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

Legislation and Regulation Committee Report

Jessica Crowley, Licensee Member, Chair
Nicole Thibeau, Licensee Member, Vice Chair
Trevor Chandler, Public Member
Kartikeya Jha, Licensee Member
Maria Serpa, Licensee Member

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

II. Public Comment for 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 July 17, 2024, Committee Meeting Minutes

Attachment 1 includes a copy of the July 17, 2024, draft minutes.

IV. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Provided below are several measures for the Committee's consideration. A brief summary of each measure is provided along with staff comments and recommendations. A link to each measure and committee bill analysis is also provided, where available. During the meeting, members will have the opportunity to discuss each measure.

a) Assembly Bill 50 (Bonta, 2025) Pharmacists: Furnishing Contraceptives
Version: As Amended April 2, 2025
Status: Referred to Assembly Health Committee
Committee Analysis: Assembly Business and Professions
Summary: Would update provisions related to pharmacist-furnished hormonal contraception to explicitly allow for pharmacists to furnish over-the-counter contraception without following the standardized procedures required for prescription-only hormonal contraception. Further, would allow for the furnishing of up to at 12-month supply at one time of OTC contraception.
Recommended Position: Support

Comments: This measure is similar to the Board's sunset issue related to pharmacist-furnished over-the-counter hormonal contraception. The measure includes an urgency provision.

Support:

- Birth Control Pharmacist (Co-Sponsor)
- Essential Access Health (Co-Sponsor)
- National Health Law Program (Co-Sponsor)
- American College of Obstetricians & Gynecologists – District IX
- Asian Americans Advancing Justice – Southern California
- California Pan – Ethnic Health Network
- California Pharmacists Association
- California Primary Care Association
- California Women's Law Center
- Citizens for Choice
- Courage California
- Disability Rights Education & Defense Fund
- Glide
- Health Access California
- Latino Coalition for a Healthy California
- Reproductive Freedom for All California
- South Asian Network
- The Children's Partnership
- Western Center on Law & Poverty
- Women's Foundation California

Opposition: None on file

Fiscal Impact: Minor and absorbable.

b) Assembly Bill 447 (González, 2025) Emergency Room Patient Prescriptions: Dispensing Unused Portions Upon Discharge

Version: As Amended March 28, 2025

Status: Assembly Business and Professions Committee hearing April 8, 2025

Committee Analysis: None available

Summary: Would allow a prescriber to dispense an unused portion of a dangerous drug acquired by the hospital pharmacy to an emergency room patient under specified conditions, including the dangerous drug is not a controlled substance, the dangerous drug has been ordered and administered to the emergency room patient, and dispensing the unused portion of the dangerous drug is required to continue treatment of the patient. Further, as amended, would exempt from licensure an AUDS that is used to dispense to an emergency room patient pursuant to Business and Professions Code section 4068.

Recommended Position: Watch

Comments: The Board may wish to consider if it is appropriate to limit or seek further clarification on the definition of an "unused portion of a dangerous drug".
Fiscal Impact: The measure could result in a loss of revenue associated with the licensure and renewal of AUDS currently used in emergency departments.
Support:

- California Chapter of the American College of Emergency Physicians (Sponsor)
- California State Association of Psychiatrists (CSAP)
- California Emergency Nurses Association

Opposition: Unknown

c) Assembly Bill 529 (Ahrens, 2025)
Version: As introduced February 11, 2025
Status: Referred to Assembly Appropriations Committee
Committee Analysis: Assembly Business and Professions
Summary: Would extend the Board's authority to continue to waive a provisions of pharmacy law for up to 120 days following the terminations of a declared emergency.
Recommended Position: Support
Fiscal Impact: Minor and absorbable
Support: Mental Health America of California
Opposition: None of file

d) Assembly Bill 667 (Solache, 2025) Professions and Vocations: License Examination Interpreters
Version: As Amended April 1, 2025
Status: Assembly Business and Professions Committee hearing April 8, 2025
Committee Analysis: None available
Summary: Would, beginning July 1, 2026, require boards within the DCA to permit an applicant who cannot read, speak, or write in English, to use an interpreter, at no cost to the applicant. Would specify that the interpreter cannot have a license for which the applicant is taking the examination. Would require the board to post information regarding the provisions. Would, beginning July 1, 2027, require boards to update applications to ask the applicant to identify their preferred language and require boards to conduct an annual review of the language preferences of applicants. Board would be required to report this information annually to specified committees of the Legislature as specified beginning January 1, 2029.
Recommended Position: Watch
Comments: Board staff have concerns that as drafted the measure could apply to the NAPLEX examination. Board staff have reached out to NABP for information about potential impact.

Fiscal Impact: The fiscal impact could be significant.

e) Assembly Bill 669 (Haney, 2025) Substance Use Disorder Coverage
Version: As Introduced February 14, 2025
Status: Assembly Health Committee hearing April 22, 2025
Committee Analysis: None available
Summary: Would, effective January 1, 2027, ensure 28 days of inpatient, intensive outpatient or partial hospitalization for substance use disorder treatment for patients. Would prohibit insurers from requiring prior authorization for FDA-approved medications used to treat addiction that are deemed medically necessary by a doctor.
Recommended Position: Support
Comments: The Board has historically supported measures that address barriers to access to treatment for substance use disorder.
Fiscal Impact: Any impact would be minor and absorbable.
Support:
- California Consortium of Addiction Programs and Professionals (co-sponsor)
- California Behavioral Health Association (co-sponsor)
- Addiction Treatment Advocacy Coalition (co-sponsor)
- A New PATH (Parents for Addiction Treatment and Healing) (co-sponsor)

Oppose: Unknown

f) Assembly Bill 957 (Ortega, 2025) Cigarette and Tobacco Products: Retail Sale: Pharmacies
Version: As Introduced February 20, 2025
Status: Assembly Business and Professions Committee hearing April 8, 2025
Committee Analysis: None available
Summary: Would prohibit a pharmacy from selling cigarettes or tobacco products.
Recommended Position: Support
Comments: This measure appears consistent with the below Board policy statement adopted October 29, 2014.

