspicious Orders may include, but is not limited to: an order of a controlled substance of unusual size; an order of a controlled substance deviating substantially from a normal pattern, and; orders of controlled substances of unusual frequency (USC 832[a][3], USC 802[57], CFR 1301.74[b])

CORRECTIVE ACTION OR ACTION PLAN _____

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12. Policies and Procedures

12.1. Does this business maintain and adhere to policies and procedures for the following:

Yes No N/A

☐ ☐ ☐ 12.1.1. Receipt of drugs
☐ ☐ ☐ 12.1.2. Security of drugs
☐ ☐ ☐ 12.1.3. Storage of drugs (including maintaining records to document proper storage)
☐ ☐ ☐ 12.1.4. Inventory of drugs (including correcting inaccuracies in inventories)
☐ ☐ ☐ 12.1.5. Distributing drugs
☐ ☐ ☐ 12.1.6. Identifying, recording and reporting theft or losses
☐ ☐ ☐ 12.1.7. Correcting errors and inaccuracies in inventories (CCR 1780[f], 360eee–1[c][4])

Physically quarantining and separating:

☐ ☐ ☐ 12.1.8. returned, damaged, outdated, deteriorated, misbranded or adulterated drugs
☐ ☐ ☐ 12.1.9. drugs that have been partially used
☐ ☐ ☐ 12.1.10. drugs where the outer or secondary seals on the container have been broken
☐ ☐ ☐ 12.1.11. drugs returned to your business, when there is doubt about the safety, identity, strength, quality, or purity of the drug

Yes No N/A

☐ ☐ ☐ 12.1.12. drugs where the conditions of return cast doubt on safety, identity, strength, quality or purity

☐ ☐ ☐ 12.1.13. drugs that are a suspect or illegitimate product (CCR 1780[e],[f], USC 360eee–1[c][4], USC 360eee–3[d][2][C][i],[iii][VI])

CORRECTIVE ACTION OR ACTION PLAN _____

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13. Training

Yes No N/A

☐ ☐ ☐ 13.1 Are training and experience provided to all employees to assure all personnel comply with all licensing requirements? (CCR 1780[f][4])

List the types of training you have provided to staff in the last calendar year and the dates of that training.

_____

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CORRECTIVE ACTION OR ACTION PLAN _____

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14. Dialysis Drugs

Yes No N/A

☐ ☐ ☐ 14.1. Does your business provide dialysis drugs directly to patients, pursuant to a prescription? (BPC 4054, 4059[c]) If so, please complete the next 4 questions, if not proceed to Section 15.

☐ ☐ ☐ 14.2. Do home dialysis patients complete a training program provided by a dialysis center licensed by Department of Health Services? Prescriber must provide proof of completion of this training to your business. (BPC 4059[d])

☐ ☐ ☐ 14.3. Do you have written or oral orders for authorized dialysis drugs for each dialysis patient being serviced. Are such orders received by either a DR or a pharmacist? Note: Refill orders cannot be authorized for more than 6 months from the date of the original order. (CCR 1787[a],[b],[c])

☐ ☐ ☐ 14.4. Does your business provide an "expanded invoice" for dialysis drugs dispensed directly to the patient including name of drug, manufacturer, quantities, lot number, date of shipment, and name of the DR or pharmacist responsible for

distribution? A copy of the invoice must be sent to the prescriber, the patient and a copy retained by this business. Upon receipt of drugs, the patient or patient agent must sign for the receipt for the drugs with any irregularities noted on the receipt. (CCR 1790)

Yes No N/A

☐ ☐ ☐ 14.5. Is each case or full shelf package of the dialysis drugs dispensed labeled with the patient name and the shipment? Note that additional information as required is provided with each shipment. (CCR 1791)

CORRECTIVE ACTION OR ACTION PLAN _____

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15. Record Keeping Requirements

15.1. If you are a WLS, do you only engage in the following activities under a purchase or sales record that includes the date of sale, your business name and address, the new owner's business name and address, if applicable, and the names and quantities of the drugs sold?

Yes No N/A

☐ ☐ ☐ 15.1.1. Purchase or sale of drugs.

☐ ☐ ☐ 15.1.2. Receipt or distribution of drugs.

☐ ☐ ☐ 15.1.3. Disposal of drugs. (CCR 1783[e], BPC 4059[b], 4081, 4105[a],[c], CFR 205.50[f])

In addition, for drugs that are subject to the Drug Supply Chain Security Act, do you maintain the following records?

☐ ☐ ☐ 15.1.4. When you purchase drugs, the transaction information, transaction history, and transaction statement you receive from the previous owner, as applicable.

☐ ☐ ☐ 15.1.5. When you sell drugs, the transaction information, transaction history, and transaction statement you provide to the subsequent owner, as applicable.

☐ ☐ ☐ 15.1.6. When you investigate drugs that are a suspect product, records of your investigation.

☐ ☐ ☐ 15.1.7. When you dispose of drugs that are an illegitimate product, records of the disposal. (21 USC 360eee-1[c][1][A][v][I])

15.2. If you are a WLS, are records for all activities described in Section 15.1, above, retained on the appropriate licensed premises for the following periods of time?

☐ ☐ ☐ 15.2.1. For records that are not subject to the Drug Supply Chain Security Act, at least **3 years** from the date of making?

☐ ☐ ☐ 15.2.2. For records described in Sections 15.1.4 through 15.1.7, at least **6 years** from the date of the activity? (CCR 1783[e], BPC 4081, 4105[a],[c],

4169[a][5], 4081[a], 4332, 4333, CFR 205.50[e][1],[f][2],[g][4], USC 360eee–3[d][2][C][iii][I],[VII])

15.3. If you are a 3PL:

Yes No N/A

☐ ☐ ☐ 15.3.1. When you receive, ship, or dispose of drugs, do you maintain records of the receipt, shipment, or disposal?

☐ ☐ ☐ 15.3.2. When you distribute drugs to a new owner, is there a purchase and sales record that includes the date of sale, the former owner's business name and address, the new owner's business name and address, and the names and quantities of the drugs sold? (CCR 1783[e], BPC 4059, 4081, 4105[a],[c], 4169[a][5], 4332, USC 360eee–3[d][2][C][iii][I],[VII])

☐ ☐ ☐ 15.4. If you sell or distribute drugs outside of California, either to another state within the United States or a foreign country, do you maintain a guaranty or undertaking, signed by the drugs' supplier, that the drugs are not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act and, if the drugs are a new drug, that the FDA has approved a New Drug Application (NDA) for the drugs? (USC 333[c][2])

☐ ☐ ☐ 15.5. Are all records retained in a readily retrievable form? (BPC 4081, 4105[a], 4332, 4333, CFR 205.50[f])

☐ ☐ ☐ 15.6. Is a current accurate inventory maintained for all dangerous drugs or devices? (BPC 4081, 4332, CCR 1718, CFR 205.50[f])

☐ ☐ ☐ 15.7. If you temporarily remove records from a licensed premises, do you retain on the licensed premises at all times, a photocopy of each record temporarily removed? (BPC 4105[b])

☐ ☐ ☐ 15.8. Are required records stored off-site only if a board issued written waiver has been granted? (BPC 4105[e], CCR 1707[a])

If your business has a written waiver, write the date the waiver was approved and the off-site address where the records are stored below.

Date _____ Address_____

15.9. If an off-site written waiver is in place:

☐ ☐ ☐ 15.9.1. Is the storage area secure from unauthorized access? (CCR 1707[b][1])

☐ ☐ ☐ 15.9.2. Are the records stored off-site retrievable within 2 business days? (CCR 1707[b][2], CFR 205.50[f][3])

Yes No N/A

☐ ☐ ☐ 15.10. Can the records that are maintained electronically be produced immediately in hard copy form by any DR, if the DRIC/RM is not present? (BPC 4105[d][2])

☐ ☐ ☐ 15.11. Are records of training provided to employees to assure compliance with licensing requirements, retained for 3 years? (CCR 1780[f][3],[4], BPC 4082, 4105, CFR 1301.12[b][1], 1301.35[c], 1309.21[a], 1309.23[b][1], USC 822[a][1], 957[a])

☐ ☐ ☐ 15.12. Has the WLS/3PL, this place of business, or the DRIC/RM of this place of business, been cited, fined or disciplined by the board or any other state or federal agency within the last 3 years? If so, list each incident with a brief explanation (BPC 4162[a][5], 4162.5[a][4], 4302, 4307[a], CCR 1702.2[c], 1702.5[a], USC 360eee–3[d][2][E])

_____

_____

☐ ☐ ☐ 15.13. Has the licensed premises received any orders of correction from the board? A copy of the order and the corrective action plan must be on the licensed premises for 3 years. (BPC 4083)

☐ ☐ ☐ 15.14. Has this licensed premises received a letter of admonishment from the board? A copy must be retained on the premises for 3 years from the date of issue. (BPC 4315[f])

☐ ☐ ☐ 15.15. If this licensed premises dispenses dialysis drugs directly to patients, are the prescription records retained for 3 years, including refill authorizations and expanded invoices for dialysis patients? (CCR 1787[c], 1790)

CORRECTIVE ACTION OR ACTION PLAN _____

_____

Note: There are specific requirements for wholesaling, receipt, storage, distribution, and disposal of controlled substances – these additional requirements are in Section 11 of this document.

16. Reporting Requirements to the Board and Federal Agencies

Yes No N/A

☐ ☐ ☐ 16.1. A DRIC/RM who terminates employment at this business, must notify the board within 30 days of the termination. (BPC 4101[b], 4305.5[c])

☐ ☐ ☐ 16.2. The owner must report to the board within 30 days the termination of the DRIC/RM (BPC 4305.5[a])

16.3. A WLS must report to the FDA the following:

☐ ☐ ☐ 16.3.1 In an annual report, the state and license number of each WLS license held by the WLS, the name, address, and contact information of each facility, and all names under which the WLS conducts business.

☐ ☐ ☐ 16.3.2. Any significant disciplinary action taken against the WLS by a state or the federal government. (USC 353[e][2])

16.4. Each facility of a 3PL must report to the FDA the following:

☐ ☐ ☐ 16.4.1. In an annual report, the state and license number of its 3PL license, the name and address of the facility, and all names under which the 3PL conducts business.

☐ ☐ ☐ 16.4.2. The FDA also requests all 3PL facilities to report any significant disciplinary action taken against them by a state or the federal government. (USC 360eee–3[b], FDA Draft Guidance, January 10, 2017, and August 21, 2017)

16.5. A WLS that has investigated drugs that are a suspect product must notify the following parties:

☐ ☐ ☐ 16.5.1. If the drugs are an illegitimate product, the WLS must notify the FDA and the immediate trading partners that it believes may have received the drugs within **24 hours**.

☐ ☐ ☐ 16.5.2. If the drugs are not an illegitimate product, the WLS must promptly notify the FDA before further distributing the drugs. (USC 360eee–1[c][4][A][i],[c][4][B][ii])

☐ ☐ ☐ 16.6. The owner must report to the board within 30 days of discovery, any loss of controlled substances, including amounts and strengths of the missing drugs. (CCR 1715.6)

☐ ☐ ☐ 16.7. The owner must notify the DEA, on a DEA form 106, any theft or significant loss of controlled substances upon discovery. (CFR 1301.74[c])

Yes No N/A

☐ ☐ ☐ 16.8. Do your employees know about their obligation to report any known diversion or loss of controlled substances to a responsible person within your business? (CFR 1301.91)

☐ ☐ ☐ 16.9. The owner must notify the board within 30 days of any change in the beneficial ownership of this business. (BPC 4201[j], CCR 1709[b])

☐ ☐ ☐ 16.10. When called upon by the board, your business can report all sales of dangerous drugs or controlled substances subject to abuse. (BPC 4164[a])

☐ ☐ ☐ 16.11. The wholesaler maintains a tracking system for individual sales of dangerous drugs and devices at preferential or contract prices to pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities. Your system must:

☐ ☐ ☐ 16.11.1. identify pharmacies that primarily or solely dispense prescription drugs to patients of long-term care facilities

☐ ☐ ☐ 16.11.2. identify purchases of any dangerous drugs at preferential or contract prices

☐ ☐ ☐ 16.11.3. identify current purchases that exceed prior purchases by 20 percent over the previous 12 calendar months. (BPC 4164[b])

☐ ☐ ☐ 16.12 I understand that this license is not transferable to a new owner. A change of ownership must be reported to the board, as soon as the parties have agreed to the sale. Before the ownership actually changes, an additional application for a temporary permit must be submitted to the board if the new owner wants to conduct business while the board is processing the change of ownership application and until the new permanent permit is issued. A company cannot transfer the ownership of the business via a contract with another individual or business, without the board's approval (BPC 4201[g])

☐ ☐ ☐ 16.13. The owner of this business must immediately notify the board in writing if any assignment is made for the benefit of creditors, if the business enters into any credit compromise arrangement, files a petition in bankruptcy, has a receiver appointed, or enters into liquidation or any other arrangement that might result in the sale or transfer of drugs. (CCR 1705)

☐ ☐ ☐ 16.14. If this business is discontinued, the owner must notify the board in writing before the actual discontinuation of business. (CCR 1708.2). If the business holds a DEA registration, the owner must notify the DEA promptly of the discontinuation of business and all unused DEA 222 order forms must be returned to the DEA. (CFR 1301.52[a], 1305.14)

Yes No N/A

☐ ☐ ☐ 16.15. If you are a WLS, you must notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler. (BPC 4169.1)

CORRECTIVE ACTION OR ACTION PLAN _____

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17. Additional Licenses/Permits Required

17.1. List all licenses and permits required to conduct this business, including local business licenses, licenses held in other states, permits or licenses required by foreign countries or other entities (BPC 4059.5[e], 4107, CFR 1305.11[a]) Use additional sheets if necessary.

_____

_____

DESIGNATED REPRESENTATIVE-IN-CHARGE / RESPONSIBLE MANAGER CERTIFICATION:

I, (please print) _____, hereby certify that I have completed the self-assessment of this licensed premises of which I am the designated representative-in-charge (DRIC) / responsible manager (RM). I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury that the information contained in this self-assessment form is true and correct.

Signature _____ Date _____
Designated Representative-in-Charge (DRIC) / Responsible Manager (RM)

ACKNOWLEDGEMENT BY OWNER, PARTNER OR CORPORATE 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 could result in the revocation of the premises license issued by the California State Board of Pharmacy.

Signature _____ Date _____

Legal References

The following Legal References are used in the self-assessment form. Many of these references can be viewed on the Board of Pharmacy's internet website at www.pharmacy.ca.gov at the California State Law Library, or at other libraries or internet websites:

Business and Professions Code (BPC), Division 2, Chapter 1 – General Provisions

BPC, Division 2, Chapter 9 – Pharmacy

California Code of Regulations (CCR), Title 16, Division 17 – California State Board of Pharmacy

Code of Federal Regulations (CFR), Title 21, Chapter 2 – Drug Enforcement Administration, Department of Justice

Health and Safety Code (HSC), Division 10 – Uniform Controlled Substances Act

HSC, Division 104, Part 5 (Sherman Food, Drug, and Cosmetics Law, Chapter 6 – Drugs and Devices

HSC, Division 116 – Surplus Medication Collection and Distribution

USC, Title 21, Chapter 9, Subchapter V, Part H – Pharmaceutical Distribution Supply Chain (Drug Supply Chain Security Act)

ATTACHMENT 3

VI. Discussion and Consideration of Proposed Revisions to Self-Assessment Forms

e. Automated Drug Delivery Systems Self-Assessment (17M-112)

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

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715 of Title 16 of the California Code of Regulations, evaluating the pharmacy's compliance with pharmacy law relating to the use of the ADDS. The assessment shall be performed annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in this Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date [CCR 1715.65(c)]: _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____**RPH#**_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:** _____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____
_____

Check off reason for completing self-assessment:

- ☐ **Performing self-assessment annually before July 1 of every year. [BPC 4427.7, CCR 1715.1(a)]**
- ☐ **Completing a self-assessment within 30 days when a new ADDS license was issued. [BPC 4427.7(a), CCR 1715.1(b)(1)]**
- ☐ **Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.2(a), CCR 1715.1(b)(2)]**
- ☐ **Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]**

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

☐☐☐ 1.3 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a

drug room or hospital emergency room when the pharmacy is closed. [BPC 4427.2(i), BPC 4056, BPC 4068]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

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SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)-(a)(11)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

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_____
_____
_____

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.
- The pharmacy's policy and procedures included provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

☐☐☐ 3.5 A prelicensure inspection was conducted within 30 days of a completed application for the ADDS license at the proposed location(s). [BPC 4427.2(e)]
List date(s) of pre-license inspection(s):

_____
_____
_____

☐☐☐ 3.6 The pharmacy is aware a relocation of an ADDS shall require a new application for licensure. [BPC 4427.2(e)]

Yes No N/A

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e)]

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

Yes No N/A

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

☐☐☐ 3.22 The record of quality assurance review, as provided in California Code of Regulation section 1711(e) is immediately retrievable in the pharmacy for at least one year from the date the record was created. [CCR 1711(f)]

☐☐☐ 3.23 Any quality assurance record related to the use of a licensed ADDS is also submitted to the Board within 30 days of completion of the quality assurance review and any facility with an unlicensed ADDS reports the quality assurance review to the Board at the time of annual renewal.

☐☐☐ 3.24 The Pharmacist-in-Charge of **EACH** ADDS must complete a self-assessment of the pharmacy must complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law and is performed [CCR 1715.1(a)(b)]:

- Annually, before July 1 of every year.
- Within 30 days whenever a new ADDS licensed has been issued.
- Within 30 days when there is a change in PIC or he/she becomes the new PIC .
- When there is a change in the licensed location of an ADDS to a new address.

☐☐☐ 3.25 The Pharmacist-in-Charge of an ADDS shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev -----) entitled "Automated Drug Delivery System Self-Assesment and shall be used for all ADDS. [CCR 1715.1(c)]

Yes No N/A

☐☐☐ 3.26 The PIC shall respond "yes", "no" or "not applicable about whether the ADDS is, at the time of the self assessment, in compliance with laws and regulation that apply to that pharmacy setting.

☐☐☐ 3.27 For each "no" response, the PIC shall provide a written corrective action or action plan to come into compliance with the law. [CCR 1715.1(c)(3)]

☐☐☐ 3.28 The PIC initialed each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form. [CCR 1715.1(c)(4)]

☐☐☐ 3.29 The PIC has certified the last page of the self-assessment that he or she is the PIC and has certified a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledged all responses are subject to verification by the Board of Pharmacy. The certification is made under penalty of perjury of the laws of the State of California and 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. [CCR 1715.1(c)(5)]

☐☐☐ 3.30 The ADDS owner has certified the final page of the self-assessment that 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 ADDS license issued by the Board. The certification is made under penalty of perjury of the laws of the State of California with an original handwritten signature or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form. [CCR 1715.1(c)(6)]

☐☐☐ 3.31 Each self-assessment was completed in its entirety and kept on file in the underlying pharmacy for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board. [CCR 1715.1(d)]

☐☐☐ 3.32 Any identified area of noncompliance shall be corrected as specified in the self-assessment. [CCR 1715.1(e)]

☐☐☐ 3.33 The PIC of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite ADDS ensures: [CCR 1715.65(h)]

- All controlled substances added to an ADDS are accounted for;
- Access to the ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

_____
_____
_____
_____

CHECK OFF THE TYPE OF ADDS USED BY THE PHARMACY AND COMPLETE THE FOLLOWING SECTION(S) AS IT APPLIES TO THE TYPE OF ADDS THE PHARMACY IS USING.

Please Note: The Pharmacist-in-Charge of the pharmacy and the owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 ~~– ADDS~~ APDS adjacent to the secured pharmacy area or located in Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6.
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- ☐ SECTION 8 – ADDS operated by a correctional clinic.
- ☐ SECTION 9 - AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (when the hospital pharmacy is closed and no pharmacist is available).
- ☐ SECTION 10 – AUDS located in a licensed general acute hospital facility or a licensed acute psychiatric hospital facility pursuant to HSC 1250(a) or (b) used for dispensing only and exempt from ADDS licensure.

SECTION 4: APDS USED TO PROVIDE PHARMACY SERVICES TO COVERED ENTITIES AND MEDICAL PROFESSIONALS CONTRACTED WITH A COVERED ENTITY

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 4.1 A Covered Entity May Contract with Pharmacy to Provide Services- The operating pharmacy providing pharmacy services to the patients of the covered entity, including, unless prohibited by any other law, patients enrolled in the Medi-Cal program, shall be under contract with the covered entity as described in BPC section 4126 to provide those pharmacy services through the use of the APDS. [BPC 4119.11(a)(2)]

☐☐☐ 4.2 Contracts between the covered entities and the pharmacy shall comply with the guidelines published by the Health Resources and Services Administration and are available for inspection by Board during normal business hours. [BPC 4126(a)]

Yes No N/A

☐☐☐ 4.3 Drugs purchased and received pursuant to section 256b of Title 42 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

☐☐☐ 4.13 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11), CCR 1713(f)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____
☐ Annual; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

☐☐☐ 4.16 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records will be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.17 The pharmacy is aware that the drugs stored in an APDS are a part of the operating pharmacy's drug inventory and the drugs dispensed by the APDS shall be considered to have been dispensed by that pharmacy. [BPC 4119.11(a)(3)]

Yes No N/A

☐☐☐ 4.18 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

☐☐☐ 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]

☐☐☐ 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐☐☐ 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

☐☐☐ 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐☐☐ 4.27.1 The pharmacy has developed, ~~and~~ implemented and maintain written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F), CCR 1713(e)(1)-(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS

- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients~~,~~ including when consultation is needed.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.27.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

☐☐☐ 4.27.3 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to the patient.

☐☐☐ 4.27.4 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3), CCR 1713(d)(3)]

☐☐☐ 4.27.5 The pharmacist has performed all clinical services as part of the dispensing process including but not limited to drug utilization review and consultation. [BPC 4119.11(d)(4)]

☐☐☐ 4.27.6 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]

☐☐☐ 4.27.7 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4119.11(d)(6), CCR 1713(d)(3)]

- The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon request of a patient.

Yes No N/A

☐☐☐ 4.27.8 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐☐☐ 4.27.9 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

☐☐☐ 4.27.10 Any complaint, error or omission involving the APDS shall be reviewed as a part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4119.11(d)(9), CCR 1713(d)(4)]

☐☐☐ 4.28 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.29 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]

☐☐☐ 4.30 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.31 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and

electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

☐☐☐ 4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA OR LOCATED IN MEDICAL OFFICES~~.~~ OR OTHER LOCATION WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT AND THE APDS IS ONLY USED TO DISPENSE DANGEROUS DRUGS AND DEVICES TO PATIENT OF THE PRACTION.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains the APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4427.6(l), CCR 1713(f)]

☐☐☐ 5.2 The pharmacy developed and implemented, and reviewed annually the APDS written policy and procedures pertaining to the APDS, including: [BPC 4427.6(a)]

- Maintaining the security of the APDS and the dangerous drugs and devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients~~.~~, including when consultation is needed.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medications, including those delivered via the APDS.
- Describing assignment of responsibilities to, and training of, pharmacy personnel and other personnel using the APDS at the location where the APDS is placed, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patients when expected prescription medications are not available in the APDS, and ensuring patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Yes No N/A

☐☐☐ 5.3 The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4427.6(k)] List of current APDS licenses:

1._____2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 5.4 A pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 5.5 Drugs are dispensed from the APDS only upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 5.6 The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS. The consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities. [BPC 4427.6(f), CCR 1713(d)(3)]

☐☐☐ 5.7 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following:

[CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: _____
☐ Annual; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 5.9 The stocking of the APDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an APDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the APDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 5.10 Access to the APDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 5.11 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 5.12 Drugs and devices not immediately transferred into an APDS upon arrival at the APDS location are stored for no longer than 48 hours in a secured room within the APDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 5.13 Drugs stored in the APDS are part of the inventory of the operating pharmacy and drugs dispensed by the APDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

Yes No N/A

☐☐☐ 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

☐☐☐ 5.15 The pharmacist determined each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of prescription medication to the patient. [CCR 1713(d)(1)

☐☐☐ 5.16 The APDS has a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4427.6(c)]

☐☐☐ 5.17 The APDS has a notice, prominently posted on the APDS, which provides the name, address, and phone number of the pharmacy. [BPC 4427.6(g)]

☐☐☐ 5.18 Any incident involving the APDS where a complaint, error, or omission occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i), CCR 1713(d)(4)]

☐☐☐ 5.19 If the APDS is located and operated in a medical office or other location where patients are regularly seen for purposes of diagnosis and treatment, the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice. [BPC 4427.6(j)]

☐☐☐ 5.20 The labels on all drugs and devices dispensed by the APDS comply with section 4076 and with section 1707.5 of Title 16 of the California Code of Regulations. [BPC 4427.6(h)]

☐☐☐ 5.21 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.22 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]

☐☐☐ 5.23 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.24 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.25 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 5.26 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4427.6 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4427.7(b)]

☐☐☐ 5.27 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 5.28 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.29 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.30 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6 (a)(3)]

Yes No N/A

☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

☐☐☐ 6.2 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6 (d)(1)]

☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]

☐☐☐ 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]

☐☐☐ 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]

☐☐☐ 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]

☐☐☐ 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

☐☐☐ 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS are accounted for;

- Access to ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

☐☐☐ 6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.11 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.14 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

Yes No N/A

☐☐☐ 6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed

the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:

Yes No N/A

☐☐☐ 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]

☐☐☐ 6.21 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), HSC 1261.6(f)(4)]

☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]

☐☐☐ 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in

place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]

Yes No N/A

☐☐☐ 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

☐☐☐ 6.29 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

Yes No N/A

☐☐☐ 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]

☐☐☐ 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 The pharmacist has determined that each patient using the APDS meets inclusion criteria for the use of the APDS established by the pharmacy prior to delivery of prescription medication to the patient. [CCR 1713(d)(1)]

Yes No N/A

☐☐☐ 7.4 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.5 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.6 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.7 The clinic shall keep records of the kind and amounts of drugs purchased, administered, and dispensed and the records shall be available and maintained for a minimum of three years for inspection by all authorized personnel. [BPC 4180(a)(2)]

☐☐☐ 7.8 The proposed ADDS installation location meets the requirement of BPC 4427.3 and the ADDS is secure from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

☐☐☐ 7.9 The clinics licensed under BPC 4180 or BPC 4190 perform periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. [CCR 1715.65(a)]

☐☐☐ 7.10 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

☐☐☐ 7.11 The clinic shall report in writing identified drug losses and known cause to the Board within 30 days of discovery. Cases of the loss is due to theft, diversion or self-use shall be reported to the Board within 14 days of discovery. If the clinic is unable to identify the cause of loss, further investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. [CCR 1715.65(d)]

☐☐☐ 7.12 The individuals performing the inventory AND the clinic professional director shall date and sign the inventory reconciliation reports. The reports shall be readily retrievable at the clinic for 3 years. [CCR 1715.65(e)]

Yes No N/A

☐☐☐ 7.13 Any incident involving the APDS where a complaint, error, or omission has occurred is reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125. [BPC 4427.6(i), CCR 1713(d)(4)]

☐☐☐ 7.14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.15 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]

☐☐☐ 7.16 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.17 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 7.18 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 7.19 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.20 Does the pharmacy have no more than 15 ADDS licensed as APDS units? [BPC 4427.6(k)]
List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITY

Yes No N/A

☐☐☐ 7.21 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.22 Drugs are removed from the ADDS system only upon the authorization of the pharmacist after the pharmacist has reviewed the prescription and patient profile for potential contraindications and adverse drug reactions. [BPC 4186(b)]

☐☐☐ 7.23 The pharmacist shall conduct a review on a monthly basis including a physical inspection of the drugs in the ADDS for cleanliness and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4186(d)]

Date of Last Review: _____

☐☐☐ 7.24 The pharmacist licensed by the board performs all clinical services conducted as part of the dispensing process, including, but not limited to, drug utilization review and consultation. [BPC 4427.6(d)]

☐☐☐ 7.25 Drugs are dispensed from the APDS after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.6(e)]

☐☐☐ 7.26 All prescribed drugs and devices dispensed to the patient from an APDS for the first time shall be accompanied by a consultation conducted by a pharmacist licensed by the board via telecommunication link with a two-way audio and video. [BPC 4427.6(f)]

☐☐☐ 7.27 The APDS has a notice, prominently posted on the APDS, with the name, address, and phone number of the pharmacy holding the ADDS license for the APDS. [BPC 4427.6(g)]

☐☐☐ 7.28 The pharmacist shall provide patient consultation pursuant to CCR 1707.2 via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS. In addition, the pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of the patient [BPC 4186(e)]

☐☐☐ 7.29 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

Yes No N/A

☐☐☐ 7.30 The clinic consultant pharmacist shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. The clinic shall develop written policies and procedures for performing the inventory reconciliation reports. (CCR 1715.65(b))

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.31 The pharmacy has developed and implemented, and reviewed annually, written policies and procedures pertaining to the APDS, including all the following: [BPC 4427.6(a), CCR 1713(e)(1)-(6)]

- Maintaining the security of the APDS and dangerous drugs and dangerous devices within the APDS.
- Determining and applying inclusion criteria regarding which drugs and devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware consultation with a pharmacist is available for any prescription medication, including those delivered via the APDS.
- Describing assignments of responsibilities to, and training of, pharmacy personnel, and other personnel using the APDS at the location where the APDS is placed pursuant to subdivision (b) of section 4427.3, regarding maintenance and filing procedures for the APDS.
- Orienting participating patients on the use of the APDS, notifying patient when expected prescription medications are not available in the APDS, and ensuring the patient use of the APDS does not interfere with delivery of drugs and devices.
- Ensuring delivery of drugs and devices to patients expecting to receive them from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐☐☐ 7.32 Is the APDS only used for patients who have signed a written consent form demonstrating their informed consent to receive prescribed drugs and devices from an APDS, and whose use of the APDS meets inclusion criteria established by policies and procedures. [BPC 4427.6(b)]

☐☐☐ 7.33 The APDS shall have a means of identifying each patient and only release the identified patient's drugs and devices to the patient or patient's agent. [BPC 4427.6(c), CCR 1713(d)(2)]

Yes No N/A

☐☐☐ 7.34 The pharmacy holding the ADDS license for an APDS maintains its policies and procedures for three (3) years after the last date of use of an APDS. [BPC 4427.6(l)]

☐☐☐ 7.35 Does the pharmacy maintain all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintain these records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

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SECTION 8: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

Yes No N/A

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

☐☐☐ 8.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

Yes No N/A

☐☐☐ 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

☐☐☐ 8.14 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

☐☐☐ 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

☐☐☐ 8.22 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

Yes No N/A

☐☐☐ 8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 9: AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states he/she intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a),(f)]

☐☐☐ 9.2 The prescriber in a hospital emergency room dispenses drug from the AUDS when the hospital pharmacy is closed and there is no pharmacist available in the hospital. The drugs are acquired by the hospital pharmacy. The dispensing information is recorded and provided to the

pharmacy when the pharmacy reopens. The hospital pharmacy retains the dispensing information. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available at the time of dispensing to the patients. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. [BPC 4068(a)(1)(2)(3)(4)(5)(6)]

Yes No N/A

☐☐☐ 9.3 The prescriber ensures the label on the drug contains all the information required by BPC 4076, CCR 1707.5

☐☐☐ 9.4 The federal warning labels prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 9.5 The prescription drug is 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 request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 9.6 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4069(a)(4), HSC 11165(d)]

☐☐☐ 9.7 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 9.8 The hospital has written policies and procedures to ensure each patient receive information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 10 – AUDS LOCATED IN A LICENSED GENERAL ACUTE HOSPITAL FACILITY OR A LICENSED ACUTE PSYCHIATRIC HOSPITAL FACILITY PURSUANT TO HSC 1250(A) AND (B(USED FOR DISPENSING ONLY AND EXEMPT FROM ADDS LICENSURE.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 10.1 The AUDS operated by a licensed hospital pharmacy, as defined in Section 4019 of Business and Professions Code and is used solely to provide doses administered to patients while in a licensed general acute hospital facility or a licensed acute psychiatric hospital facility is exempt from obtaining an ADDS license and the AUDS must comply with all other requirements for an ADDS. [BPC 4427.2(i)]

☐☐☐ 10.2 The AUDS is exempt from the requirements of obtaining an ADDS license if the licensed hospital pharmacy owns or lease the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS. [BPC 4427.2(i)]

☐☐☐ 10.3 The licensed hospital pharmacy must maintain a list of the locations of each AUDS it operates and shall make the list available to the Board upon request. [BPC 4427.7(i)]

☐☐☐ 10.4 The PIC of an inpatient hospital pharmacy ensures the following: [CCR 1715.56(g)(1)-(4)]

- All controlled substances added to an ADDS are accounted for;
- Access to the ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed;
- Confirmed losses of controlled substance are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE

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CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. 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 _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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 could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. 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 _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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 could result in the revocation of the pharmacy's license issued by the California State Board of Pharmacy.

Signature _____Date _____

Attachment 4

STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY • GOVERNOR GAVIN NEWSOM

LEGAL AFFAIRS DIVISION
1625 N. Market Blvd., Suite S 309, Sacramento, CA 95834
P (916) 574-8220 F (916) 574-8623 | www.dca.ca.gov

MEMORANDUM

DATE	October 20, 2020
TO	Maria Serpa, Chair of Enforcement and Compounding Committee via Anne Sodergren, Executive Officer California State Board of Pharmacy
FROM	Eileen Smiley, Attorney III
SUBJECT	Alternative Enforcement Model

The purpose of this memorandum is to discuss and analyze the proposed alternative enforcement model that is under consideration by the Board. The purpose of this proposal is to attempt to settle some cases before an operative pleading is filed to achieve time and costs savings to the Board and licensees or applicants.

Latest Proposal

The latest proposal is to add section 4300.2 to the Business and Professions Code (BPC). All section references in this memorandum refer to the proposed section 4300.2 of the BPC. The current proposal encompasses two board members (one professional member and one public member) participating in settlement negotiations after completion of an investigation but prior to the filing of an operable pleading. To participate in the process, the licensee must agree to waive the administrative adjudication provisions of the Administrative Procedure Act (Act). The licensee then may submit mitigation and rehabilitation evidence as specified in the board's Disciplinary Guidelines. The proposed model establishes time deadlines to complete a Stipulated Settlement and Disciplinary Order based on the findings of the investigation. If the parties cannot agree to the terms of the Stipulated Settlement and Disciplinary Order within the time periods set out in paragraph 5 of the proposal, the staff may proceed with filing the appropriate disciplinary pleading.

Sections 2 and 3 of the Proposal

Currently, after completion of the investigation, enforcement staff provides the licensee with its findings of violation(s) including some of the evidence found and provides the licensee with 14 days to provide additional information as part of the investigative process. Upon receipt of any additional information provided by the licensee, the enforcement staff evaluates the findings. Supervising and

executive staff review the matter and determine whether to refer the matter to the Office of the Attorney General. This part of the investigative process will not change.

Under proposed section 4300.2(3), the licensee would have 15 days after being advised that a matter will be referred to the Office of the Attorney General to indicate in writing their desire to participate in this process and waive the provisions of the Administrative Procedure Act (Act). Proposed section 4300.2(3) should be amended to reflect that the 15-day election period begins after a licensee is informed that a referral will be made to the Office of the Attorney General. Respondents may waive their rights under the Act, but such a waiver must be an informed waiver and signed by the licensee. Generally, the Accusation or Statement of Issues sets out the alleged conduct in greater detail and stipulated settlements generally refer to the operative pleading for the details to ensure a licensee is making an informed waiver of the rights under the Act. The staff might have to create a new document that provides more detail than the notice of violation(s) typically given to licensees during the investigative process. This new document will serve as the disclosure document that a potential respondent would receive to constitute an informed waiver of the rights afforded by the Act. Also, although an Accusation may not have to be drafted, the Stipulated Judgment will have to incorporate in some fashion the causes of action resulting in the stipulated settlement presumably by the Attorney General's office, which will entail some of the same attorney costs to draft as an Accusation. If time and cost savings are of primary importance, then this process may not realize complete cost savings, especially if settlement is not reached through this alternative enforcement process as the Board would be incurring additional enforcement-related costs.