> *The California State Board of Pharmacy recognizes that pharmacists are health care providers and pharmacies are in the business of improving customer health; therefore, the board recommends that pharmacies and chain stores that include pharmacies eliminate the sale of tobacco, e-cigarettes and tobacco products, as these products are known to cause cancer, heart disease, lung disease and other health problems.*

Fiscal Impact: Minor and absorbable.
Support:
- American Cancer Society (sponsor)
- Campaign for Tobacco-Free Kids (sponsor)

- American Lung Association (sponsor)

Opposition: Unknown

g) Assembly Bill 1037 (Elhawary, 2025) Public Health: Substance Use Disorder
Version: As Introduced February 20, 2025
Status: Assembly Health Committee hearing April 8, 2025
Committee Analysis: None available
Summary: As related to Pharmacy Law, would remove the January 1, 2026 sunset date related to pharmacist authority to furnish hypodermic needles and syringes for human use without a prescription under specified conditions.
Recommended Position: Support.
Staff Comments: The Board has a history of support NEPs.

h) Assembly Bill 1460 (Rogers, 2025) Prescription Drug Pricing
Version: As Introduced February 21, 2025
Status: Referred to Assembly Health Committee
Committee Analysis: None available
Summary: Would prohibit a prescription drug manufacturer from engaging in discriminatory practices that would impose additional conditions or otherwise interfere with a covered entity's purchase or delivery of a drug subject to federal pricing requirements under specified conditions.
Recommended Position: Support
Staff Comments: This measure appears to address recent efforts to undermine 340B programs.

i) Assembly Bill 1503 (Committee on Business and Professions, 2025) Pharmacy: Sunset Review: Advanced Pharmacist Practitioner
Version: As Introduced February 24, 2025
Status: Assembly Business and Professions Committee hearing April 29, 2025
Committee Analysis: None available
Summary: This is the Board's Sunset measure. In its current form would update the term "advanced practice pharmacist" to "advanced pharmacist practitioner"
Recommended Position: Support
Staff Comments: The Board's oversight hearing was March 11, 2025. The Board will be considering its draft responses to issues raised by the oversight committees during the April 9-10, 2025, Board meeting.

j) Senate Bill 41 (Wiener) Pharmacy Benefits
Version: As Amended March 17, 2025
Status: Health Committee hearing scheduled for April 23, 2025

Committee Analysis: None
Summary: Would establish the regulation of Pharmacy Benefit Managers (PBMs) within the California Department of Insurance (CDI) as specified, including the following:

- Establish licensure requirements for PBMs by CDI
- Would require a PBM to provide to the CDI, on or before July 1, 2028, and each subsequent year, a report that contains specified information.
- Would require the CDI to publish a report on or before January 1, 2029, and each subsequent year, information relating to PBM reporting.
- Would define specialty drug as one that exceeds the threshold for a specialty drug under Medicare Part D program for purposes of reporting requirements under the measure.
- Would establish actions that are prohibited by a PBM.
- Would establish disclosure obligations on PBMs.
- Would require PBMs to use passthrough pricing model.
- Would require CDI to perform specified actions, including publishing on its website a record of consumer complaints against a PBM that have been justified by CDI.
- Would require PBMs to reimburse a pharmacy the cost of a prescription drug in an amount that is no less than the National Average Drug Acquisition Cost or the pharmacy's wholesale acquisition cost of that drug (under specific circumstances) at the time of the drug being dispensed.

Recommended Position: Support
Staff Comments: Staff notes that the Board has received public comments and complaints from consumers and health care providers stemming from actions by PBMs. Such complaints range in the types of medications involved from maintenance medications (such as the treatment of high blood pressure) to specialty medications (generally high-cost medications used to treat complex, chronic conditions). Investigations have revealed that the root cause of some delays in access, for example, stems from mandates established by PBM. Under the provisions of the measure, the Board can refer such investigations to CDI for investigation.

k) Senate Bill 470 (Laird) Healing Arts: Bagley-Keene Open Meeting Act: Teleconferencing
Version: As Introduced February 19, 2025
Status: Governmental Organization Committee hearing March 25, 2025
Committee Analysis: None
Summary: The act authorizes a state body to hold a meeting by teleconference subject to specified requirements, including, among others, that at least one member of the state body is physically present at each teleconference location, as defined, that a majority of the members

of the state body are physically present at the same teleconference location, except as specified, and that members of the state body visibly appear on camera during the open portion of a meeting that is publicly accessible via the internet or other online platform, except as specified. Under specified circumstances, the act authorizes a member of the state body to participate from an undisclosed remote location, that is not accessible to the public. The act repeals these provisions on January 1, 2026. This bill would delete the January 1, 2026, repeal date, thereby authorizing the above-described additional, alternative set of teleconferencing provisions indefinitely.

Recommended Position: Support

Comments: The Board currently conducts its meetings consistent with the Bagley-Keene Open Meeting Act requirements. This bill would allow the Board to continue its hybrid approach to public meetings.

Fiscal Impact: Board staff anticipates a cost savings of approximately $35,000/annually.

Support:

- Alzheimer's Association
- California Association of Licensed Investigators
- California Commission on Aging
- Little Hoover Commission

Opposition:

- ACLU California Action
- California Chamber of Commerce
- First Amendment Coalition

l) Senate Bill 497 (Wiener) Legally protected health care activity

Version: As Introduced February 19, 2025

Status: Referred to Senate Judiciary and Public Safety Committees

Committee Analysis: None

Summary: This bill would prohibit the following:

- The release of medical information related to a person seeking or obtaining gender-affirming health care or gender-affirming mental health care in response to a criminal or civil action, including a foreign subpoena, based on another state's law that interferes with an individual's right to seek or obtain gender-affirming health care or gender-affirming mental health care.
- Cooperation with or providing medical information to an individual, agency, or department from another state or, to the extent permitted by federal law, to a federal law enforcement agency that would identify an individual and that is related to an individual seeking or obtaining gender-affirming health care, as specified.
- The release of medical information related to sensitive services, as defined, in response to a foreign subpoena that is based on a violation

of another state's laws authorizing a criminal action against a person or entity for provision or receipt of legally protected health care activity, as defined.
- The issuance of a subpoena based on a violation of another state's law that interferes with a person's right to seek or obtain gender-affirming health care or gender-affirming mental health care, as specified.
- Out-of-state law enforcement from having access to CURES data through the interstate data sharing hub.

Recommended Position: Support

m) Senate Bill 548 (Reyes) California Overdose Death and Addiction Reduction Act of 2025
Version: As Amended March 24, 2025
Status: Re-referred to Senate Committee on Health
Committee Analysis: None
Summary: This bill would require the California Health and Human Services Agency, on or before January 1, 2028, to create a set of recommendations to support a five-year implementation plan for reducing alcohol- and drug-related addiction deaths by 50% by 2031 and convene a state advisory group for the purposes of advising the agency on those recommendations. The bill would require the advisory group to consist of representatives from specified entities, including the State Department of Health Care Services, among others. The bill would require the agency to adopt the recommendations provided by the advisory group and to consider specified information, including quality and performance measures, in establishing minimum standards for the effective delivery of services.
Recommended Position: Support
Comments: Staff note that the Board is not included on the list of advisory group members.

n) Senate Bill 641 (Ashby) Department of Consumer Affairs (DCA) and Department of Real Estate: States of Emergency: Waivers and Exemptions
Version: As Introduced February 20, 2025
Status: Senate Business and Professions Committee hearing, April 7, 2025
Committee Analysis: None
Summary: This bill would authorize the Boards within DCA to waive the application of certain provisions of Board licensure requirements for licensees and applicants impacted by a declared federal, state, or local emergency or whose home or business is located in a declared disaster area, including certain examination, fee, and continuing education requirements. Additionally, it would require all applicants and licensees of the Board to provide the Board with an email address.

Recommended Position: Support
Comments: In 2021, the Board promulgated a regulation requiring applicants and licensees to provide the Board with an email address *if the individual has one* and notify the Board within 30 days of any change in their email address. A regulation change would be necessary.
Fiscal Impact: Due to the waiver of fees, the Board's fiscal impact is unknown and will be based on the extent of the declared emergency.

V. Discussion and Consideration of Board Regulations

The full timelines for each regulation are included within the respective attachments.

a. Board-Adopted Regulations Final Rulemaking Documents Undergoing Review by the Office of Administrative Law

Attachment 2

1. Proposed Regulation to Add Title 16 CCR Section 1700 Related to Digital Signatures

   Summary of Regulation: This proposal established the board's regulations regarding the requirements for digital signatures.

   Status: Submitted to OAL for final review on March 26, 2025.

b. Board-Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs, or Business, Consumer Services and Housing Agency

Attachment 3

1. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to Medication-Assisted Treatment Protocol

   Summary of Regulation: This proposal adds to the board's regulations regarding medication-assisted treatment.

   Status: Submitted for pre-review on March 17, 2025.

2. Proposed Regulation to Amend Title 16 CCR section 1707.4 Related to Central Fill Pharmacies

   Summary of Regulation: This proposal amends the board's regulations regarding the requirements for Central Fill pharmacies.

Status: Submitted for pre-review on March 16, 2025.

c. Board-Approved Regulations – Board Staff Drafting Initial Rulemaking Documents

Attachment 4

1. Proposed Regulation to Amend Title 16 CCR section 1715.1 Related to Automated Drug Delivery Systems Self-Assessment

   Summary of Regulation: This proposal amends the board's regulations regarding the ADDS Self-Assessment Form.

   Status: Approved by the Board on April 25, 2024. Board staff drafting rulemaking documents.

2. Proposed Regulation to Add Title 16 CCR sections 1750 and 1750.1 Related to Outsourcing Facilities

   Summary of Regulation: This proposal adds to the board's regulations regarding the licensure requirements for Outsourcing facilities.

   Status: Board staff revising rulemaking documents.

VI. Future Committee Meeting Dates

- June 11, 2025

VII. Adjournment

Attachment 1

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Business, Consumer Services and Housing Agency
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LEGISLATION AND REGULATION COMMITTEE
Draft MEETING MINUTES

DATE: July 17, 2024

Location: OBSERVATION AND PUBLIC COMMENT IN PERSON:
California State Board of Pharmacy
2720 Gateway Oaks Drive, First Floor Hearing Room
Sacramento, CA 95833

Board of Pharmacy staff members were present at the observation and public comment location.

PUBLIC PARTICIPATION AND COMMENT FROM REMOTE LOCATIONS VIA WEBEX

COMMITTEE MEMBERS PRESENT: Jessi Crowley, PharmD, Licensee Member, Chair
Nicole Thibeau, PharmD, Licensee Member, Vice Chair
Kartikeya "KK" Jha, Licensee Member
Maria Serpa, PharmD, Licensee Member

COMMITTEE MEMBERS NOT PRESENT: Trevor Chandler, Public Member

STAFF MEMBERS PRESENT: Anne Sodergren, Executive Officer
Julie Ansel, Assistant Executive Officer
Shelley Ganaway, DCA Staff Counsel
Jennifer Robbins, DCA Staff Counsel
Debbie Damoth, Executive Specialist Manager

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

Chairperson Crowley called the meeting to order at 2:05 p.m. Chairperson Crowley reminded all present that the Board is a consumer protection agency charged with administering and enforcing Pharmacy Law. The meeting moderator provided instructions on how to participate during the meeting, including the process to provide public comment.