Section 4 of the Proposal

Paragraph 4 of proposed section 4300.2(4) provides that licensees should submit evidence of rehabilitation and mitigation to facilitate settlement. Implicit in this statement is that the licensee must admit, for purposes of this process, the violations alleged. If a licensee wants to challenge factual matters or the application of the law to the facts determined during the investigation then the case should go through the process under the Act. The waiver signed by the licensee should explicitly state that for purposes of this process, the licensee is admitting the allegations as found during the investigation. The waiver should also explicitly state that any admission to the findings cannot be used against the licensee in later proceedings if the parties fail to agree on a Stipulated Judgment and Disciplinary Order (Settlement).

The proposal does not specify how mitigation and rehabilitation evidence will be submitted - solely through a paper process or some type of hearing. From an evidentiary standpoint and monitoring purposes, a paper process is preferable to show new policies or changes implemented as a result of the violations found. Because a committee of the Board would be involved, if there is a hearing component such hearing must be conducted in public during a public meeting, although deliberation on the matter would occur in closed session. Also, inclusion of a hearing component raises issues such as who will conduct the hearing, what evidentiary rules would apply and whether statements or

evidence considered by the Committee are admissible if the parties cannot reach agreement on a Settlement. As the hearing is conducted in public, arguably a judge would be required to swear in witnesses and preside over the hearing. Further, a public record of the hearing would be made. Typically, under the Act, matters between attorneys through the settlement process are not public. That could change with a hearing component. As a practical matter, if the hearing conducted via the alternative enforcement model does not result in a Settlement, or the Board subsequently non-adopts a stipulated settlement, under the proposal, the matter will transition to the APA process. Legal issues could arise at this point. Specifically, the public record created through the alternative enforcement model exists. Typically, an administrative law judge presiding over a disciplinary matter is not privy to settlement negotiations or other relevant information to ensure impartiality. A hearing component also would raise practical issues of the evidentiary and probative value of statements made by Committee members that may not reflect the Board's overall opinion on the matter and whether evidence introduced at a first hearing that may not be relevant to an adjudication under the Act. Evidence from the first hearing could unduly complicate the record at the later disciplinary proceeding and on appeal if a writ is filed appealing the administrative decision.

In addition to the issues raised above, it appears that inclusion of a hearing also runs contrary to the stated policy goals of the alternative model - - to reduce costs and the time of resolving certain matters. If the parties cannot agree on a Settlement, inclusion of a hearing component would impose additional costs on the board and potentially to the licensee in permissible cost recovery from having two hearings on the same matter. It could also delay ultimate determination of the matter.

Time Delays

Because one purpose of the proposal is to reduce the delay in resolving some matters, there should be hard deadlines for the licensee to submit mitigation and rehabilitation evidence (Section 2) which is currently silent. Section 5 provides that the Stipulated Judgment and Disciplinary Order must be agreed to within 60 days of the licensee's signed waiver but gives the committee the power to extend this time period. This power should be used sparingly or it could result in significant time delays if the parties do not agree to a Settlement.

Recusal Issues-Participating Board Members

Paragraph 7 of proposed section 4300.2 provides that if a Settlement is reached that the participating board members in the process would be recused from voting on the approval of the final Stipulated Settlement and Disciplinary Order. However, the proposed section is silent about the recusal of the participating board members from participating in voting on a later disciplinary proceeding if the parties do not agree to a Settlement. The participating board members in the settlement process should be recused from both voting on any agreed Settlement and in a later proceeding if the parties fail to agree to a Settlement because of their participation in the settlement process. As a practical

matter, this could raise quorum issues if other board members in a case must recuse themselves for other reasons.

Conclusion

Although, counsel does not see any legal prohibitions in including an alternate method of resolving uncontested matters in an expeditious manner prior to filing an Accusation or Statement of Issues if the appropriate statutory changes are made, as outlined above, there are some legal issues and practical considerations issues that must be considered before implementing such a proposal that includes board members as well as a hearing component.

Attachment 5

MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED HUMAN DRUG PRODUCTS BETWEEN THE [insert STATE BOARD OF PHARMACY OR OTHER APPROPRIATE STATE AGENCY] AND THE U.S. FOOD AND DRUG ADMINISTRATION

I. PURPOSE

This Memorandum of Understanding (MOU) establishes an agreement between the [insert State Board of Pharmacy or other appropriate State agency] and the U.S. Food and Drug Administration (FDA) regarding the distribution of inordinate amounts of compounded human drug products interstate[1] and the appropriate investigation by the [insert State Board of Pharmacy or other appropriate State agency] of complaints relating to human drug products compounded in [insert State] and distributed outside such State.[2] This is the MOU provided for by section 503A(b)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 353a), and does not apply to veterinary drug products, biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262), and drugs that are compounded by outsourcing facilities under section 503B of the FD&C Act.

II. BACKGROUND

a. Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist or licensed physician to be exempt from three sections of the FD&C Act requiring:

    1. Compliance with current good manufacturing practice (section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B));

[1] For purposes of this MOU, see the definitions of "inordinate amounts" and "distribution of compounded human drug products interstate" (also referred to as "distributed interstate") in Appendix A.

[2] As described herein, the State Board of Pharmacy or other appropriate State agency signatory is agreeing to take certain actions as described in Section III below. For example, if a State Board of Pharmacy signs the MOU, the State Board of Pharmacy agrees to take the actions described in Section III below with respect to drugs compounded by pharmacies in that State; in addition, the State Board of Pharmacy agrees that if it receives information about complaints or becomes aware of information about drugs compounded by physicians in the State and distributed interstate, it will forward the information to FDA and the appropriate State regulator of physicians as described in Section III.

2. Labeling with adequate directions for use (section 502(f)(1) (21 U.S.C. 352(f)(1)); and

3. FDA approval prior to marketing (section 505 (21 U.S.C. 355)).

b. To qualify for these exemptions, a compounded human drug product must, among other things,[3] meet the conditions in section 503A(b)(3)(B) of the FD&C Act, under which the drug product is compounded in a State that:

1. Has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State (section 503A(b)(3)(B)(i)); or

2. Has not entered into an MOU with FDA and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (section 503A(b)(3)(B)(ii)).

c. Section 503A(b)(3) of the FD&C Act directs FDA to develop a standard MOU, in consultation with the National Association of Boards of Pharmacy (NABP), for use by the States in complying with section 503A(b)(3)(B)(i). This MOU is the standard MOU developed by FDA for this purpose.

III. SUBSTANCE OF AGREEMENT

a. Investigation of Complaints Relating to Compounded Human Drug Products Distributed Outside the State

1. The [insert State Board of Pharmacy or other appropriate State agency] will investigate complaints of adverse drug experiences and product quality issues[4] relating to human drug products compounded at a pharmacy in [insert State] and distributed outside the State. Any investigations will be performed pursuant to the [insert State Board of Pharmacy or other appropriate State agency]'s established investigatory policies and procedures, including those related to prioritizing complaints, provided they are not in conflict with the terms of this MOU.

[3] To qualify for the exemptions under section 503A, a compounder must obtain a prescription for an individually identified patient (section 503A(a) of the FD&C Act). This MOU does not alter this condition.
[4] For purposes of this MOU, see the definitions of "adverse drug experience" and "product quality issue" in Appendix A.

2. Any investigations performed by the [insert State Board of Pharmacy or other appropriate State agency] under this MOU will include taking steps to assess (1) whether there is a public health risk associated with the compounded drug product; and (2) whether any public health risk associated with the product is adequately contained.

3. After the [insert State Board of Pharmacy or other appropriate State agency]'s investigation, if the complaint is substantiated, the [insert State Board of Pharmacy or other appropriate State agency], in accordance with and as permitted by State law, will take the action that the [insert State Board of Pharmacy or other appropriate State agency] considers to be appropriate and warranted to ensure that the relevant pharmacy investigates the root cause of the problem that is the subject of the complaint and undertakes sufficient corrective action to address any identified public health risk relating to the problem, including the risk that future similar problems may occur.

4. The [insert State Board of Pharmacy or other appropriate State agency] will maintain records of the complaint about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy, the investigation of the complaint, and any response to or action taken as a result of the complaint, beginning when the [insert State Board of Pharmacy or other appropriate State agency] receives notice of the complaint. The [insert State Board of Pharmacy or other appropriate State agency] will maintain these records for at least 3 years. The 3-year period begins on the date of final action on a complaint, or the date of a decision that the complaint requires no action.

5. As soon as possible, but no later than 5 business days after receiving a complaint involving a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will, by submission to an Information Sharing Network[5] or by email to StateMOU@fda.hhs.gov, provide FDA with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.i-iii).[6]

[5] For purposes of this MOU, see the definitions of "serious adverse drug experience," "serious product quality issue," and "Information Sharing Network" in Appendix A.

[6] The information includes the following: (i) Name and contact information of the complainant, if available; (ii) Name and address of the pharmacy that is the subject of the complaint; and (iii) Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

6. After the [insert State Board of Pharmacy or other appropriate State agency] concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will share with FDA, as described in the Submission and Disclosure of Information section of this MOU (section III.c.1.a.iv-v),[7] the results of the investigation as permitted by State law.

7. If the [insert State Board of Pharmacy or other appropriate State agency] receives a complaint involving an adverse drug experience or product quality issue relating to a human drug product compounded by a physician and distributed outside the State, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will also notify FDA by submission to an Information Sharing Network or by sending an email to StateMOU@fda.hhs.gov with the information described in the Submission and Disclosure of Information section of this MOU (section III.c.2.a.-c), if available, as soon as possible, but no later than 5 business days, after receiving the complaint.

b. Distribution of Inordinate Amounts of Compounded Human Drug Products Interstate[8]

1. For purposes of this MOU, a pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of:

(i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus

(ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the

[7] The information includes: (i) [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and (ii) Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

[8] The distribution of inordinate amounts of compounded human drug products interstate is a threshold for the [insert State Board of Pharmacy or other appropriate State agency] to identify and report certain information to FDA, not a limit on the distribution of compounded human drug products interstate.

facility in which they were compounded during that same calendar year.

Figure 1. Calculating an Inordinate Amount

$$\frac{A}{B} = X, \text{ where:}$$

A = Number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year

B = The sum of the number of prescription orders for compounded human drug products (i) that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year

If *X* is greater than 0.5, it is an inordinate amount and is a threshold for certain information identification and reporting under the MOU.

2. On an annual basis, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using surveys, reviews of records during inspections, data submitted to an Information Sharing Network, or other mechanisms available to the [insert State Board of Pharmacy or other appropriate State agency], pharmacies that distribute inordinate amounts of compounded human drug products interstate.

3. For pharmacies that have been identified as distributing inordinate amounts of compounded human drug products interstate during any calendar year, the [insert State Board of Pharmacy or other appropriate State agency] will identify, using data submitted to an Information Sharing Network or other available mechanisms, during that same calendar year:
    a. the total number of prescription orders for sterile compounded human drugs distributed interstate;
    b. the names of States in which the pharmacy is licensed;
    c. the names of States into which the pharmacy distributed compounded human drug products; and
    d. whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

4. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, notify FDA of such pharmacy, through an Information Sharing Network or by email to StateMOU@fda.hhs.gov, and will include the

information described in the Submission and Disclosure of Information section of this MOU (section III.c.1.b).

5. If the [insert State Board of Pharmacy or other appropriate State agency] becomes aware of a physician who is distributing any amount of compounded human drug products interstate, the [insert State Board of Pharmacy or other appropriate State agency] will notify the appropriate regulator of physicians within the State. The [insert State Board of Pharmacy or other appropriate State agency] will, within 30 business days of identifying a physician who is distributing any amount of compounded human drug products interstate, also notify FDA by submission to an Information Sharing Network or by email to StateMOU@fda.hhs.gov.

c. Submission and Disclosure of Information
    1. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a pharmacy and distributed outside the State, or regarding distribution of inordinate amounts of human drug products compounded by a pharmacy interstate, the following minimum information will be included. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

        a. Complaints:

            i. Name and contact information of the complainant, if available;

            ii. Name and address of the pharmacy that is the subject of the complaint;

            iii. Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint;

            iv. [Insert State Board of Pharmacy or other appropriate State agency]'s assessment of whether the complaint was substantiated, if available; and

            v. Description and date of any actions the [insert State Board of Pharmacy or other appropriate State agency] has taken to address the complaint.

        b. Inordinate Amounts:

i. Name and address of the pharmacy that distributed inordinate amounts of compounded human drug products interstate;

ii. The number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year;

iii. The number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year;

iv. The total number of prescription orders for compounded human drug products distributed interstate during that same calendar year;

v. The total number of prescription orders for sterile compounded human drug products distributed interstate during that same calendar year;

vi. The names of States in which the pharmacy is licensed and the names of States into which the pharmacy distributed compounded human drug products during that same calendar year; and

vii. Whether the [insert State Board of Pharmacy or other appropriate State agency] inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients during that same calendar year.

2. When submitting information using StateMOU@fda.hhs.gov regarding complaints relating to human drug products compounded by a physician, or regarding distribution of any amount of human drug products compounded by a physician interstate, the following minimum information will be included, if available. Note, this information can be submitted to an Information Sharing Network for sharing with FDA.

   a. Name and contact information of the complainant or notifier;

   b. Name and address of the physician that is the subject of the complaint or notification; and

c. Description of the complaint or notification, including a description of any compounded human drug product that is the subject of the complaint or notification.

3. The parties to this MOU will share information consistent with applicable statutes and regulations. The parties recognize that a separate agreement under 21 CFR 20.88 may be necessary before FDA can share information that is protected from public disclosure. Such an agreement will govern FDA's sharing of the following types of information:

- Confidential commercial information, such as information that would be protected from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA) (5 U.S.C. 552(b)(4));

- Personal privacy information, such as information that would be protected from public disclosure under Exemption 6 or 7(C) of the FOIA (5 U.S.C. 552(b)(6) and(7)(C)); or

- Information that is otherwise protected from public disclosure by Federal statutes and their implementing regulations (e.g., the Trade Secrets Act (18 U.S.C. 1905), the Privacy Act (5 U.S.C. 552a), other FOIA exemptions not mentioned above (5 U.S.C. 552(b)), the Health Insurance Portability and Accountability Act (Public Law 104-191), and FDA's regulations in parts 20 and 21 (21 CFR parts 20 and 21)).

FDA agrees that information provided to FDA by the [insert State Board of Pharmacy or other appropriate State agency] will only be disclosed consistent with applicable Federal law and regulations governing the disclosure of such information, including the FOIA (5 U.S.C. 552(b)), the FD&C Act (21 U.S.C. 301 et seq.), 21 U.S.C. 331(j), 21 U.S.C. 360j(c), the Trade Secrets Act (18 U.S.C. 1905), FDA's regulations in 21 CFR parts 20 and 21, and other pertinent laws and regulations.

IV. ENFORCEMENT AUTHORITIES AND LEGAL STATUS OF AGREEMENT

The parties to this MOU recognize that FDA and the [insert State Board of Pharmacy or other appropriate State agency] retain the statutory and regulatory authorities provided by the FD&C Act, other Federal statutes and attendant regulations, and State statutes and regulations. The parties also recognize that this agreement does not restrict FDA or any other Federal agency from taking

enforcement action, when appropriate, to ensure compliance with Federal statutes, including the FD&C Act and attendant regulations, or prevent the [insert State Board of Pharmacy or other appropriate State agency] from taking enforcement action, as appropriate, to ensure compliance with applicable State statutes and regulations. This MOU does not create or confer any rights for or on any person. By signing this MOU, the [insert State Board of Pharmacy or other appropriate State agency] affirms that it now possesses and will maintain, at the discretion of the State legislature, the legal authority (under State statutes and/or regulations) and the resources necessary to effectively carry out all aspects of this MOU. If State law changes such that the [insert State Board of Pharmacy or other appropriate State agency] no longer has the legal authority or resources necessary to effectively carry out all aspects of this MOU, the [insert State Board of Pharmacy or other appropriate State agency] will notify FDA within 60 calendar days of the change in legal authority.

V. NAME AND ADDRESS OF PARTICIPATING AGENCIES

U.S. Food and Drug Administration
Center for Drug Evaluation and Research
Office of Compliance
Office of Unapproved Drugs and Labeling Compliance
10903 New Hampshire Avenue
Bldg. 51, Suite 5100
Silver Spring, MD 20993-0002
Telephone: (301) 796-3110
Email: StateMOU@fda.hhs.gov

[Insert State Board of Pharmacy or other appropriate State agency and its contact information]

Upon signing the MOU, each party must designate one or more liaisons to act as points of contact. Each party may designate new liaisons at any time by notifying the other party's liaison(s) in writing. If, at any time, an individual designated as a liaison under this agreement becomes unavailable to fulfill those functions, the parties will name a new liaison within 2 weeks and notify the other party's liaison(s).

VI. PERIOD OF AGREEMENT

a. When accepted by both parties, this MOU will be effective from the date of the last signature and will continue until terminated by either party. It may be terminated in writing by either party, upon a 60 calendar day notice of termination. Notice of termination will be sent to the address listed in section V of this MOU.

b. If the [State Board of Pharmacy or other appropriate State agency] does not adhere to the provisions of this MOU, including conducting an investigation of complaints related to compounded human drug products distributed outside the State, the MOU may be terminated upon a 60 calendar day notice of termination.

In case of termination, FDA will post a notice of the termination on its Web site and the [insert State Board of Pharmacy or other appropriate State agency] will notify all pharmacies that compound drug products in the State and notify the State authority that licenses or regulates physicians of the termination and advise them that as of 60 calendar days from the date of the posting of the termination notice, compounded human drug products may be distributed (or caused to be distributed) out of the State only "in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed" by the licensed pharmacy or physician (section 503A(b)(3)(B)(ii) of the FD&C Act).

VII. APPROVALS

APPROVED AND ACCEPTED FOR THE U.S. FOOD AND DRUG ADMINISTRATION	APPROVED AND ACCEPTED FOR [insert State Board of Pharmacy or other appropriate State agency]
By (Type Name)	By (Type Name)
Title	Title
Date	Date

Appendix A. Definition of Terms for the Purposes of this MOU

- **Adverse Drug Experience**: Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action (21 CFR 310.305(b)).