Chairperson Crowley took roll call. The following members were present: KK Jha, Licensee Member; Maria Serpa, Licensee Member; Nicole Thibeau, Licensee Member; and Jessi Crowley; Licensee Member. A quorum was established.

Dr. Crowley reminded Committee members to remain visible with cameras on throughout the open session of the meeting. Dr. Crowley advised if members needed to temporarily turn off their camera due to challenges with internet connectivity, they must announce the reason for their non-appearance when the camera was turned off.

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

Members of the public in Sacramento were provided the opportunity to provide comments on items not on the agenda; however, there were no comments made.

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

An opioid stewardship pharmacist at UC Davis asked the Board to clarify which California laws prohibit methadone dispensing from inpatient hospital pharmacies to patients under the new DEA 72-hour rule updated in 2022. Business and Professions Code (BPC) section 4126.5 states a pharmacist may furnish dangerous drugs only to a patient or another pharmacy pursuant to a prescription or as otherwise authorized by law. The pharmacist asked the Board to comment if the new DEA exception 21 CFR 1306.07 qualifies as otherwise allowed by law; and if dispensing from a hospital would be permitted under AB 2115 if and when it was passed in the Senate.

A pharmacist requested a status on the Board approved regulation for title 16, California Code of Regulation (CCR) section 1709.1 related to pharmacist-in-charge (PIC) qualifications.

Staff will confer with counsel before giving guidance to the Chair regarding a future agenda item related to methadone. The commenter was advised the subject of methadone was discussed at the April 2024 Legislation and Regulation Committee meeting minutes under SB 1468 about education.

III. Approval of the April 11, 2024, Committee Meeting Minutes

Members were provided the opportunity to provide comments on the draft minutes. Dr. Serpa requested a change to page 14 correcting the statement that Dr. Serpa thought opposed unless amended (OUA) would be better than oppose position.

Motion: Approve the April 11, 2024, Legislation and Regulation Committee meeting minutes with changes requested.

M/S: Serpa/Thibeau

Members of the public located in Sacramento or participating via WebEx were provided the opportunity to provide comments; however, no comments were made.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

IV. Discussion and Consideration of Pending Legislation Impacting the Practice of Pharmacy, the Board's Jurisdiction, or Board Operations

Chairperson Crowley advised there were a number of measures included on the agenda. Dr. Crowley added having already passed several legislative deadlines, the legislature was currently on Summer Recess and reconvened August 5, 2024. Dr. Crowley noted a number of the proposals included on the agenda were previously discussed and referenced the meeting materials noting the Board's position. She advised new measures were also included where the Board established a position through the delegated authority of the President. Dr. Crowley added a few measures were no longer included as they did not meet legislative deadlines, including Assembly Bill 3026 and Assembly Bill 3146. Dr. Crowley reminded at the April 2024 Committee meeting, it was determined that the Committee and Board did not need to monitor some measures though staff would continue to monitor (*e.g.*, Assembly Bill 82 related to dietary supplements for Weight Loss and Over the Counter Diet Pills). Dr. Crowley advised related to Assembly Bill 82, the measure continued to move and would be considered by the Senate Appropriations Committee on August 5.

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

a. Assembly Bill 164 (Committee on Budget, 2024) State Government

Dr. Crowley advised AB 164 was a companion measure with Senate Bill 164 as it contained similar provisions. Neither measure was previously considered by the Committee or Board. The measure was included to ensure the Board and the Board's regulated public were aware of a change in the annual CURES fee. Specifically, as Chaptered the CURES fee will increase from $9 annually to $15 annually. Given this legislation, as an example, a pharmacist will be assessed a $30 CURES fee each renewal cycle, beginning with licenses that expire on or after July 1, 2025.

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

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

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

b. Assembly Bill 1842 (Reyes) Health Care Coverage: Medication-Assisted Treatment

Dr. Crowley advised AB 1842 would prohibit a health care service plan or health insurer from requiring prior authorization or step therapy for a naloxone or other opioid antagonist approved by the FDA or a buprenorphine or long-acting injectable naltrexone for detoxification or maintenance treatment of a substance use disorder. The Board established a support position on this measure. At the April 2024 Committee meeting, the Board noted having a long history of supporting measures that facilitate better access to naloxone and other medication assisted treatments. Dr. Crowley believed the Board's current support position remained appropriate and did not recommend changes.

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

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

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

c. Assembly Bill 1902 (Alanis) Prescription Drug Labels: Accessibility

AB 1902 would require pharmacies to provide translated directions for use on prescription labels under specified conditions and further would require a pharmacy to provide a person, at no additional cost, an accessible prescription label that among other conditions, was appropriate to the disability and language of the person making the request through the use of audible, large print, Braille, or translated labels. As amended this measure would not apply if the dispenser was a veterinarian. The Board previously considered this measure and determined a position was not appropriate. As shared during the April 2024 Committee Meeting, the policy goals of the measure were laudable. The measure enjoyed broad support. According to the recent Senate Floor analysis, the measure had no opposition on file. Dr. Crowley recommended the Board continue to monitor this legislation.

Members were provided the opportunity to comment. Members agreed to watch closely as the language was not clear of impact to pharmacies. Members agreed with the intent but expressed concern with logistics of implementation.

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

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

d. Assembly Bill 2115 (Haney) Controlled Substances

Dr. Crowley advised as amended AB 2115 would authorize a nonprofit or fee clinic to dispense a schedule II controlled substance for the purpose of relieving acute withdrawal symptoms while arrangements were being made for referral for treatment. The measure would also make changes to narcotic treatment programs. The measure was recently scheduled for hearing during the Assembly Business and Professions Committee hearing on April 16, 2024.