- **Distribution of compounded human drug products interstate**: Means that a pharmacy or physician has sent (or caused to be sent) a compounded drug product out of the State in which the drug was compounded.

- **Information Sharing Network:** An information sharing network designated by FDA for purposes of this MOU to collect, assess, and allow review and sharing of information pursuant to this MOU.

- **Inordinate Amounts**: A pharmacy has distributed an inordinate amount of compounded human drug products interstate if the number of prescription orders for compounded human drug products that the pharmacy distributed interstate during any calendar year is greater than 50 percent of the sum of: (i) the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year; plus (ii) the number of prescription orders for compounded human drug products that were dispensed (e.g., picked up by a patient) at the facility in which they were compounded during that same calendar year.[9]

- **Product Quality Issue**: Information concerning (1) any incident that causes the drug product or its labeling to be mistaken for, or applied to, another article; or (2) any bacteriological contamination; any significant chemical, physical, or other change or deterioration in the distributed drug product; or any failure of one or more distributed batches of the drug product to meet the applicable specifications (21 CFR 314.81(b)(1)). Contamination in general, including but not limited to mold, fungal, bacterial, or particulate contamination, is a product quality issue.

- **Serious Adverse Drug Experience**: Any adverse drug experience occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital

[9] The definition of *inordinate amounts* in this MOU is separate and distinct from and should not be used in relation to the term *inordinate amounts* as it is used in section 503A(b)(1)(D) of the FD&C Act (pertaining to compounding a drug product that is essentially a copy of a commercially available drug product). The interpretation of this term in each instance necessarily is based on the particular context of the distinct provisions within 503A in which the term appears.

anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse (21 CFR 310.305(b)).

- **Serious Product Quality Issue**: Any product quality issue that may have the potential to cause a serious adverse drug experience (e.g., possible contamination, superpotent product).

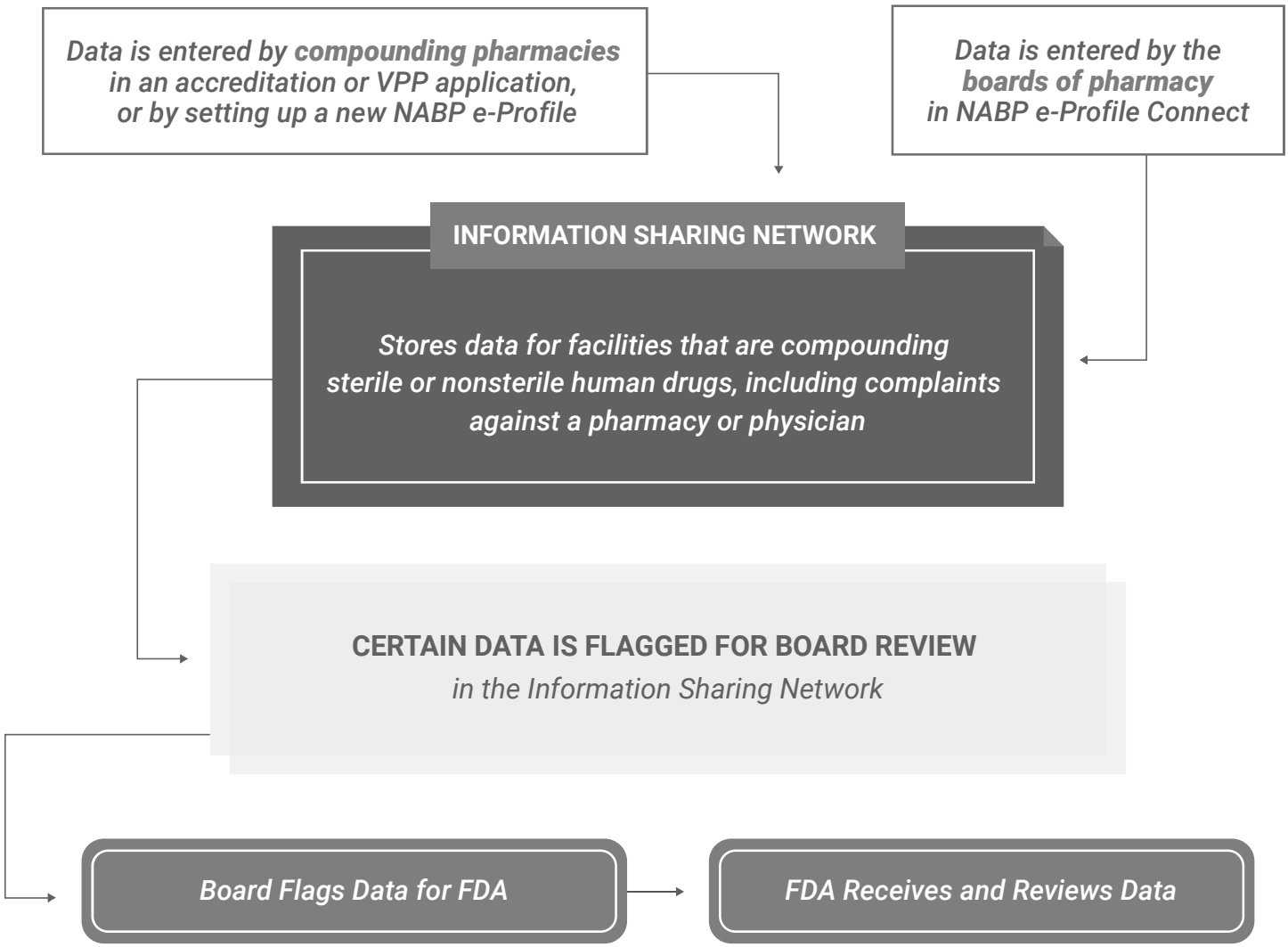
Collect and Share Compounding Data With NABP's Information Sharing Network

NABP's Information Sharing Network helps state boards of pharmacy collect, manage, and share data related to compounding pharmacies with Food and Drug Administration (FDA). Access to the network is free and allows your board to meet the obligations outlined in the memorandum of understanding (MOU) on compounded human drug products.

PATHWAYS FOR DATA ENTRY

& the flow of data through NABP e-Profile Connect

Developed as an expansion of NABP e-Profile Connect, the Information Sharing Network will be available for boards of pharmacy to begin entering data in early 2021.



Visit *www.nabp.pharmacy/Compounding-Project* for more information on how the Information Sharing Network works or to access the FDA MOU.

Data Collected

The Information Sharing Network collects the following pharmacy and complaint data.

General Pharmacy Information – Entered by the Pharmacy or the Board

- Name and address of state-licensed entity
- Whether the pharmacy participates in the following activities during an identified calendar year:
  - Human drug compounding — sterile or nonsterile
  - Patient-specific or non-patient-specific compounding
- If a pharmacy is compounding sterile or nonsterile human drug products, additional data is collected related to licensing, prescription orders, and distribution numbers

Complaint Information – Entered by the Board

Complaints of adverse drug experiences or product quality issues relating to human drug products that are compounded by a physician and distributed interstate are also entered by the board. Data collected includes:

- Name and contact information of the complainant or notifier
- Description of the complaint, including a description of any compounded human drug product that is the subject of the complaint
- The board's assessment of whether the complaint was substantiated, if available
- Description of any actions that the board has taken to address the complaint

Complaints of adverse drug experiences, product quality issues, or distribution of human drug products that are compounded by a physician are also entered by the board.

For a complete list of data collected in the Information Sharing Network, visit ***www.nabp.pharmacy/Compounding-Project.***

Data for Board Review

The Information Sharing Network flags data for the boards of pharmacy to review based on certain criteria.

- Pharmacies that are compounding human drug products and distributing inordinate amounts interstate.
- Complaints of serious adverse experiences or quality issues relating to drugs compounded by pharmacies and distributed interstate.
- Complaints of adverse experiences or quality issues relating to drugs compounded by a physician and distributed interstate.

By logging in to e-Profile Connect, *https://dashboard.clearinghouse/* the boards can review and submit the information to FDA with the click of a button.

Sending Data to FDA

Boards must submit the required information to FDA in accordance with the timelines outlined in the MOU, which can be as little as five days depending on the type of complaint.

A list of the data transmitted to FDA and the associated timelines can be found at *www.nabp.pharmacy/Compounding-Project.*

Nutrishare, Inc.
The Home TPN Pharmacy

January 8, 2020

Gregory N. Lippe, President
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Re: FDA Final Standard Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products

FDA Docket No. FDA–2018–N–3065

Federal Register Doc. 2020-10336, 5/14/2020

Dear President Lippe,

I am writing on behalf of Nutrishare, Inc. to raise a matter of vital concern for the continuation of our operations in California. In sum, I am writing to urge the California Board of Pharmacy to participate in the Food and Drug Administration (FDA) *Memorandum of Understanding (MOU) Addressing Certain Distributions of Compounded Human Drug Products,* which seeks to better track the distribution of compounded pharmacological products across state lines.

For background, Nutrishare is a 503(a) compounding pharmacy that provides life-sustaining nutrition support known as Total Parenteral Nutrition (TPN) to our family of long-term, stable consumers. Our consumers suffer from a number of underlying etiologies, such as Short Bowel Syndrome, which renders them unable to absorb nutrients via oral or tube feeding. In order to sustain life, TPN is administered intravenously via a centrally placed catheter in the consumer's chest.

For nearly thirty years we have provided TPN to over 500 consumers with an ongoing need for continuing, highly specialized nutrition support. To date, we have shipped over 1 million bags of TPN across state lines without a single incident of contamination or a single adverse effect to a consumer. The TPN we provide to our consumers is compounded on location in Elk Grove, California, by our staff of pharmacists and pharmacy technicians in collaboration with our consumers physicians.

Our consumers vary in age, physical ability, caloric and nutritional needs, and each prescription is compounded to custom specifications as ordered by their physician. Our pharmacy practice is highly specialized, and only a handful of pharmacies in the country are currently capable of meeting the needs of long term TPN consumers. For this reason, our Elk Grove location continually ships to our consumers in 34 other states.

Nutrishare® Inc.
The Home TPN Pharmacy

The FDA is seeking to define 503(a) pharmacy operations that distribute an "inordinate" amount of compounded sterile medications across state lines in order to be able to better trace outbreaks stemming from contaminated compounded medications. In states that sign the MOU, the FDA will simply require additional information collection when a 503(a) compounding pharmacy ships more than 50% of its total distributed / dispensed medications across state lines. However, 503(a) pharmacies that are located in states that do not sign the MOU will have a hard cap of 5% total allowable compounded medications to be shipped across state lines.

To be clear, there is no way that Nutrishare would be able to continue to operate in our current capacity in any state that does not sign the MOU. Our TPN is highly specialized and compounded specifically to meet the needs of each individual consumer. Only a handful of pharmacies in the country have the capability to provide this service. Due to our specialized nature, we must ship across state lines in order to continue to operate in California.

Without state participation in the MOU, our operations would be severely impacted and our consumers will face uncertainty as their choice in providers is severely restricted. For these reasons I urge you to please sign the MOU when the policy is implemented by the FDA. Thank you for your time and attention to this vitally important matter. Please do not hesitate to reach out to me if you have any questions regarding our position on this important matter. I can be reached directly at rod@nutrishare.com or via mobile phone at (916) 956-4611.

Sincerely,

Rodney Okamoto
President,
Nutrishare, Inc.

Cc: Members, California State Board of Pharmacy

CALIFORNIA
9850 Kent Street, Elk Grove, California 95624
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Attachment 6

Insanitary Conditions at Compounding Facilities

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

November 2020
Compounding and Related Documents

Insanitary Conditions at Compounding Facilities

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance

November 2020
Compounding and Related Documents

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Guidance for Industry[1]
Insanitary Conditions at Compounding Facilities

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

I. INTRODUCTION

Under section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351(a)(2)(A)), a drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health . . ."[2] Drug products prepared, packed, or held under insanitary conditions could become contaminated and cause serious adverse events, including death.

Under sections 503A and 503B of the FD&C Act (21 U.S.C. 353a and 353b), compounded human drug products can qualify for exemptions from specified provisions of the FD&C Act if certain conditions are met. However, neither section provides an exemption from section 501(a)(2)(A) of the FD&C Act. Drugs (including biological products) prepared, packed, or held (hereinafter referred to as "produced") under insanitary conditions are deemed to be adulterated, regardless of whether the drugs qualify for exemptions set forth in sections 503A or 503B of the FD&C Act.

This guidance describes examples of insanitary conditions that FDA has observed. This guidance specifically addresses drugs (including biological products) produced by pharmacies, federal facilities, and outsourcing facilities that compound or repackage drugs, or that mix, dilute, or repackage biological products.[3] For purposes of this guidance, we refer to such entities as "compounding facilities."

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research, in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] *Insanitary conditions* are conditions that could cause a drug to become contaminated with filth or rendered injurious to health. The drug itself need not actually be contaminated. A drug that is actually contaminated with any filthy, putrid, or decomposed substance is deemed to be adulterated under section 501(a)(1) of the FD&C Act (21 U.S.C. 351(a)(1)).

[3] At this time and based on our current understanding of the risks, FDA generally does not intend to take action under section 501(a)(2)(A) against a physician who is compounding a drug product, repackaging an FDA-approved drug product, or who is mixing, diluting, or repackaging an FDA-licensed biological product, provided that such production by the physician occurs in the physician's office for in-office administration, to his or her individual patients.

FDA is issuing this guidance to help compounding facilities and state regulatory agencies understand some examples of what FDA considers to be insanitary conditions that could cause a drug product to become contaminated or rendered injurious to health. These examples are intended to help compounding facilities prevent the occurrence of these and other insanitary conditions. This guidance is also intended to help compounding facilities identify and remediate such insanitary conditions when they already exist.

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

II. BACKGROUND

FDA has investigated numerous outbreaks of infections and deaths found to be the result of drug products that were contaminated because they were produced under insanitary conditions. Most notably, in 2012, injectable drug products produced by a compounding facility and shipped across the country caused a fungal meningitis outbreak that resulted in more than 750 cases of infection and 60 deaths. FDA has investigated numerous other serious adverse events, including deaths, associated with contaminated drug products produced by compounding facilities, and it is likely that adverse events are underreported.

Since the 2012 fungal meningitis outbreak, FDA has identified insanitary conditions at many of the compounding facilities that it has inspected, and numerous compounding facilities have voluntarily recalled drug products intended to be sterile and temporarily or permanently ceased sterile operations because of those findings. FDA routinely inspects outsourcing facilities.[4] There are also numerous state-licensed pharmacies in the United States engaged in compounding, repackaging drugs, or mixing, diluting, or repackaging biological products that do not register as outsourcing facilities with FDA. Generally, state boards of pharmacy have primary responsibility for the day-to-day oversight of state-licensed pharmacies that are not registered as outsourcing facilities. While FDA conducts inspections of such state-licensed pharmacies, it does not inspect the vast majority of them unless, for example, FDA receives a complaint, such as a report of a serious adverse event or product quality issue. As a result, the Agency is often not aware of these pharmacies, their conditions and practices, and potential problems with the quality and safety of their drug products.

Regardless of whether a facility is routinely inspected by FDA, it is critical that both state-licensed pharmacies and outsourcing facilities prevent the occurrence of insanitary conditions within their facilities. Upon identification, insanitary conditions should be remediated before the conditions result in drug contamination and patient injury.

[4] See section 503B(b)(4) of the FD&C Act.

In addition, to protect the public health, both FDA and state regulatory agencies may take action when compounding facilities produce drugs under insanitary conditions. Based on its inspections, FDA determines whether compounding facilities produce drugs under insanitary conditions in violation of section 501(a)(2)(A) of the FD&C Act, and if so, the Agency may initiate regulatory action. However, compounding facilities that are not registered with FDA as outsourcing facilities are primarily overseen by the states and, as explained above, generally are not routinely inspected by FDA. FDA strongly encourages state regulatory agencies to assess during inspections whether compounding facilities that they oversee engage in poor practices, including those described below. Where insanitary conditions are identified, FDA encourages states to take appropriate action, consistent with state laws and regulations, and to contact FDA.

III. POLICY

Section III.A of this guidance provides examples of conditions that FDA has observed at one or more compounding facilities it has inspected and considers to be insanitary conditions under section 501(a)(2)(A) of the FD&C Act. **These examples do not constitute an exhaustive list of insanitary conditions that could be present in a compounding facility; other conditions not described in this guidance may also be considered insanitary**.

Section III.B of this guidance describes corrective actions that compounding facilities should take when they identify insanitary conditions. It also describes actions that are recommended to prevent the occurrence of insanitary conditions. Of note, this section includes a list of particularly concerning conditions that FDA has observed. When these particular insanitary conditions are identified, FDA strongly recommends that a facility immediately recall purportedly sterile drugs and cease sterile operations until these insanitary conditions have been remediated.

Finally, section III.C of this guidance discusses regulatory actions FDA may take in response to insanitary conditions we identify at a compounding facility. Although FDA expects all insanitary conditions to be remediated in a timely manner, FDA considers the entire set of conditions at the facility, including any aggravating and mitigating factors, as well as evidence of timely and appropriate remediation activities, when determining the type of regulatory action to take against a compounding facility.

Note that the examples of insanitary conditions described in this guidance for products intended to be sterile can exist in cleanroom and associated controlled environments, as well as segregated compounding areas (SCAs), as described in United States Pharmacopeia (USP) Chapter <797> (USP <797>). FDA has significant sterility assurance concerns regarding sterile compounding within an International Standard Organization (ISO) 5 area located within an unclassified space. However, at this time and based on our current understanding of the risks, when a compounding facility other than an outsourcing facility produces drugs in an SCA, FDA generally does not intend to take action with respect to certain conditions described in this guidance identified with an asterisk (*), provided that the compounding facility: (1) complies with all criteria for an SCA in USP <797>; (2) assigns beyond-use-dates that do not exceed 12 hours when stored at room temperature and 24 hours when refrigerated or frozen; and (3) does not have any additional insanitary conditions.