Dr. Crowley added the Board had a support position on the measure. The measure was amended twice since the Committee's last review in part to clarify the measure and address concerns from other stakeholders engaged in the process. Amendments included a requirement for a clinic,

when applicable, to establish policies and procedures in specified areas as related to clinic dispensing of narcotic drugs consistent with the authorities being established. Dr. Crowley believed the Board's support position remained appropriate and didn't recommend any action.

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

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

Members of the public via WebEx were provided the opportunity to provide comments.

A member of the public asked if the bill could be used by inpatient hospitals dispensing up to a 72-hour supply of methadone to patients who were going to be discharged and starting in a methadone treatment program after discharge.

Members were provided the opportunity to comment; however, no comments were made. Dr. Crowley advise staff would discuss with counsel to address the question.

e. Assembly Bill 2169 (Bauer-Kahan) Prescription Drug Coverage: Dose Adjustments

Dr. Crowley noted AB 2169 would authorize a health care professional to request authority to adjust the dose or frequency of a drug to meet specific medical needs of the enrollee without prior authorization under specified conditions, including that the dose had not been adjusted more than two times without prior authorization**.** Dr. Crowley reminded the Board had a support position on the measure and added the measure had not been amended since the Committee's last consideration. The measure was scheduled to be considered during the August 5, 2024 Senate Appropriations Committee.

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

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

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

f. Assembly Bill 3063 (McKinnor) Pharmacies: Compounding

Dr. Crowley advised AB 3063 was similar to AB 782 last year. Dr. Crowley reminded the Board initially established an oppose unless amended position in the hopes the Board could work with the author's office to discuss implementation challenges that some pharmacies may have indicated they would experience as a means to facilitate the policy goal of the measure without creating a conflict with state and federal law and national standards. Dr. Crowley noted regrettably that did not occur adding the primary difference between the two measures was the AB 3063 included a sunset date, meaning that conflict would only exist until January 1, 2030. Dr. Crowley added as previously discussed, inclusion of the sunset date did not address the Board's concerns. The Board ratified the oppose unless amended position established by President Oh as part of the April 2024 Board Meeting.

Dr. Crowley advised since that time, staff conveyed amendments to the author's office for consideration. Specifically, the amendments would have focused on actions to facilitate implementation of the USP requirements; however, regrettably those amendments were not accepted. Dr. Crowley believed a change to an oppose position was appropriate.

Dr. Crowley noted there was published research that demonstrated the impacts of flavoring agents on medications. As an example, in published research entitled, Interactions and incompatibilities of pharmaceutical excipients with pharmaceutical ingredients, a comprehensive review, "Most excipients have no direct pharmacological action, but they can impart useful properties to the formulation. However, they can also give rise to inadvertent and/or unintended effects such as increased degradation of the drug. Physical and chemical interactions between drugs and excipients can affect the chemical nature, the stability and bioavailability of drug products, and consequently, their therapeutic efficacy and safety (1)." Dr. Crowley added such a conclusion reinforces the importance of compliance with the national standards, most notably provisions for establishing beyond-use dates.

Members were provided the opportunity to comment. Members were disappointed to hear the author didn't take minor suggested amendments that would help licensees and encouraged changing the position to oppose.

Motion: Recommend to the Board to change to an oppose position.

M/S: Serpa/Thibeau

Members of the public located in Sacramento or participating via WebEx were provided the opportunity to provide comments; however, no comments were provided.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

g. Senate Bill 954, (Manjivar, 2024) Sexual Health

Dr. Crowley advised SB 954 had not been previously considered by the Committee or Board as it was identified as a potential measure for consideration after the April 2024 Committee Meeting. She recommended the measure be included on the agenda not because of policy concerns but to ensure the Board and members of the regulated public were aware of pending provisions in the Health and Safety Code that pharmacies may not routinely monitor for changes. Dr. Crowley continued under the provisions of the measure, pharmacies would be prohibited from refusing to furnish nonprescription contraception to a person based solely on age. Dr. Crowley agreed with the policy of the measure and didn't believe the Board needed to engage in the legislation. Dr. Crowley believed it would be appropriate to include this measure in any educational materials released related to changes in pharmacy law.

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

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

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

h. Senate Bill 966 (Wiener) Pharmacy Benefits

Dr. Crowley advised as amended, Senate Bill 966 would establish the regulation of Pharmacy Benefits Managers (PBM) within the Department of Insurance. She recalled the initial version of the measure would have placed the regulation of BPMs within the Board's purview. The measure was most recently amended July 3, 2024 and was referred to the Assembly Appropriations Committee. Dr. Crowley added the Board had a support position on the measure. She believed the Board's current support position remained appropriate.

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

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

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

i. Senate Bill 1067 (Smallwood-Cuevas) Healing Arts: Expedited Licensure Process: Medically Underserved Area or Population

Dr. Crowley advised SB 1067 would require the Board to develop a process to expedite the licensure process for an applicant that demonstrated they intend to practice in a medically underserved area or serve a medically underserved population. When previously considering this measure, the Board did not establish a position. As policy in California continues to seek to expedite certain types of applications, other applicants experience delays based to the priority that must be placed on certain applications. Dr. Crowley still believed the Board didn't need to establish a position on the measure. The measure had been amended since we previously considered it. As amended, the measure includes a sunset date of January 1, 2029.

Members were provided the opportunity to comment. Members discussed concerns related to a definition of "underserved" and issues related to backlogs and delays for other applicants.