A. Examples of Insanitary Conditions[5]

Although product sterility is not a requirement for non-sterile drugs, it is possible for non-sterile drugs to become contaminated with microorganisms of a type or at a level that can cause patient harm. Non-sterile aqueous solutions are particularly susceptible to microbial growth if contaminated. Contamination may also include non-viable filth and the presence of unintended drug components.

The following are examples of insanitary conditions that have been observed and are applicable to both sterile and non-sterile drug production and applicable to the production of sterile drugs only. These examples do not constitute an exhaustive list.

1. Insanitary Conditions Applicable to the Production of Sterile and Non-Sterile Drugs

- Vermin (e.g., insects, rodents) or other animals (e.g., dogs) or evidence of their presence (e.g., urine, feces) in the production area[6] or adjacent areas
- Visible microbial contamination (e.g., bacteria, mold) in the production area or adjacent areas
- Foreign matter in the production area (e.g., rust, glass shavings, hairs, paint chips)
- Producing drugs while construction is underway in a nearby area without adequate controls to prevent contamination of the production area and product
- Standing water or evidence of water leakage in the production area or adjacent areas
- Handling bulk drug substances or drug products that are hazardous, sensitizing, or highly potent (e.g., hormones) with inadequate controls to prevent cross-contamination. This includes:
    - inadequate dedication, segregation, and containment (e.g., a powder-containment hood) of a suite, room, or piece of equipment based on risk;
    - inadequate cleaning of rooms, work surfaces, and equipment (e.g., utensils), including spills;
    - inadequate segregation of HVAC systems (as appropriate for the operation); and
    - inadequate control over the movement of personnel and materials

[5] Note that USP <797> provides descriptions of select terms used in this section, including buffer room and anteroom.

[6] For the purpose of this guidance, *production area* includes, with respect to sterile compounding any ISO classified area or SCA, and with respect to non-sterile compounding, any room or area in which non-sterile compounding occurs.

- Processing of beta-lactams without complete and comprehensive separation from non-beta-lactam products[7]

- Using active ingredients, inactive ingredients, or processing aides, that have or may have higher levels of impurities compared to compendial or pharmaceutical grade equivalents (e.g., ingredients with potentially harmful impurities, ingredients labeled with "not for pharmaceutical use" or an equivalent statement)

2. Insanitary Conditions Applicable to the Production of Sterile Drugs Only

a. Gowning and Aseptic Practices

- Engaging in aseptic processing wearing nonsterile gown components (e.g., gloves)

- Putting on gowning apparel in a way that may cause the gowning apparel to become contaminated. This includes, for example:
  - gowning in non-classified areas*
  - allowing gowning apparel (except for foot covers) to touch the floor, or other surface area that could cause apparel to be contaminated, or
  - putting on sterile gloves improperly (e.g., touching the outside of a glove with bare hands)

- Failing to disinfect or change gloves frequently enough given the nature of the operations to prevent contamination. This includes, for example, gloves exiting and re-entering the ISO 5 area without changing or sanitizing them, touching a non-sterile object and returning to compounding without first changing or sanitizing gloves, cleaning up after a spill without changing gloves when returning to compounding, and not changing the sterile gloves when glove integrity may have been compromised

- Engaging in aseptic processing after leaving the cleanroom and re-entering from a non-classified area without first replacing gowning apparel (e.g., gowns, mask, goggles, foot covers, gloves)[8]*

- Performing aseptic manipulations with exposed hair or skin (e.g., on hands, wrists, forehead, mouth, or legs)

- Performing aseptic manipulations outside of a certified ISO 5 area (or area of higher quality air)

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[7] For the purposes of this guidance, "processing of beta-lactams" does not refer to mixing, reconstituting, or other such acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling [at the immediate point of dispensing for administration to the intended patient].

[8] Note that personnel moving in and out of the cleanroom without regowning may bring contaminants from non-classified areas into the cleanroom.

- Conducting aseptic manipulations in an area where the movement of "first air"[9] in the ISO 5 area is blocked or disrupted (e.g., by equipment, supplies, or operator manipulations)[10,11]

- Exposing sterile drugs and materials to lower than ISO 5 quality air. This would include, for example, exposing partially stoppered drug products or stock solutions in a container/closure system that is not fully closed (airtight), and open packages of sterile wipes

- Failing to disinfect containers of sterile drug components or supplies immediately prior to opening for any use in operations

- Failure to use pre-sterilized or sterilized primary containers and closures to fill sterile products

- Using a non-sterile tool, manually contacting the inner surface of a sterile container or closure, or manually touching a product contact surface

    - This includes, for example, touching the top of an open container, or the lower side or bottom of a closure during manual stoppering (e.g., hand stoppering)[12]

- Moving quickly in a critical area or in an area immediately adjacent to a critical area[13] such that unidirectional airflow is likely to be disrupted[14]

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[9] *First air* means air that is from a HEPA filter and that has not yet contacted any items/surfaces.

[10] Note that if unidirectional air over the critical surface is blocked, the area is no longer protected. If it is blocked by personnel conducting aseptic manipulations, contamination on personnel could be introduced to the critical area.

[11] At this time and based on our current understanding of the risks, FDA generally does not intend to object to the temporary blocking or disruption of first air in the ISO 5 area when necessary for the safe handling of radiopharmaceuticals, such as the placement of a shielding material for the radiopharmaceutical in the ISO 5 area.

[12] Note that this could contaminate the drug in the vials even with the use of sterile gloves and appropriate glove sanitization.

[13] A *critical area* is an area designed to maintain sterility of sterilized materials. Sterilized product, containers or closures, and equipment may be exposed in critical areas. The ISO 5 area is the critical area, and the terms are used interchangeably throughout this guidance.

[14] Note that while conducting aseptic manipulations, ISO 5 airflow must be unidirectional to protect the product from contaminating particles. Quick movement of personnel disrupts the airflow and increases the risk of bringing lesser quality air into the ISO 5 area. At this time and based on our current understanding of the risks, FDA generally does not intend to object to the temporary blocking or disruption of first air in the ISO 5 area when necessary for the safe handling of radiopharmaceuticals, such as rapid movement, as appropriate to minimize radiation exposure.

- Staging open sterile vials within the critical area without protective cover longer than needed for the process of filling drug product

b. Equipment/Facilities

- Microbial contamination in the ISO 5 area

- Lack of adequate routine environmental monitoring[15]

  - This includes nonviable airborne particulate sampling; viable airborne particulate sampling; and surface sampling, including but not limited to equipment, work surfaces, and room surfaces

- Lack of adequate personnel sampling (including glove fingertip sampling)

- Lack of routine and rigorous certification of the ISO 5 area, including smoke studies performed under dynamic conditions[16]

- A facility designed or operated in a way that permits the influx of lesser quality air into a higher quality air area

  - This includes, for example:
    - inadequate pressure differentials between areas of higher quality air and lower quality air*
    - material flow directly between an unclassified area and a room in which sterile compounding is conducted (e.g., unclassified pass-through)*
    - an ISO 5 area open to the surrounding area with minimal or no physical barriers separating it from non-aseptic activities (e.g., weighing of non-sterile materials, gowning, container labeling)*
    - air returns located next to the high efficiency particulate arrestance (HEPA) filter rather than near the floor*
    - an open door or series of open doors between an uncontrolled area and the room in which sterile compounding is conducted*

- Failure to detect and adequately address a change in air quality (e.g., through the environmental monitoring program) of any classified area before there is a loss of environmental control that may impact drug sterility

[15] Note that environmental monitoring provides information on the quality of the aseptic processing environment. If the results reflect a poor quality aseptic processing environment, the compounding facility should promptly identify potential routes of contamination and perform corrective actions.

[16] Note that if the ISO 5 area is not periodically re-certified or does not pass all certification requirements, there is insufficient assurance that the ISO 5 area filters are functioning and delivering the quality of air intended.

- No or infrequent measurement of room pressure differentials during operations to demonstrate proper airflow (i.e., airflow from areas of higher quality air to adjacent areas with lower quality air)*
- A pattern of frequent or acute pressure reversals from areas of less clean air to areas of higher air cleanliness
- A lack of HEPA-filtered air, or inadequate HEPA filter coverage or airflow, over the critical area
- HEPA filters that are not sealed around the perimeter[17]
- Rooms not properly classified for the activities conducted within them
- Unsealed or loose ceiling tiles in production areas
- Production areas or equipment that are difficult to clean or contain porous, particle-generating, or visibly dirty (e.g., rusty) equipment or surfaces (e.g., shelving, floors, walls, doors, ceilings)
- Buffer room or ISO 5 areas that contain overhangs or ledges capable of collecting dust (e.g., utility pipes and horizontal surfaces, such as windowsills)
- The presence of sinks, drains, or water sources in the buffer room where the ISO 5 area is located; the presence of floor drains in the anteroom[18]
- The presence of equipment unnecessary for aseptic operations, particularly particle-generating equipment, in the ISO 5 area
- Equipment within or in close enough proximity to the ISO 5 area that could compromise the air in the ISO 5 area
- Exposing sterile products to non-sterile or non-depyrogenated supplies (e.g., transfer tubing, temporary bulk containers)
- Using lyophilizers that are not sterilized by routine sterilization cycles and protected from contamination by sterilizing filters on vacuum break air lines/vents

[17] Note that the air entering the cleanroom needs to be HEPA filtered to remove airborne particles. If HEPA filters are not sealed, air that is not HEPA filtered could enter the cleanroom.

[18] Note that sinks and drains are sources of microbial contamination.

c. Sterilization

- Using a filter for the purposes of product sterilization that is not appropriately graded for sterilization, not appropriate for pharmaceutical use, or used in excess of its volume or pressure capacity

- Using a filter in drug production whose integrity is compromised; failing to conduct post-use filter-integrity testing on filters used to sterilize products

- Using a particle-shedding filter in any stage of sterile drug production

- Using parameters for sterilization (e.g., temperature, pressure, and time) that are not lethal to resistant microorganisms

d. Cleaning and Disinfecting

- Using non-sterile disinfecting agents and cleaning pads/wipes in ISO-classified areas

- Lack of, improper, or infrequent use of a sporicidal agent in the facility's ISO 5 areas and other classified areas

- Failing to appropriately and regularly clean and disinfect (or sterilize) equipment located in the ISO 5 area

- Lack of disinfection of equipment and/or supplies at each transition from areas of lower quality air to areas of higher quality (e.g., from non-classified to first classified room, from anteroom to buffer room, from buffer room to ISO 5 area)

- Using disinfectant in a manner insufficient to achieve adequate levels of disinfection (e.g., using insufficient disinfectant contact time (also known as "dwell time"), concentration, or coverage of the item/surface being disinfected)

- Using sterile cleaning and disinfecting agents past their expiry date or "discard after opening" date

- Using cleaning and disinfecting agents that may leave residues or not adequately rinsing such agents from containers, closures, or equipment that come into direct contact with drugs

e. Other Insanitary Conditions

- Allowing operators with topical or respiratory infections or with open wounds to work within compounding operations

- Compounding with components, containers (e.g., in-process or finished), or other materials that have not been verified to assure that they do not contribute endotoxin contamination that may be objectionable given the product's intended use

- Compounding under processing conditions that offer insufficient assurance that the finished product will meet an endotoxin specification appropriate for its route of administration

- Failure to conduct media fills that closely simulate aseptic production operations under the worst-case, most-challenging and stressful conditions

B. Preventative and Corrective Actions for Insanitary Conditions

It is critical that all compounding facilities prevent the occurrence of any insanitary conditions within their facility (including those not included as examples in this guidance). Prevention of insanitary conditions begins with the identification of risks associated with a process, procedure, or facility. Risk management tools[19] offer a way to evaluate risk and to develop controls designed to prevent the occurrence of insanitary conditions within a compounding facility. In the event that insanitary conditions occur, having adequate monitoring and other management controls should facilitate the identification of insanitary conditions before the conditions result in drug contamination and patient harm. FDA recommends that compounding facilities consider consulting a third party with relevant drug production expertise to conduct this risk assessment and to help develop appropriate controls.

Upon identifying insanitary conditions, a compounding facility should immediately assess the impact of the insanitary conditions on drug products produced. The compounding facility's assessment should include an evaluation of how widespread the insanitary conditions are and over what period of time the conditions have existed, as well as the lots of drug product that remain on the market that could be affected.

The compounding facility should also determine whether to cease production of drug products until the conditions have been corrected and whether to initiate a recall[20] of all potentially affected lots on the market within expiry. Below is a list of insanitary conditions that FDA has observed and considers to be particularly serious. If any one of these conditions exists, FDA strongly recommends that a compounding facility immediately initiate a recall of purportedly sterile drugs and cease sterile operations until the condition has been corrected.

- Vermin (e.g., insects, rodents) or other animals (e.g., dogs) in ISO 5 areas or areas immediately accessible to production

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[19] Examples of risk management tools can be found in the ICH guidance for industry *Q9 Quality Risk Management* (June 2006) at https://www.fda.gov/media/71543/download. We update guidances periodically. For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[20] Subpart C of Part 7 of FDA regulations (21 CFR 7.40–59) provides guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at FDA's request.

- Visible microbial growth (e.g., bacteria, mold) in the ISO 5 area or in adjacent areas
- Sources of foreign matter in the ISO 5 area (e.g., rust, glass shavings, hairs, paint chips)
- Performing aseptic manipulations outside of a certified ISO 5 area or area of higher quality air
- Personnel aseptic practices that are a contamination hazard to an exposed sterile drug product or its constituent sterile components
- Exposing sterile drugs and materials to lower than ISO 5 quality air for any length of time. This would include, for example, exposing partially stoppered drug products or stock solutions in a container/closure system that is not fully closed (airtight), and open packages of sterile wipes.
- Cleanroom areas with unsealed or loose ceiling tiles
- Production of drugs while construction is underway in a nearby area without adequate controls to prevent contamination of the production area and product
- A pattern of frequent or acute pressure reversals from areas of less clean air to areas of higher air cleanliness
- Using a filter for the purposes of product sterilization that is not appropriately graded for sterilization, not appropriate for pharmaceutical use, or used in excess of its volume or pressure capacity
- Using parameters for sterilization (e.g., temperature, pressure, time) that are not lethal to resistant microorganisms

If a compounding facility decides to initiate a product recall, we recommend that it document the implementation of the recall in accordance with the facility's procedures and immediately notify its local FDA Drug Division recall coordinator.[21] We also recommend that the compounding facility notify the applicable state regulatory body in the state(s) to which the facility ships drugs, consistent with state laws and guidance.

In addition to the immediate actions recommended above, if a compounding facility identifies insanitary conditions, it should comprehensively assess its operations, including facility design, procedures, personnel, processes, materials, and systems, as applicable to prevent the occurrence of insanitary conditions within its facility. FDA recommends that the facility consider consulting a third party with relevant drug production expertise to conduct this comprehensive evaluation and to help implement appropriate corrective actions.

[21] *See* guidance for industry *Product Recalls, Including Removals and Corrections* (March 2020).

Compounding facilities producing purportedly sterile drug products under insanitary conditions should not rely upon or cite a passing sterility test result as an indication of product sterility. Microbial contamination, when present, is not uniformly distributed within a batch; therefore, it may not be identified in a sterility test.[22] Compounding facilities must correct all insanitary conditions at their facility regardless of whether the drugs pass a sterility test.[23]

C. Regulatory Action

If a compounding facility produces drugs under insanitary conditions, the facility and responsible individuals may be subject to several regulatory actions, including, but not limited to, a warning letter, seizure of product, or injunction. FDA may also recommend that the facility initiate a recall of some or all of its drugs and cease operations until the insanitary conditions have been adequately addressed. The applicable state regulatory agency may also pursue regulatory action against the facility under applicable state authorities.

[22] USP Chapter <71> concerning sterility testing states, "[t]hese Pharmacopeial procedures are not by themselves designed to ensure that a batch of product is sterile or has been sterilized. This is accomplished primarily by validation of the sterilization process or of the aseptic processing procedures."

[23] See section 501(a)(2)(A) of the FD&C Act.

Attachment 7

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

January 2017
Compounding and Related Documents
Revision 1

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

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Compounding and Related Documents
Revision 1

Contains Nonbinding Recommendations

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Guidance for Industry[1]

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

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

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or Agency) interim regulatory policy concerning compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act). Section 503A of the FD&C Act includes certain restrictions on the bulk drug substances that can be used in compounding and directs FDA to develop a list of bulk drug substances that can be used in compounding under that section. FDA is developing this list of bulk drug substances (the 503A bulks list), and this guidance describes FDA's interim regulatory policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians that compound human drug products using bulk drug substances while the list is being developed.[2,3]

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

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded from bulk drug substances for use in animals. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances*.

> All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[3] FDA is developing a separate list of bulk drug substances that can be used in compounding under section 503B of the FD&C Act. Because section 503B contains different criteria for that list and provides for a different process for its development, the section 503B bulks list is covered under a separate guidance (see guidance for industry, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act*).

II. BACKGROUND

A. Compounding From Bulk Drug Substances Under Section 503A of the Act

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and section 501(a)(2)(B) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist, or licensed physician compounds the drug product using bulk drug substances that:

1. Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or
3. If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.[4]

A bulk drug substance is defined as meaning "the same as active pharmaceutical ingredient as defined in 21 CFR 207.1(b)." See 21 CFR 207.3. Active pharmaceutical ingredient is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body," but the term "does not include intermediates used in the synthesis of the substance" (see section 503A(b)(1)(A) and 21 CFR 207.3).[5,6] FDA has interpreted "an applicable USP or NF

[4] See Section 503A(b)(1)(A)(i) of the FD&C Act.

[5] Section 503A references the definition of bulk drug substances in FDA's drug establishment registration and listing regulations, which was codified at 21 CFR 207.3(a)(4) when section 503A was enacted. On August 31, 2016, FDA published a final rule in the Federal Register to update its registration and listing regulations in Part 207, which made minor changes to the definition of bulk drug substance and moved the definition to 21 CFR 207.3 *See* 81 FR 169 (August 31, 2016). Under the previous definition, bulk drug substance was defined to mean "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances."