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

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

j. Senate Bill 1089 (Smallwood-Cuevas) Addressing Food Injustice: Notice of Grocery and Pharmacy Closures

Dr. Crowley advised the Committee and Board did not previously discuss this measure as it was not identified in advance of notice requirements. As related to the Board's regulated public, the measure would require a pharmacy to provide advanced notice of closures to employees and specified agencies. Dr. Crowley reported through his delegated authority, President Oh established a support if amended position, requesting the Board be included in the list of agencies that receive notification of closure. Dr. Crowley noted that the amendment sought was consistent with the Board's policy in this area where the Board was seeking amendment to regulations to require such notification. Dr. Crowley reported the author accepted the Board's amendment and the Board was now included as one of the agencies to receive such reports under specified conditions. Dr. Crowley believed given the change, it was appropriate to change the Board's position to support.

Members were provided the opportunity to comment. Counsel provided clarification the measure was related to permanent closure.

Motion: Recommend changing the Board's position to support.

M/S: Thibeau/Serpa

Members of the public located in Sacramento or participating via WebEx were provided the opportunity to provide comments; however, no comments were provided.

Support: 4 Oppose: 0 Abstain: 0 Not Present: 1

Board Member	Vote
Chandler	Not Present
Crowley	Support
Jha	Support
Serpa	Support
Thibeau	Support

k. Senate Bill 1365 (Glazer) Pharmacy Technicians

Dr. Crowley reported as originally introduced SB 1365 would update the pharmacist to pharmacy technician ratio to 1:6, from the current ratio in

place of 1:1 or 1:2. The measure was amended April 24, 2024 to update the pharmacist to pharmacy technician ratio to 1:4 from the current ratio in place. Dr. Crowley recalled during the April 2024 Committee Meeting and April 2024 Board Meeting, members expressed concern with the measure and after considerable discussion determined it appropriate to establish an oppose position on the measure. Dr. Crowley advised the measure was held in the Senate Appropriations Committee on the suspense file and would not be moving forward. Dr. Crowley determined it was appropriate to include this measure on the agenda to ensure all interested parties were aware of the outcome. Dr. Crowley advised no action was required.

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

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

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

l. Senate Bill 1468 (Ochoa Bogh and Roth) Department of Consumer Affairs

Dr. Crowley advised SB 1468 would allow a practitioner who was not specifically registered to conduct a narcotic treatment program to dispense not more than a 3-day supply of narcotic drugs under specified conditions. Similar to the AB 2115, the Board established a support position on this measure. The measure was amended since the Board previously considered the measure to include a provision that states that the provisions do not apply the Veterinary Medical Board.

c. The Committee heard comments from a member of the public noting the measure didn't provide guidance if it was permissible for an inpatient hospital pharmacy to provide methadone under the three-day rule. A pharmacist commented providing his personal account of experience working on the measure.

m. House Resolution 58 (Jackson) Reliable and Safe Access to Care

Dr. Crowley recalled both Committees and the Board have received a number of public comments requesting that the Board take action to address the issue of drug shortages. Dr. Crowley believed generally speaking drug shortages were outside of the scope of the Board's purview. She requested House Resolution 58 be included on the agenda

to ensure the Board and interested parties were aware of the House resolution that made a number of legislative finding related to access to ADHD medication and that the state Assembly urged the California Health and Human Services Agency to hold pharmaceutical companies and others accountable for actions to address the current ADHD medication shortages and to meet with the US Department of Health and Human Services and DEA regarding modifications of any insufficiently justified quotas.

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

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

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

V. Discussion and Consideration of Board Regulations

Chairperson Crowley advised all items included in the regulations portion of the report were for information only. The Board had several regulations in various stages of promulgation. Dr. Crowley reported the Board had two regulations undergoing post-adoption review by the Office of Administrative Law including the Board's continuing education regulations and Board's section 100 updates to the Board's fee schedule that includes all fees except fees related to pharmacy technicians. The regulations related to pharmacy technicians were undergoing pre-notice review along with several other proposed rulemakings. Dr. Crowley noted the compounding regulations comment period recently closed and would be discussed during the Board meeting.

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

Members of the public located in Sacramento were provided the opportunity to provide comments; however, no comments were provided.

Members of the public participating via WebEx were provided the opportunity to provide comments; however, no comments were provided.

VI. Discussion and Consideration of Committee's Strategic Goals

Dr. Crowley reported the Legislation and Regulation Committee had six strategic

objectives and referenced meeting materials included updates to the respective objectives over the past year. She noted the updates highlighted the work of the Board in its policy making efforts to protect California consumers. Dr. Crowley added there was one objective for which there were no status updates included, which was for strategic goal 3.1 related to advocating for provider status. While there were no specific updates to provider status, she noted the passage of AB 317 provides for reimbursements under specified conditions, which was related to the policy goal of provider status. Dr. Crowley believed the objectives remained appropriate and didn't believe any changes were appropriate.

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

Members of the public located in Sacramento were provided the opportunity to provide comments; however, no comments were provided.

Members of the public participating via WebEx were provided the opportunity to provide comments. A pharmacist requested clarification on the first strategic goal regarding provider status and was reminded of the Board's jurisdiction was within California.

VII. Future Committee Meeting Dates

Chairperson Crowley advised the next Committee meeting date was scheduled for April 10, 2025 and encouraged participants to watch the Board's website for updates.

VIII. Adjournment

Chairperson Crowley adjourned the meeting at 3:02 p.m.

Attachment 2

Discussion and Consideration of Board Regulations

Regulation Timeline

V.a. Board-Adopted Regulations Undergoing Review by the Office of Administrative Law

1. Proposed Regulation to Add Title 16 CCR Section 1700, Related to Digital Signatures

   Timeline:

   Approved by Board: April 24, 2024
   Submitted to DCA for Pre-Notice Review: May 24, 2024
   Comment Period: December 20, 2024 – February 3, 2025
   Adopted by Board: March 6, 2025
   Submitted to DCA for Final Review: March 14, 2025
   Submitted to OAL for Final Review: March 26, 2025

Digital Signatures
16 CCR § 1700

Department of Consumer Affairs
Title 16. Board of Pharmacy

Proposed Regulation Text
Digital Signatures

Legend: Added Text is indicated with an underline.

Add section 1700 to Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1700. Digital Signatures

Consistent with the authority established in Government Code Section 16.5, in any written communication, application or other document in which a signature is required or used, the Board shall accept digital signatures that meet the requirements set forth in the California Code of Regulations, Title 2, section 22003(a).

NOTE: Authority Cited: Section 16.5, Government Code. Reference: Section 16.5, Government Code.

Attachment 3

Discussion and Consideration of Board Regulations

Regulation Timeline

V.b. Board-Approved Regulations Undergoing Pre-Notice Review by the Department of Consumer Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Add Title 16 CCR section 1746.6 Related to Medication Assisted Treatment Protocol

   Timeline:

   Approved by Board: February 7, 2023
   Submitted to DCA for Pre-Notice Review: June 23, 2023
   Returned to Board staff for Review: January 30, 2024
   Return to DCA for Pre-Notice Review: November 7, 2024
   Returned to Board staff for Review: January 9, 2025
   Return to DCA for Pre-Notice Review: March 17, 2025

2. Proposed Regulation to Amend Title 16 CCR section 1707.4, Related to Central Fill Pharmacies

   Timeline:

   Approved by Board: August 1, 2024
   Submitted to DCA for Pre-Notice Review: March 16, 2025

Medication Assisted Treatment Protocol 16 CCR § 1746.6

Proposal to Add CCR Section 1746.6 Pharmacist Provided Medication-Assisted Treatment

(a) A pharmacist may initiate, modify, administer, or discontinue medication-assisted treatment pursuant to Section 4052(a)(14) consistent with all relevant provisions of federal law and shall satisfy the requirements of this section.
    1. The pharmacist possesses appropriate education and training to provide such treatment consistent with the established standard of care used by other health care practitioners providing medication-assisted treatment including nationally accepted guidelines.
    2. The pharmacist must ensure a confidential patient care area is used to provide the services. The patient may not waive consultation.
    3. Assessment of the substance use disorder is performed including physical and laboratory examinations for signs and symptoms of substance use disorder. Initial assessment may be waived if the patient is referred to the pharmacist for treatment following diagnosis by another health care provider.
    4. Development of a treatment plan for substance use disorder including referral to medical services, case management, psychosocial services, substance use counseling, and residential treatment is provided as indicated.
    5. Documentation of the pharmacist's assessment, clinical findings, plan of care, and medications dispended and administered will be documented in a patient record system and shared with a patient's primary care provider or other prescriber, if one if identified.
    6. A pharmacist performing the functions authorized in this section shall do so in collaboration with other health care providers.

(b) For purposes of this section medication assisted treatment includes any medication used to treat a substance use disorder.

Central Fill Pharmacies 16 CCR § 1707.4

DEPARTMENT OF CONSUMER AFFAIRS
Title 16. Board of Pharmacy

PROPOSED REGULATORY LANGUAGE
Central Fill Pharmacies

Proposed changes to the current regulation language are shown by ~~strikethrough~~ for deleted language and underline for added language.

Amend Section 1707.4 to Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1707.4. Procedures for ~~Refill~~ Central Fill Pharmacies.

(a) For purposes of this section, a central fill pharmacy is defined as a California-licensed pharmacy that, pursuant to a contract or on behalf of a pharmacy under common ownership, prepares and packages prescriptions for another pharmacy to dispense to the patient.
(b) For the purposes of this section, the originating pharmacy is defined as the pharmacy that received the patient's initial prescription and dispenses the medication to the patient.
(c) A central fill pharmacy located in California and licensed by the B~~b~~board may process a request for ~~refill of a~~ prescription medication received by ~~a~~ another pharmacy ~~within this state~~, provided:
(1) The pharmacy that is to ~~re~~fill the ~~prescription~~ medication either has a contract with the pharmacy which received the prescription or has the same owner as the other pharmacy.
(2) The prescription container:
(A) is clearly labeled with all information required by ~~S~~sections 4076 and 4076.5 of the Business and Professions Code; and
(B) as applicable, clearly shows the name and address of the pharmacy ~~re~~filling the ~~prescription~~ medication ~~and/~~or the name and address of the pharmacy which receives the ~~refilled prescription~~ medication to dispense to the patient. Nothing in this subsection should be interpreted as preventing inclusion of the name and address of both pharmacies.
(3) The patient is provided with written information indicating that the prescription was filled at a central fill pharmacy, and written information, either on the prescription label or with the prescription container, that describes which pharmacy to contact if the patient has any questions about the prescription or medication.
(4) Both pharmacies maintain complete and accurate records ~~of the refill~~, including:
(A) the name of the pharmacist who ~~re~~filled the prescription;
(B) the name of the pharmacy ~~re~~filling the prescription; and
(C) the name of the pharmacy that received the prescription ~~refill request~~.
(5) The pharmacy which ~~re~~fills the prescription and the pharmacy ~~to~~ which receives the ~~refilled~~ prescription ~~is provided~~ for dispensing to the patient shall each be responsible

for ensuring the order has been properly filled. Pharmacists working at the originating pharmacy may perform final product verification prior to dispensing, including through review of images of the final product in lieu of physical visual verification. A pharmacist shall not be required to perform final product verification where product verification by a pharmacist is performed at the time of stocking the automated dispensing device, if the dispensing device is not further accessed by pharmacy personnel, and the medication is dispensed into a labeled container (with a label that meets the requirements set forth in section 1707.5 of this Article).

(6) The originating pharmacy is responsible for compliance with the requirements set forth in ~~S~~sections 1707.1, 1707.2, and 1707.3 of the California Code of Regulations.