[6] Inactive ingredients are not subject to section 503A(b)(1)(A)(i) or the policies described in this guidance because they are not included within the definition of a bulk drug substance. *See* 21 CFR 207.3. Pursuant to section 503A(b)(1)(B), inactive ingredients used in compounding must comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists, and the USP chapter on pharmacy compounding.

monograph" to mean an official USP or NF **drug substance** monograph. Accordingly, FDA does not consider USP monographs for dietary supplements to be "applicable" USP or NF monographs within the meaning of section 503A(b)(1)(A)(i)(I).

Under section 503A(c)(1), before developing this list through regulation, FDA must convene and consult an advisory committee on compounding unless FDA determines that the issuance of such regulation before consultation with the advisory committee is necessary to protect the public health. FDA must also consult with USP when promulgating the regulations.[7] The criteria for determining which bulk drug substances should appear on the section 503A bulks list "shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify."[8]

Bulk drug substances used in compounding under section 503A must also meet certain other requirements, including: (1) the bulk drug substance must be manufactured by an establishment registered under section 510 of the FD&C Act and (2) the bulk drug substance must be accompanied by a valid certificate of analysis (COA).[9]

In July 2014, FDA issued a guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, that states:

> Until a bulk drug substances list is published in the *Federal Register* as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.[10]

FDA has received comments that this policy could be causing unnecessary and inappropriate disruptions in patient care because there are patients receiving drugs compounded with bulk drug substances that are not components of FDA-approved drugs, or the subject of an applicable USP or NF monograph, but that may ultimately be included on the 503A bulks list, and those patients' care should not be disrupted while the list is under development. After considering this issue, FDA has decided to use this guidance to describe its interim policy concerning compounding with bulk drug substances while the 503A bulks list is being developed. FDA has revised the July 2014 guidance to state:

> FDA's interim policy concerning bulk drug substances that are not components of drugs approved under section 505 of the FD&C Act or that are not the subject of applicable USP or NF monographs can be found in the guidance, *Interim Policy on*

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[7] See section 503A(c)(2) of the FD&C Act.

[8] See section 503A(c)(2) of the FD&C Act.

[9] See section 503A(b)(1)(A) of the FD&C Act.

[10] See page 5 of the guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act.

FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them and promulgates the regulations required under section 503A. Therefore, as described further below, FDA is issuing this interim guidance stating that it does not intend to take regulatory action for compounding drug products under section 503A using a bulk drug substance when an applicable USP or NF monograph for the substance does not exist and the substance is not a component of an FDA-approved product if, among other conditions, FDA has determined that the nomination for the bulk drug substance included adequate information for FDA to evaluate the substance and at this time, the substance does not appear to present significant safety risks.

B. Efforts to Develop the List of Bulk Drug Substances under Section 503A

1. Section 503A Bulks List — Early History

Section 503A was enacted in 1997 as part of the Food and Drug Administration Modernization Act. In the *Federal Register* of April 7, 1998 (63 FR 17011), FDA invited all interested persons to nominate bulk drug substances for inclusion on the list of bulk drug substances that can be used in compounding under section 503A and received nominations for 41 different drug substances. In November 1998, FDA published a guidance for industry, *Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.* In this guidance, FDA announced that it would not normally take regulatory action relating to a drug product that had been compounded with a bulk drug substance that had been nominated for inclusion on the bulk drug substances list on or before November 21, 1999, while the substance was being evaluated, as long as the compounding complied with the other effective requirements in section 503A and did not appear to present a significant safety risk.[11]

In January 1999, after evaluating the nominated drug substances and consulting with the Pharmacy Compounding Advisory Committee (PCAC) as required by section 503A, FDA published a proposed rule listing 20 drug substances on the section 503A bulks list (64 FR 996, January 7, 1999). The preamble to the proposed rule indicated that 10 of the 41 nominated substances were the subject of a USP or NF monograph, or components of FDA approved drugs and did not need to be considered for inclusion on the list.[12] The proposed rule also described 10 nominated substances that were still under consideration for the bulk drug substances list and stated that one of the substances was withdrawn by its nominator at the first meeting of the PCAC. The PCAC reconvened in May 1999 to discuss bulk drug substances included in the proposed rule, in addition to other bulk drug substances (64 FR 19791; April 22, 1999).

[11] The 1998 guidance was withdrawn in the *Federal Register* notice announcing the availability of the draft guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. See 78 FR 72901 (Dec. 4, 2013). The final guidance was published in July 2014.

[12] See 64 FR 996, at 997 (January 7, 1999).

However, after a 2002 U.S. Supreme Court decision holding that certain provisions of section 503A were unconstitutional,[13] FDA suspended its efforts to develop the bulk drugs list under section 503A.

Because of the amount of time that had passed between the publication of the proposed rule and the enactment of the 2013 Drug Quality and Security Act, which removed the provisions of the FD&C Act that the U.S. Supreme Court held to be unconstitutional in 2002, FDA felt it was necessary to begin again to develop the section 503A bulk drug substance list. In the December 4, 2013, *Federal Register* (78 FR 72841), FDA published a notice withdrawing the 1999 proposed rule and inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503A of the FD&C Act.

2. Current Nominations for the 503A Bulks List

In response to the December 2013, *Federal Register* notice, over 2,000 substances were nominated for the 503A bulks list. However, many of the substances nominated for the 503A list were for substances that can be compounded without being on the list because they are the subject of an applicable USP or NF monograph or are a component of an FDA-approved drug. In addition, many of the nominations were not for substances used in compounding as active ingredients, or did not include sufficient information for FDA to evaluate the nominated substances for inclusion on the list. To improve the efficiency of the process for developing the 503A bulks list, FDA reopened the nomination process in July 2014 (79 FR 37742) and provided more detailed information on what it needs to evaluate nominations for the 503A bulks list. FDA stated that bulk drug substances that were previously nominated would not be considered further unless they were re-nominated with adequate support to permit a meaningful evaluation. Substances that were already eligible for use in compounding or that were not adequately supported would not be evaluated for placement on the 503A bulks list.

In response to this request for nominations, approximately 740 unique substances were nominated. Of the nominated substances:

- Approximately 315 substances are already eligible for use in compounding under section 503A.

  These are the subject of an applicable USP or NF monograph or components of an FDA-approved drug product, which can be used in compounding pursuant to sections 503A(b)(1)(A)(i)(I) and (II) and, therefore, can be compounded without being included on the 503A bulks list. To determine if a bulk drug substance is the subject of an applicable USP or NF monograph, see the *USP-NF* available at www.USPNF.com. To determine if a bulk drug substance is a component of an FDA approved drug, see the FDA's *Orange Book:*

[13] For additional legal history of section 503A, see the guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

Approved Drug Products with Therapeutic Equivalence Evaluations, available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm

- At least one[14] of the nominated substances is not a bulk drug substance.

This is a finished drug product that was nominated by its brand name. Finished drug products are not eligible for the 503A bulks list because they do not meet the definition of a bulk drug substance in 21 CFR 207.3.

- At least one of the substances is considered a biological product subject to approval in a biologics license application (BLA) under section 351 of the Public Health Service (PHS) Act when used for the indication proposed in the nomination.

This substance is not eligible for the 503A bulks list because biological products subject to approval in a BLA under section 351 of the PHS Act are not eligible for the exemptions in section 503A of the FD&C Act.[15] No biological products subject to approval in a BLA will be considered for the 503A bulks list.

- At least four of the nominated substances appear on the list published by FDA of substances that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (withdrawn or removed list).[16]

Such substances cannot be used in compounding under section 503A of the FD&C Act and, therefore, are not eligible for inclusion on the 503A bulks list.

- One of the nominated substances has no currently accepted medical use and is included on Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. § 812(c)).[17]

The CSA does not allow possession or distribution of Schedule I substances (21 USC §§ 841(a)(1) and 829), except for research purposes (21 U.S.C. § 823(f)), and these substances will not be considered for the 503A bulk drug substances list at this time. Those desiring to do research on a Schedule I substance can apply to do so under an investigational new drug application (IND).

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[14] The over-the-counter finished drug product Maalox was nominated. Maalox is not a bulk drug substance.

[15] The nominated substance is sodium hexachloroplatinate (IV) hexahydrate. See the revised draft guidance, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* for FDA's proposed policies regarding State-licensed pharmacies, Federal facilities, and outsourcing facilities that mix, dilute, or repackage biological products outside the scope of an approved BLA.

[16] See Section 503A(b)(1)(C) of the FD&C Act. See also 21 CFR 216.24. The four substances are: chloroform reagent, cobalt chloride hexahydrate, cobalt gluconate, and phenacetin.

[17] An extract of cannabidiol (CBD) and tetrahydrocannabinol (THC) derived from marijuana (marihuana) was nominated. Marijuana (marihuana) is a Schedule I substance.

- Of the substances that are not components of an approved drug or the subject of an applicable USP or NF monograph and that are not biological products subject to licensure in a BLA or included on Schedule I of the CSA, and do not appear on the withdrawn or removed list, approximately 350 substances were nominated without sufficient supporting evidence for FDA to evaluate them.

- The remaining substances may be eligible for inclusion on the 503A list and were nominated with sufficient supporting information for FDA to evaluate them. However, FDA has identified significant safety risks relating to the use of some of these bulk drug substances in compounded drug products.

FDA's website identifies the following categories of substances nominated for the 503A bulks list:[18]

503A Category 1 – Substances Nominated for the Bulks List Currently Under Evaluation: These substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list.

503A Category 2 – Substances Nominated for the Bulks List That Raise Significant Safety Risks: These substances were nominated with sufficient supporting information to permit FDA to evaluate them and they may be eligible for inclusion on the 503A bulks list. However, FDA has identified significant safety risks relating to the use of these substances in compounding pending further evaluation, and therefore does not intend to adopt the policy described for the substances in Category 1. If FDA adds a substance to Category 2, it will publish a public communication (e.g., a safety alert) describing the safety risks and will post the communication on FDA's human drug compounding website,[19] advising that the substance has been added to Category 2 and is no longer eligible for the policies that apply to substances in Category 1.

503A Category 3 – Substances Nominated for the Bulks List Without Adequate Support: These substances may be eligible for inclusion on the 503A bulks list, but were

[18] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. As discussed in the July 2014 Federal Register notice requesting nominations for the 503A bulks list (79 FR 37742), nominators were to confirm that all substances nominated for the list are active ingredients that meet the definition of a "bulk drug substance." Inclusion of a substance in any of these categories does not reflect a determination by FDA that the substance is a bulk drug substance. Whether a substance is a bulk drug substance subject to the conditions in section 503A(b)(1)(A) depends on whether it meets the definition of a bulk drug substance in 21 CFR 207.3. If the substance is used in a compounded drug as an inactive ingredient, then it does not meet the definition of a bulk drug substance in 21 CFR 207.3, is not subject to the conditions in section 503A(b)(1)(A), and need not appear on the 503A bulks list to be eligible for use in compounding. Instead, when used as an inactive ingredient, the substance is subject to the conditions in section 503A(b)(1)(B), which applies to ingredients other than bulk drug substances used in compounded drugs.

[19] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm. FDA also encourages compounding facilities to subscribe to FDA's list serve to receive updates at: http://service.govdelivery.com/service/subscribe.html?code=USFDA_429.

nominated with insufficient supporting information for FDA to evaluate them. These substances can be re-nominated with sufficient supporting information through a docket that FDA has established, as discussed below in section III.B.

3. Process for Developing the 503A List

FDA is currently evaluating the substances that were nominated for the 503A bulks list with sufficient information to permit evaluation. FDA is considering a number of factors in prioritizing the order in which it reviews the nominated bulk drug substances, including but not limited to the following:

- Safety concerns about use of the bulk drug substance in compounding
- Whether the bulk drug substance was nominated by multiple parties or identified as necessary by medical professional organizations
- The efficiency with which the evaluation can be completed, based on ease of acquiring the necessary information to conduct the review, available resources, and other logistical issues

FDA may also group some nominated drug substances to facilitate efficient review and discussion. These include drugs that raise similar issues (e.g., vitamins or botanicals) or have been nominated for the treatment of the same condition (e.g., warts).

In conducting its evaluations, FDA reviews the information provided in support of the nomination and other available information to assess each bulk drug substance according to the following four criteria discussed at the PCAC meeting on February 23, 2015:

- The physical and chemical characterization of the substance
- Any safety issues raised by the use of the substance in compounded drug products
- Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature
- The available evidence of effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists

In evaluating candidates for the 503A bulks list under these criteria, FDA is using a balancing test. No single one of these criteria is dispositive; rather, FDA is considering each criterion in the context of the others and balancing them, on a substance-by-substance basis, to evaluate whether a particular substance is appropriate for inclusion on the list.

Once the evaluation of a substance is complete, FDA will present the results of its review to the PCAC to obtain its advice on whether to include the substance on the list.[20]

[20] See Section 503A(c)(1) of the FD&C Act.

Section 503A requires that FDA create the 503A bulks list by regulation in consultation with the USP. To this end, FDA has been periodically meeting with USP and discussing the list. FDA will publish a notice of proposed rulemaking (NPRM) that identifies substances FDA proposes for placement on the 503A bulks list and the substances FDA has evaluated but is not proposing to include on the 503A bulks list. After publication of the NPRM, the public will have an opportunity to comment on the proposed rule. After considering the comments submitted to the docket, FDA will publish a final rule that establishes the 503A bulks list and identifies the substances that were considered and will not be placed on the list. FDA does not intend to evaluate all of the sufficiently supported nominations before publishing the first NPRM. Instead, after FDA has made a decision on whether to propose a group of substances (e.g., 10 substances) it intends to publish an NPRM with respect to that group of substances and continue to prepare the list on a rolling basis.

A final rule will list the substances that FDA has determined can be used in compounding under section 503A and those substances that have been evaluated and not placed on the 503A bulks list, if any.

After a final rule is published, drug products compounded using the substances on the 503A bulks list will be eligible for the section 503A exemptions provided the drug product is compounded in compliance with the other conditions of section 503A. Those substances that have been evaluated and not placed on the 503A bulks list will not qualify for the policies described for the substances in Category 1.

III. POLICY[21]

A. Compounding from Bulk Drug Substances under Section 503A

Under section 503A of the FD&C Act, a bulk drug substance that is not the subject of an applicable USP or NF monograph or is not a component of an FDA-approved drug cannot be used in compounding unless it appears on a list promulgated as a regulation pursuant to section 503A(b)(1)(A)(i)(III) of the FD&C Act. This list will be codified at 21 CFR part 216 subpart E.

However, until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product and that is not the subject of an applicable USP or NF monograph, provided that the following conditions are met:

1. The bulk drug substance appears in 503A Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. A Category 1 substance may be eligible for inclusion on the 503A bulks list, was nominated with sufficient supporting information for FDA to

[21] See the Appendix for a chart summarizing FDA's interim policy.

evaluate it and has not been identified by FDA as a substance that presents a significant safety risk in compounding prior to the publication of a final rule.

2. The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i)) of the FD&C Act);

3. The bulk drug substance is accompanied by a valid COA; and

4. The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FD&C Act.

Original manufacturer means the entity that originally produced the bulk drug substance and not a subsequent packer, repacker, labeler, or distributor.

This policy does not apply to a licensed pharmacist in a State-licensed pharmacy or Federal facility, or a licensed physician, that compounds a drug using a bulk drug substance that does not meet each of the above conditions, and the bulk drug substance is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug.

B. Substances Not Nominated or Nominated Without Adequate Support

As stated above, one of the categories of bulk drug substances FDA has identified on its website is substances nominated for the 503A bulks list that may be eligible for inclusion on the list, but that FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for FDA to evaluate them (503A Category 3). In the *Federal Register* of October 27, 2015, FDA established a docket (October docket) where these substances can be re-nominated with sufficient supporting information or where nominations for substances that were not previously nominated can be submitted.

After a substance is nominated to the October docket,[22] FDA will determine whether the nomination is supported with sufficient information to allow FDA to evaluate it. After FDA makes that determination, the nominated substance will be placed in one of the three categories described in section II.B.2 above, and the categorization will be published on the FDA website. Once the category of a substance is published, FDA intends to apply the policy described in Section III.A of this guidance to that substance. FDA generally expects to categorize bulk drug substances nominated to the October docket and to publish updated categories on its website on the first business day of each month. Please note that until substances nominated for the October docket have been categorized, the policy does ***not*** apply to those substances.

C. Comments about Nominated Bulk Drug Substances

[22] This includes re-nominations of substances with sufficient supporting information.

If you feel that a substance that you nominated does not appear on the appropriate list or category as described in this guidance you can submit your comment to docket number FDA-2015-N-3534. If you have new information on a previously nominated substance that was placed in Category 3, the substance can be re-nominated with the additional information.

A nominator may also submit a comment to the docket requesting withdrawal of any of its nominations. If the party nominating the substance was the sole nominator, FDA will update the categories described in this guidance to reflect the withdrawn nomination.[23] FDA intends to provide notice to the public before removing any nominated substances from Category 1 or Category 2.

Withdrawal of a nomination upon the nominator's request and the resulting updates to the categories described in this guidance, do not reflect a determination by FDA regarding the validity of the nomination or of any reasons given by the nominator for requesting withdrawal. In addition, FDA may continue to evaluate a substance at its discretion even if the nominator submits a comment requesting withdrawal of the nomination.

[23] If multiple parties nominated the same substance, each party that nominated the substance must withdraw its nomination for the nominated substance to be considered withdrawn and for the categories to be updated to reflect that withdrawal.

APPENDIX: SUMMARY OF POLICY

The following table summarizes the interim policy for bulk drug substances set forth in this guidance:

Category	FDA Policy
The bulk drug substance appears in 503A Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. Such substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear to present a significant safety risk.	FDA does not intend to take action for compounding a drug product from a bulk drug substance in Category 1 that does not meet the conditions of section 503A(b)(1)(A)(i), provided that the bulk drug substance was manufactured by an establishment registered with FDA under section 510 of the FD&C Act and is accompanied by a valid COA from the entity that originally produced the bulk drug substance and provided that the drug compounded from the bulk drug substance is compounded in compliance with the other conditions of section 503A.
The bulk drug substance is a component of an FDA-approved drug and/or the subject of an applicable USP or NF monograph.	The bulk drug substance can be used in compounding under section 503A of the FD&C Act, provided it complies with the standards of the monograph (if one exists) and is compounded in compliance with the other conditions of section 503A.
The bulk drug substance appears on the withdrawn or removed list.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act. A drug compounded using the bulk drug substance is subject to regulatory action.
The bulk drug substance appears in 503A Category 2 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. The substance has been identified by FDA as presenting a significant safety risk pending further evaluation.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act unless and until FDA publishes a final rule authorizing its use under section 503A.
The bulk drug substance is a biological product subject to approval in a BLA.	The bulk drug substance is not eligible for the 503A bulks list. FDA has issued a separate draft guidance document describing the Agency's proposed policies concerning mixing, diluting, and repackaging biological products subject to approval in a BLA.[24]
The bulk drug substance appears in 503A Category 3 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467373.pdf. The substance may be eligible for inclusion on the 503A bulks list, but was nominated with insufficient supporting information for FDA to evaluate it.	The bulk drug substance cannot be used in compounding under section 503A of the FD&C Act. See section III.B of this guidance for information about re-nominating substances that were previously nominated with insufficient supporting information.

[24] See FDA's revised draft guidance, *Mixing, Diluting, and Repackaging Biological Products Subject to Approval in a Biologics License Application*.

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Contains Nonbinding Recommendations

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act Guidance for Industry[1]

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

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or the Agency) interim regulatory policy concerning compounding by outsourcing facilities registered under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act) [2] using bulk drug substances. Section 503B of the FD&C Act includes certain restrictions on the bulk drug substances that outsourcing facilities can use in compounding and directs FDA to develop a list of bulk drug substances that can be used in compounding under that section. FDA is developing that list of bulk drug substances (the 503B bulks list), and this guidance describes FDA's interim regulatory policy regarding outsourcing facilities that compound human drug products using bulk drug substances while the list is being developed.[3,4]

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

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[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER), in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] *Outsourcing facility* refers to a facility that meets the definition of an outsourcing facility under section 503B(d)(4) of the FD&C Act.

[3] This guidance does not apply to drugs compounded from bulk drug substances for use in animals. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances*.

> All FDA guidances are available on the FDA guidance web page. FDA updates guidances regularly. To make sure you have the most recent version of a guidance, always consult the guidance web page at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

[4] FDA is also developing a separate list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act. Because section 503A contains different criteria for that list and provides for a different process for its development, the section 503A bulks list is covered under a separate guidance (see guidance for industry, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*).

II. BACKGROUND

A. Compounding From Bulk Drug Substances Under Section 503B

Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the following three sections of the FD&C Act: section 505 (concerning the approval of drugs under new drug applications or abbreviated new drug applications); section 502(f)(1) (concerning the labeling of drugs with adequate directions for use); and section 582 (concerning drug supply chain security requirements).

One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for these exemptions is that the outsourcing facility does not compound drug products using a bulk drug substance unless (a) it appears on a list established by the Secretary identifying bulk drug substances for which there is a clinical need, or (b) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FD&C Act at the time of compounding, distribution, and dispensing. Section 503B(a)(2)(A) of the FD&C Act.

A bulk drug substance is defined as meaning "the same as active pharmaceutical ingredient as defined in 21CFR 207.1(b)." See 21 CFR 207.3. Active pharmaceutical ingredient is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body," but the term "does not include intermediates used in the synthesis of the substance" (see section 503B(a)(2) and 21 CFR 207.3).[5,6]

Bulk drug substances used in compounding under section 503B must also meet certain other requirements, including: (1) if an applicable monograph exists under the United States Pharmacopeia (USP), National Formulary (NF), or another compendium or pharmacopeia recognized by the Secretary for purposes of this paragraph, the bulk drug substance complies with the monograph; (2) the bulk drug substance must be manufactured by an establishment that is registered under section 510 of the FD&C Act; and (3) the bulk drug substance must be accompanied by a valid certificate of analysis (COA). Section 503B(a)(2) of the FD&C Act.

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[5] Section 503B references the definition of bulk drug substance in FDA's drug establishment registration and listing regulations, which was codified at 21 CFR 207.3(a)(4) at the time section 503B was enacted. On August 31, 2016, FDA published a final rule in the Federal Register to update its registration and listing regulations in Part 207, which made minor changes to the definition of bulk drug substance and moved the definition to 21 CFR 207.3. The definition is also found in 207.1. *See* 81 FR 169 (August 31, 2016). Under the previous definition, bulk drug substance was defined to mean "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances."

[6] Inactive ingredients are not subject to section 503B(a)(2) or the policies described in this guidance because they are not included within the definition of a bulk drug substance. *See* 21 CFR 207.3. Pursuant to section 503B(a)(3), inactive ingredients used in compounding must comply with the standards of an applicable United States Pharmacopeia or National Formulary monograph, if a monograph exists.

B. Section 503B Bulks List

1. Section 503B Bulks List History

Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, requires that FDA create a list of bulk drug substances for which there is a clinical need by publishing a notice in the *Federal Register* proposing bulk drug substances for inclusion on the list, providing a public comment period of 60 calendar days, and then publishing a notice in the *Federal Register* designating bulk drug substances for inclusion on the list. *See* section 503B(a)(2)(A)(i) of the FD&C Act. In the December 4, 2013, *Federal Register* (78 FR 72838), FDA published a notice inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503B of the FD&C Act.

2. Nominations for the 503B Bulks List

In response to the December 2013 *Federal Register* notice, over 2,000 substances were nominated for the 503B bulks list. However, many of the nominations for the 503B bulks list were not for substances used in compounding as active ingredients, or they did not include sufficient information to allow FDA to evaluate the nominated substances for placement on the list. To improve the efficiency of the process for developing the 503B bulks list, FDA reopened the nomination process in July 2014 (79 FR 37747), and provided more detailed information on what it needs to evaluate nominations for the list. FDA stated that bulk drug substances that were previously nominated would not be further considered unless they were re-nominated and those nominations were adequately supported. Substances that were not adequately supported would not be evaluated by FDA to be placed on the 503B bulks list. The notice stated that the following information about clinical need is necessary to provide adequate support for nominations to the 503B bulks list:

- A statement describing the medical condition(s) that the drug product to be compounded with the nominated bulk drug substances is intended to treat;
- A list of FDA-approved drug products, if any, that address the same medical condition;
- If there are any FDA-approved drug products that address the same medical condition, an explanation of why a compounded drug product is necessary;
- If the approved drug product is not suitable for a particular patient population, an estimate of the size of the population that would need a compounded drug product;
- A bibliography of safety and efficacy data for the drug product compounded using the nominated substance, if available, including any relevant peer-reviewed medical literature; and
- If there is an FDA-approved drug product that includes the bulk drug substance nominated, an explanation of why the drug product proposed to be compounded must be compounded from bulk rather than with the FDA-approved drug product.

In response to this request for nominations, approximately 2,590 unique substances were nominated. Of the nominated substances:

- Approximately 1,740 are biological products (all but one of these[7] are individual allergenic extracts) subject to approval in a biologics license application (BLA) under section 351 of the Public Health Service (PHS) Act.

These products are not eligible for the 503B bulks list because biological products subject to approval in a BLA under section 351 of the PHS Act are not eligible for the exemptions in section 503B.[8] No biological products subject to approval in a BLA will be considered for the 503B bulks list.

- At least one[9] of the nominated substances is not a bulk drug substance.

This is a finished drug product that was nominated by its brand name. Finished drug products are not eligible for the 503B bulks list because they do not meet the definition of a bulk drug substance in 21 CFR 207.3.

- At least one of the nominated substances is a radiopharmaceutical.[10]

Compounding of radiopharmaceutical products will be addressed in a separate guidance document.[11]

- At least five of the nominated substances appear on the list of drugs that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (withdrawn or removed list)

Such substances cannot be used in compounding under section 503B of the FD&C Act, and therefore are not eligible for inclusion on the 503B bulks list.[12]

- One of the nominated substances has no currently accepted medical use and is included on Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. § 812(c)).[13]

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[7] The product is sodium hexachloroplatinate (IV) hexahydrate.

[8] See the draft guidance, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* for FDA's proposed policies regarding State-licensed pharmacies, Federal facilities, and outsourcing facilities that mix, dilute, or repackage biological products outside the scope of an approved BLA.

[9] The over-the-counter finished drug product Maalox was nominated. Maalox is not a bulk drug substance.

[10] The substance is sodium iodide I-131.

[11] FDA has published a draft guidance, "Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities," for public comment. That draft guidance proposes the Agency's policy regarding the use of bulk drug substances to compound radiopharmaceuticals under section 503B of the FD&C Act. Once that guidance is final, FDA intends to update this guidance to reflect the policies set forth therein.

[12] See section 503B(a)(4) of the FD&C Act. See also 21 CFR 216.24. The five substances are: chloroform reagent, cobalt chloride hexahydrate, cobalt gluconate, methapyrilene fumarate, and phenacetin.

The CSA does not allow possession or distribution of Schedule I substances (see 21 U.S.C. §§ 841(a)(1) and 829), except for research purposes (21 U.S.C. § 823(f)), and these substances will not be considered for the 503B bulk drug substances list at this time. Those desiring to do research on a Schedule I substance can apply to do so under an investigational new drug application (IND).

- Of the substances that may be eligible for use in compounding under section 503B, approximately 650 substances were nominated without sufficient supporting evidence for FDA to evaluate them.

- The remaining substances that were nominated for inclusion on the 503B bulks list may be eligible for inclusion on the list and were nominated with sufficient supporting information for FDA to evaluate them. However, FDA has identified significant safety risks relating to the use in compounded drug products of some of these bulk drug substances.

FDA's website identifies the following categories of substances nominated for the 503B bulk drug substances list:[14]

503B Category 1 –Substances Nominated for the Bulks List Currently Under Evaluation: These substances may be eligible for inclusion on the 503B bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list.

503B Category 2 –Substances Nominated for the Bulks List That Raise Significant Safety Risks: These substances were nominated with sufficient supporting information to permit FDA to evaluate them and they may be eligible for inclusion on the 503B bulks list. However, FDA has identified significant safety risks relating to the use of these substances in compounding pending further evaluation, and therefore does not intend to adopt the policy described for the substances in category 1. If FDA adds a substance to Category 2, it will publish a public communication (e.g. a safety alert) describing the safety risks and will post

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[13] An extract of cannabidiol (CBD) and tetrahydrocannabinol (THC) derived from marijuana (marihuana) was nominated. Marijuana (marihuana) is a Schedule I substance.

[14] http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. As discussed in the July 2014 Federal Register notice requesting nominations for the 503B bulks list ((79 FR 37747), nominators were to confirm that all substances nominated for the list are active ingredients that meet the definition of a "bulk drug substance." Inclusion of a substance in any of these categories does not reflect a determination by FDA that the substance is a bulk drug substance. Whether a substance is a bulk drug substance subject to the conditions in section 503B(a)(2) depends on whether it meets the definition of a bulk drug substance in 21 CFR 207.3. If the substance is used in a compounded drug as an inactive ingredient, then it does not meet the definition of a bulk drug substance in 21 CFR 207.3, is not subject to the conditions in section 503B(a)(2), and need not appear on the 503B bulks list to be eligible for use in compounding. Instead, when used as an inactive ingredient, the substance is subject to the conditions in section 503B(a)(3), which applies to ingredients other than bulk drug substances used in compounded drugs

the communication on FDA's human drug compounding website[15] advising that the substance has been added to Category 2 and is no longer eligible for the policies that apply to substances in Category 1.

503B Category 3 –Substances Nominated for the Bulks List Without Adequate Support: These substances may be eligible for inclusion on the 503B bulks list, but were nominated with insufficient supporting information for FDA to evaluate them. These substances can be re-nominated with sufficient supporting information through a docket that FDA has established, as discussed below in section III.B.

3. Process for Developing the 503B Bulks List

FDA is currently evaluating the bulk drug substances nominated for the 503B bulks list with sufficient supporting information for evaluation. FDA is considering a number of factors in prioritizing the order in which it reviews these nominated bulk drug substances, including but not limited to the following:

- Safety concerns about use of the bulk drug substance in compounding
- Whether the bulk drug substance was nominated by multiple parties or identified as necessary by medical professional organizations
- The efficiency with which the evaluation can be completed, based on ease of acquiring the necessary information to conduct the review, available resources, and other logistical issues

FDA may also group some nominated drug substances to facilitate efficient review and discussion. These include drug substances that raise similar issues (e.g., vitamins or botanicals) or that are nominated for the treatment of the same condition (e.g., warts).

FDA intends to publish a notice in the *Federal Register* that describes its proposed position on each substance it has evaluated along with the rationale for that proposal, for public comment. We note that there is no requirement in section 503B to consult the Pharmacy Compounding Advisory Committee (PCAC) before developing a 503B bulks list, as is required by section 503A(c)(1) for the 503A bulks list. However, after considering public comment on the nominated substances, FDA will determine whether PCAC input on any of the substances would be helpful to the Agency in making its determination, and if so, it will seek PCAC input. Once FDA makes a determination, it will publish in the *Federal Register* a list identifying the bulk drug substances for which it has determined there is a clinical need and FDA's rationale in making that determination. FDA will also publish in the *Federal Register* a list of those substances it considered but found that there is no clinical need to use in compounding and FDA's rationale in making this determination.

[15] http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm. FDA also encourages compounding facilities to subscribe to FDA's list serve to receive updates at: http://service.govdelivery.com/service/subscribe.html?code=USFDA_429.

Once FDA publishes a 503B bulks list in the *Federal Register* that reflects its determination regarding particular bulk drug substances, drug products compounded with substances on the 503B bulks list will be eligible for the 503B exemptions, provided the drug products are compounded in compliance with the other conditions of section 503B.[16] Once FDA has published in the *Federal Register* its decision not to place a particular substance on the 503B bulks list, the policy described in section III of this guidance no longer applies.

FDA intends to evaluate the substances nominated for the 503B list on a rolling basis. FDA will begin by publishing a *Federal Register* notice identifying a group of substances (e.g., 10 substances) that it has considered and whether it proposes the substances for inclusion on the list. Under section 503B, an outsourcing facility may only compound using bulk drug substances that are on FDA's 503B bulks list or that are used to compound drugs that appear on the shortage list in effect under section 506E of the FD&C Act at the time of compounding, distribution, and dispensing. To avoid unnecessary disruption to patient treatment while FDA considers the substances that were nominated with sufficient support to permit FDA to evaluate them, FDA is issuing this guidance stating that at this time it does not intend to take action against an outsourcing facility for failing to compound in accordance with section 503B(a)(2) if certain conditions are met. Those conditions include that the nomination for the relevant bulk drug substance was submitted with adequate information for FDA to evaluate the substance and that FDA has not identified significant safety risks about its use in compounding prior to publication of the *Federal Register* notice identifying those substances FDA has determined will or will not be placed on the 503B bulks list.

III. POLICY[17]

A. Compounding from Bulk Drug Substances Under Section 503B

Under section 503B of the FD&C Act, a bulk drug substance cannot be used in compounding unless it is used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distribution, and dispensing, or it appears on the 503B bulks list.

FDA does not intend to take action against an outsourcing facility for compounding a drug product using a bulk drug substance that is not on the 503B bulks list if the drug compounded from the bulk drug substance: (i) appeared on FDA's drug shortage list within 60 days of distribution and dispensing, and (ii) was to fill an order that the outsourcing facility received for the drug while it was on FDA's drug shortage list.[18]

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[16] See section 503B(a)(11) of the FD&C Act.

[17] See Appendix A for a summary of FDA's interim policy.

[18] An outsourcing facility may not be able to predict when a drug shortage will be resolved, and the facility may have orders for a compounded drug in-house that were in progress when the drug was removed from FDA's drug shortage list (e.g., the outsourcing facility may have compounded a drug while it was in shortage, but the shortage ended while the outsourcing facility awaits the results of sterility testing before release.) This policy provides some regulatory flexibility where an outsourcing facility fills orders that it received while a drug was in shortage. However, this policy does not apply if an outsourcing facility continues to fill orders received after the shortage

In addition, at this time FDA does not intend to take action against an outsourcing facility for compounding a drug using a bulk drug substance that does not appear on the 503B bulks list and that is not used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distribution, and dispensing, provided that the following conditions are met:

1. The bulk drug substance appears on 503B Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. A Category 1 substance may be eligible for inclusion on the 503B bulks list, was nominated for inclusion on the 503B bulks list with adequate supporting information for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present a significant safety risk in compounding before a determination as to whether to place it on the 503B bulks list has been made.

2. The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i)) of the FD&C Act;

3. The bulk drug substance is accompanied by a valid COA;

4. If the bulk drug substance is the subject of an applicable USP or NF monograph, the bulk drug substance complies with the monograph; and

5. The drug product compounded using the bulk drug substance is compounded in compliance with all other provisions of section 503B of the FD&C Act.

Original manufacturer means the entity that originally produced the bulk drug substance and not a subsequent packer, repacker, labeler, or distributor.

This policy does not apply to an outsourcing facility that compounds a drug using a bulk drug substance that does not meet each of the above conditions and where the bulk drug substance was not used to compound a drug that appears on the FDA drug shortage list at the time of compounding, distribution, and dispensing, or that appeared on the FDA drug shortage list within 60 days of distribution and dispensing.

B. Substances Not Nominated or Nominated Without Adequate Support

As stated above, FDA is providing a list on its website of substances nominated for the 503B bulks list that may be eligible for inclusion on the list, but that FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for FDA to evaluate them (503B Category 3). In the *Federal Register* of October 27, 2015, FDA established a docket (October docket) where these substances can be re-

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ends, or if the outsourcing facility continues to fill orders more than 60 days after the drug was removed from FDA's drug shortage list.

nominated with sufficient supporting information or where nominations for substances that were not previously nominated can be submitted.

After a substance is nominated to the October docket,[19] FDA will determine whether the nomination is supported with sufficient information to allow FDA to evaluate it. After FDA makes that determination, the nominated substance will be placed in one of the three categories described in section II.B.2 above, and the categorization will be published on the FDA website. Once the category of a substance is published, FDA intends to apply the policy described in section III.A. of this guidance to that substance. FDA generally expects to categorize bulk drug substances nominated to the October docket and to publish updated categories on its website on the first business day of each month. Please note that until substances nominated for the October docket have been categorized, the policy does ***not*** apply to those substances.

C. Comments about Nominated Bulk Drug Substances

If you feel that a substance that you nominated does not appear on the appropriate list or category as described in this guidance you can submit your comment to docket number FDA-2015-N-3469. If you have new information on a previously-nominated substance that was placed in Category 3, the substance can be re-nominated with the additional information.

A nominator may also submit a comment to the docket requesting withdrawal of any of its nominations. If the party nominating the substance was the sole nominator, FDA will update the categories described in this guidance to reflect the withdrawn nomination.[20] FDA intends to provide notice to the public before removing any nominated substances from Category 1 or Category 2.

Withdrawal of a nomination upon the nominator's request, and resulting updates to the categories described in this guidance, do not reflect a determination by FDA regarding the validity of the nomination or of any reasons given by the nominator for requesting withdrawal. In addition, FDA may continue to evaluate a substance at its discretion even if the nominator submits a comment requesting withdrawal of the nomination.

[19] This includes re-nominations of substances with sufficient supporting information.

[20] If multiple parties nominated the same substance, each party that nominated the substance must withdraw its nomination for the nominated substance to be considered withdrawn and for the categories to be updated to reflect that withdrawal.

APPENDIX: SUMMARY OF POLICY

The following table summarizes the interim policy for bulk drug substances set forth in this guidance:

Category	FDA Policy
The bulk drug substance is in 503B Category 1 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. Such substances may be eligible for inclusion on the 503B bulks list, were nominated with adequate supporting information for FDA to evaluate them, and have not been identified by FDA as presenting significant safety risks.	The bulk drug substance is not on the 503B bulks list. However, pending a determination about whether to put the bulk drug substance on the 503B bulks list, FDA does not intend to take action against an outsourcing facility for compounding a drug product from a bulk drug substance that does not meet the conditions of section 503B(a)(2) provided that the bulk drug substance is manufactured by an establishment registered with FDA under section 510 of the FD&C Act, is accompanied by a valid COA, complies with an applicable USP monograph, if one exists, and provided that the drug compounded from the bulk drug substance is compounded in compliance with the other conditions of section 503B.
The bulk drug substance appears on the withdrawn or removed list.	The bulk drug substance cannot be used in compounding under section 503B of the FD&C Act.
The bulk drug substance is in 503B Category 2 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. The substance has been identified by FDA as presenting a significant safety risk in compounding pending further evaluation.	The bulk drug substance is not on the 503B bulks list, and cannot be used for compounding consistent with section 503B(a)(2) unless it is used to compound a drug that appears on FDA's drug shortage list.
The bulk drug substance is a biological product subject to approval in a BLA.	The bulk drug substance is not eligible for the 503B bulks list. FDA has issued a separate draft guidance document describing the Agency's proposed policies concerning mixing, diluting, and repackaging biological products subject to approval in a BLA.[21]
The bulk drug substance is a radiopharmaceutical product.	Compounding radiopharmaceuticals will be addressed in a separate guidance document.
The bulk drug substance is in 503B Category 3 on FDA's website at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM467374.pdf. The substance may be eligible for inclusion on the 503B bulks list but was nominated with insufficient supporting information for FDA to evaluate it.	The bulk drug substance is not on the 503B bulks list, and cannot be used for compounding consistent with section 503B(a)(2) unless the bulk drug substance is used to compound a drug that appears on FDA's drug shortage list. See section III.B of this guidance for information about supplementing inadequately supported nominations.

[21] See FDA's revised draft guidance, *Mixing, Diluting, and Repackaging Biological Products Subject to Approval in a Biologics License Application*.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
[redacted]	[redacted]
	FEI NUMBER [redacted]
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
[redacted]	
FIRM NAME	STREET ADDRESS
[redacted]	[redacted]
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
[redacted]	Producer of Sterile and Non-Sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically, the firm purchases Methylcobalamin active ingredient from [redacted] for use in the production of Methylcobalamin solution for injection. The firm has purchased and used [redacted] lots of this active ingredient that lacks a description of grade. These ungraded active ingredient batches were used in the production of [redacted] finished product batches:

[redacted]

OBSERVATION 2

Personnel donned gowning apparel improperly, in a way that may have caused the gowning apparel to become contaminated.

Specifically, on 3/9/20 we observed Sterile Technician [redacted] gowning. The sleeves of the cleanroom suit (non-sterile) came in contact with the floor of the ISO 8 ante room. The technician proceeded to enter the ISO 5 zone and produce Methylcobalamin batch 183570@8 BUD 9/5/20. Uncovered and non-sanitized sleeves were observed within the ISO 5 space.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	[redacted]	[redacted]	[redacted]

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
[redacted]	[redacted]
	FEI NUMBER [redacted]

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
[redacted]

FIRM NAME	STREET ADDRESS
[redacted]	[redacted]
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
[redacted]	Producer of Sterile and Non-Sterile Drugs

OBSERVATION 3

The ISO 5 classified aseptic processing areas had particle-generating and visibly dirty equipment or surface.

Specifically, the following equipment conditions were observed within the ISO 7 buffer room containing the ISO5 zone:

1. Rust-like discoloration below the seat of the chair at the ISO 5 LAFH. As well, white specks were observed on the seat of the chair on 3/4/20 while the room was in a cleaned status.

2. Rust-like discoloration of the garbage can was observed across all surfaces. The can is positioned within approximately 6 inches of the ISO 5 LAFH.

3. Extensive cracks are present on the [redacted] of the [redacted] the ISO 7 buffer room and the ISO 8 ante room respectively. More than four cracks pass through the entire depth of the [redacted] The [redacted] is constructed of composite board with a plastic sheet coating glued together. All materials entering the ISO7 buffer room [redacted]. The [redacted] the [redacted] composite boards to [redacted].

OBSERVATION 4

You did not make adequate product evaluation and take remedial action where actionable microbial contamination was found to be present in an area adjacent to the ISO 5 classified aseptic processing area during aseptic production.

Equipment within or in close proximity to the ISO 5 area could compromise the area in the ISO 5 area. Specifically, you keep a [redacted] in the ISO 7 buffer room. During the cleanroom recertification activity on 1/25/19 third party cleanroom certification business [redacted] identified an airborne viable environmental monitoring OOS (15 CFU) at location [redacted] corresponding to the [redacted]. The PIC identified a preventative action of not permitting the operation of the [redacted] during cleanroom recertification activities and a

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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	FEI NUMBER [redacted]
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
[redacted]	
FIRM NAME	STREET ADDRESS
[redacted]	[redacted]
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
[redacted]	Producer of Sterile and Non-Sterile Drugs

corrective action of cleaning and re-sampling the environment of the classified spaces. You have failed to investigate and eliminate the identified potential source of air contamination in the ISO 7 buffer room, background to the ISO 5 LAFH.

***DATES OF INSPECTION**

[redacted]

[redacted]

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	[redacted]	[redacted]	[redacted]

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Attachment 8

Enforcement Workload Statistics FY 2020/21

Complaint Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	592	481	0	0	1,073
Closed	561	627	0	0	1,188
Pending	1,649	1,776	0	0	1,776
Average Days for Investigation	227	257	0	0	242

Cases Under Investigation (By Team)	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Compliance / Routine	820	661	0	0	661
Drug Diversion / Fraud	175	160	0	0	160
Prescription Drug Abuse	62	68	0	0	68
Compounding	67	75	0	0	75
Outsourcing	24	20	0	0	20
Probation / PRP	28	24	0	0	24
Enforcement	187	469	0	0	469
Criminal Conviction	286	299	0	0	299

Application Investigations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Received	51	64	0	0	115
Closed					
Approved	47	49	0	0	96
Denied	8	9	0	0	17
Total Closed (includes withdrawn)	***74***	***69***	***0***	***0***	143
Pending	89	85	0	0	88

Complaint Closure Outcomes Not Resulting in Further Action	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Insufficient Evidence	124	168	0	0	292
Non-Jurisdictional	69	85	0	0	154
No Violation	70	44	0	0	114
No Further Action	47	47	0	0	94
Other - Non-Substantiated	6	7	0	0	13
Subject Educated	34	13	0	0	47

Letter of Admonishment / Citations	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
LOA Issued	48	72	0	0	120
Citations Issued	226	262	0	0	488
Proof of Abatement Requested	53	64	0	0	117
Appeals Received	17	31	0	0	48
Dismissed	0	6	0	0	6
Total Fines Collected	***$204,815***	***$207,140***	***$0***	***$0***	***$411,955***

Administrative Cases	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Referred to the AG's Office	48	36	0	0	84
Pleadings Filed	56	42	0	0	98
Pending					Quarter Ending
Pre-Accusation	117	105	0	0	117
Post-Accusation	205	180	0	0	205
Total Pending	**327**	**289**	**0**	**0**	**327**
Total Closed	50	71	0	0	121

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation					
Pharmacist	1	2	0	0	3
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	9	15	0	0	24
Designated Representative	0	1	0	0	1
Wholesaler	0	0	0	0	0
Pharmacy	1	3	0	0	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***11***	***22***	***0***	***0***	***33***

Administrative Case Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed suspension/probation					
Pharmacist	0	0	0	0	0
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	0	0	0	0
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***0***	***0***	***0***	***0***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Revocation; stayed; probation					
Pharmacist	12	13	0	0	25
Intern Pharmacist	1	0	0	0	1
Pharmacy Technician	5	4	0	0	9
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	4	0	0	0	4
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***22***	***17***	***0***	***0***	***39***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Surrender / Voluntary Surrender					
Pharmacist	10	2	0	0	12
Intern Pharmacist	0	1	0	0	1
Pharmacy Technician	2	3	0	0	5
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	13	9	0	0	22
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***25***	***15***	***0***	***0***	***40***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Public Reproval / Reprimand					
Pharmacist	5	8	0	0	13
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	0	0	1
Designated Representative	1	0	0	0	1
Wholesaler	1	0	0	0	1
Pharmacy	1	12	0	0	13
Sterile Compounding	0	0	0	0	0
Outsourcing	2	0	0	0	2
Total	***10***	***21***	***0***	***0***	***31***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Granted					
Pharmacist	0	2	0	0	2
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	0	1	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	0	0	0	0
Sterile Compounding	0	0	0	0	0
Outsourcing	0	0	0	0	0
Total	***0***	***3***	***0***	***0***	***3***

Administrative Case Outcome	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Licenses Denied					
Pharmacist	0	1	0	0	1
Intern Pharmacist	0	0	0	0	0
Pharmacy Technician	1	0	0	0	1
Designated Representative	0	0	0	0	0
Wholesaler	0	0	0	0	0
Pharmacy	0	1	0	0	1
Sterile Compounding	0	0	0	0	0
Outsourcing	0	1	0	0	1
Total	***1***	***3***	***0***	***0***	***4***

Administrative Case Cost Recovery Efforts	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Cost Recovery Requested	***$448,360***	***$439,165***	***$0***	***$0***	***$887,525***
Cost Recovery Collected	***$380,388***	***$405,001***	***$0***	***$0***	***$785,389***

Immediate Public Protection Sanctions	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Interim Suspension Orders	5	5	0	0	10
Automatic Suspension Orders	0	0	0	0	0
Penal Code 23 Restrictions	0	1	0	0	1
Cease and Desist - Unlicensed Activity	0	0	0	0	0
Cease and Desist - Sterile Compounding	0	0	0	0	0

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Quarter Ending
Licenses on Probation					
Pharmacist	236	239	0	0	239
Intern Pharmacist	13	9	0	0	9
Pharmacy Technician	29	30	0	0	30
Designated Representative	2	2	0	0	2
Wholesaler	3	3	0	0	3
Pharmacy	73	70	0	0	70
Sterile Compounding	2	2	0	0	2
Total	***358***	***355***	***0***	***0***	***355***

Probation Statistics	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Probation Office Conferences	2	25	0	0	27
Probation Site Inspections	121	139	0	0	260
Probation Terminated / Completed	7	29	0	0	36
Referred to AG for Non-Compliance	0	2	0	0	2

As of 12/31/2020

California State Board of Pharmacy
SB 1441 Uniform Standards

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

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
PRP Intakes					
PRP Self-Referrals					
PRP Probation Referrals	2				2
PRP Under Investigation					
PRP In Lieu Of (investigation conducted)					
Total Number of PRP Intakes					
New Probationers					
Pharmacists	3				3
Intern Pharmacists	1				1
Pharmacy Technicians	2				2
Total New Probationers	6				6
PRP Participants and Recovery Agreements					
Total PRP Participants					N/A
Recovery Agreements Reviewed					
Probationers and Inspections					
Total Probationers	80				N/A
Inspections Completed	53				53
Referrals to Treatment					
Referrals to Treatment (PRP and Probationers)					
Drug Tests					
Drug Test Ordered (PRP and Probationers)	744				744
Drug Tests Conducted (PRP and Probationers)	721				721
Relapses (Break in Sobriety)					
Relapsed (PRP and Probationers)	1				1
Major Violation Actions					
Cease Practice/Suspension (PRP and Probationers)	3				3
Termination from PRP	1				1
Probationers Referred for Discipline					
Closure					
Successful Completion (PRP and Probationers)	1				1
Termination (Probation)					
Voluntary Surrender (Probation)	4				4
Surrender as a result of PTR (Probation)					
Closed Public Risk (PRP)					
Non-compliance (PRP and Probationers)	23				23
Other (PRP)	2				2
Patients Harmed					
Number of Patients Harmed (PRP and Probationers)					

SB 1441 Uniform Standards

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

Board of Pharmacy	July -Sep	Oct – Dec	Jan-Mar	Apr-Jun	Total 20/21
Drug of Choice at PRP Intake or Probation					
Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol					
Ambien					
Opiates	1				1
Hydrocodone					
Oxycodone					
Morphine	1				1
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Intern Pharmacists	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	1				1
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					
Pharmacy Technicians	**July-Sep**	**Oct-Dec**	**Jan-Mar**	**Apr-Jun**	**Total 20/21**
Alcohol	2				2
Opiates					
Hydrocodone					
Oxycodone					
Benzodiazepines					
Barbiturates					
Marijuana					
Heroin					
Cocaine					
Methamphetamine					
Pharmaceutical Amphetamine					
Phentermine					
Methadone					
Zolpidem Tartrate					
Hydromorphone					
Clonazepam					
Tramadol					
Carisprodol					
Phendimetrazine					
Promethazine w/Codeine					

Board of Pharmacy

Citation and Fine Statistics FY20/21

Citation Outcomes	July - Sept	Oct - Dec	Jan - March	Apr - Jun	Total
Pharmacist with Fine	60	0	0	0	60
Pharmacist no Fine	38	0	0	0	38
Pharmacy with Fine	42	0	0	0	42
Pharmacy no Fine	47	0	0	0	47
Pharmacist-in-Charge with Fine*	29	0	0	0	29
Pharmacist-in-Charge no Fine	31	0	0	0	31
Pharmacy Technician with Fine	17	0	0	0	17
Pharmacy Technician no Fine	1	0	0	0	1
Wholesalers	3	0	0	0	3
Designated Representative	2	0	0	0	2
Clinics	0	0	0	0	0
Drug Room	0	0	0	0	0
Exempt Hospital	0	0	0	0	0
Hospital Pharmacy	6	0	0	0	6
Miscellaneous**	12	0	0	0	12
Unlicensed Premises	1	0	0	0	1
Unlicensed Person	0	0	0	0	0

*These numbers are also represented in the RPH columns, but reflect how many RPHs were cited as PICs

**Intern Pharmacist, Licensed Correctional Facilities, Exempt Pharmacies, Non-Resident Pharmacies, and Vet Retailers

Top Ten Violations by License Type

Pharmacists	%	Pharmacies	%	Pharmacists In Charge	%
1716 - Variation from prescription	31%	1716 - Variation from prescription	28%	1716 - Variation from prescription	24%
1761(a)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Schedule II,	17%	4113(d) - Every pharmacy shall notify the board in writing within 30 days of the date of a change in pharmacist-in-charge	16%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	15%
1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	10%	4113(a) - Pharmacist-in-Charge: Notification to Board; Responsibilities; Every pharmacy shall designate a pharmacist-in-charge within 30 days in writing of the identity and license number of that pharmacy	15%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	9%
4301(h) - Unprofessional Conduct – The administering to oneself, of any controlled substance, or the use of any dangerous drug or of alcoholic beverages to the extent or in a manner as to be dangerous	7%	1761(a)/11164(a) - No pharmacist shall compound or dispense	9%	1761(a)/11164(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Schedule II,	9%
1761(a)(b)/11164(a)/11152 - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…/Each prescription for a controlled substance classified in Sche	7%	1714(b) - Operational Standards and Security; pharmacy responsible for pharmacy security	6%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a patient	9%
11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	7%	4081(a)/1718 - Records of Dangerous Drugs and Devices Kept	6%	1304.11(b) - Inventory requirements-Initial inventory date	9%
11164(a)/1761(a) - Each prescription for a controlled substance classified in Schedule II, III, IV, or V, except as authorized by subdivision (b), shall be made on a controlled substance prescription	7%	1707.2(b)(1)(A) - In addition to the obligation to consult…a pharmacist shall provide oral consultation to his or her patients…whenever the prescription drug has not previously been dispensed to a pat	6%	1751.8(d)(1) - Beyond Use Dating for Sterile Compounded Drug Products; The beyond use date shall specify that storage and exposure periods cannot exceed 12 hours where the sterile compounded drug prep	6%
1764/56.10 - Unauthorized disclosure of prescription and medical information	5%	11165(d) - For each prescription for a Schedule II or Schedule III controlled substance, the dispensing pharmacy shall report to the Department of Justice…	6%	1761(a) - No pharmacist shall compound or dispense any prescription, which contains any significant error or omission…	6%
1764/56.10(a) - Unauthorized disclosure of prescription and medical information	5%	4305(b) - Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	4%	1764/56.10(a) - Unauthorized disclosure of prescription and medical information	6%
1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	5%	1715.65(c) - Inventory Reconciliation Report of Controlled Substances; at least every three months	4%	1716/1761(a) - Variation from prescription/Erroneous or uncertain prescription; no pharmacist shall compound or dispense any prescription which contains any significant error or omission…	6%