~~(b) Nothing in this section shall be construed as barring a pharmacy from also filling new prescriptions presented by a patient or a patient's agent or transmitted to it by a prescriber.~~

NOTE: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4063, 4076, 4076.5, 4081, and 4333, Business and Professions Code.

Attachment 4

Discussion and Consideration of Board Regulations
Regulation Timeline

V.c. Board-Approved Regulations – Board Staff Drafting Initial Rulemaking Documents

1. Proposed Regulation to Amend Title 16 CCR section 1715.1 Related to Automated Drug Delivery Systems Self-Assessment

   Timeline:

   Approved by the Board on April 25, 2024

2. Proposed Regulation to Amend Title 16 CCR section 1750 and 1750.1 Related to Outsourcing Facilities

   Timeline:

   Approved by Board: October 26, 2022
   Submitted to DCA for Pre-Notice Review: February 6, 2023
   Returned to Board staff for Review: April 16, 2024

Automated Drug Delivery Systems Self-Assessment 16 CCR § 1715.1

Title 16. Board of Pharmacy
Order of Adoption

Proposal to amend §1715.1 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715.1. Self-Assessment of an Automated Drug Delivery System by the Pharmacist-in-Charge.

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

(b) In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever:
  (1) A new automated drug delivery system license has been issued.
  (2) There is a change in the pharmacist-in-charge~~, and he or she becomes the new pharmacist-in-charge of an automated drug delivery system~~.
  (3) There is a change in the licensed location of an automated drug delivery system to a new address.

(c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1~~2~~/~~18~~23) entitled “Automated Drug Delivery System Self-Assessment”. Form 17M-112 shall be used for all automated drug delivery systems and is hereby incorporated by reference.
  (1) The pharmacist-in-charge shall provide identifying information about the underlying operating pharmacy including:
    (A) Name and any license number(s) of the underlying pharmacy and their expiration date(s);
    (B) Address, phone number, and website address, if applicable, of the underlying pharmacy;
    (C) DEA registration number, expiration date, and date of most recent DEA inventory;
    (D) Hours of operation of the pharmacy; and
    (E) ADDS license number, address, and hours of operation.
  (2) The pharmacist-in-charge shall respond “yes”, “no”, or “not applicable” (N/A) about whether the automated drug delivery system is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting.
  (3) For each “no” response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.
  (4) The pharmacist-in-charge shall initial each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

(5) The pharmacist-in-charge shall certify on the last page of the self-assessment that ~~he or she has~~ they have completed the self-assessment of the automated drug delivery system of which ~~he or she is~~ they are the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

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

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

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

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

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

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

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

(g) The pharmacist-in-charge of a licensed correctional pharmacy using more than one licensed automated drug delivery system at a single institution in compliancewith federal and state pharmacy law may complete a single consolidated self-assessment for all automated drug delivery systems licensed to the correctional pharmacy under the following conditions:

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

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

(3) All mechanical devices for which the single consolidated self-assessment applies shall be listed with license number and expiration date as part of the self-assessment.

Note: Authority cited: Sections 4119.11 and 4427.7, Business and Professions Code. Reference: Sections 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4117.3, 4119.1, 4119.11, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, ~~and~~ 4427.5, 4427.6, and 4427.7, Business and Professions Code; and Section 16.5, Government Code.

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

LEGEND: Proposed changes made to the current regulation language are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires that the pharmacy holding an automated drug delivery system (ADDS) license complete ~~an annual~~ a self-assessment, performed pursuant to section 1715.1 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 **before July 1 of every odd-numbered year** by the pharmacist-in-charge of each pharmacy under BPC sections 4029 (Hospital Pharmacy) or ~~section~~ 4037 (Pharmacy). The pharmacist-in-charge (PIC) 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 Division 2, 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 the signed original must be readily available and retained in the pharmacy for three (3) years after performed.

Note: For a hospital pharmacy operating an AUDS pursuant to BPC 4427.2(i) the exemption only applies to the licensure requirements for the AUDS. The hospital pharmacy is required to comply with all other requirements including completing the ADDS Self-Assessment pursuant to BPC 4427.7(a). The PIC may complete a single self-assessment for all ADDS, if the mechanical devices used are the same manufacturer, are controlled by the same software system on a single server and use same policies and procedures. Attach a list of all unlicensed ADDS, their locations and hours of operation. [CCR 1715.1(f)]

Note: **For a licensed correctional pharmacy** operating more than one licensed automated drug delivery system at a single institution, the PIC may complete a single consolidated self-assessment for all licensed ADDS, if the mechanical devices used are the same manufacturer, are controlled by the same software system on a single server and use the same policies and procedures. Attach a list of all licensed ADDS and include the ADDS license number, manufacturer and model number. [CCR 1715.1(g)]

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: _____ **Zip Code:** _____

Phone: _____ **Fax number:** _____

Website: _____

Pharmacy License #: _____ **Expiration (Exp) Date:** _____

DEA Registration #: _____ **DEA Exp~~iration~~ Date:** _____ **DEA Inventory Date:** _____

Last ~~C2~~ Controlled Substance (CS) Inventory Reconciliation Date (CCR 1715.65(c)): _____

Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____ **RPH#**_____

PIC Email: _____

ADDS License #: _____ **ADDS Expiration Date:** _____

(Attach additional sheets if necessary)

ADDS Address: _____

City: _____ **Zip Code:** _____

ADDS Hours: **M-F:** _____ **Saturday** _____ **Sunday** _____

Please explain if the ADDS hours are different than the pharmacy:

_____

_____

Reason for completing self-assessment:

☐ Performing self-assessment before July 1 of every odd-numbered 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, CCR 1715.1(b)(1)]

☐ Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.7, 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), 4427.65, ~~BPC~~ 4056, ~~BPC~~4068]

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~~APDS **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~~AUDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (HSC)~~(Long Term Care (LTC))~~ that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2), HSC 1250, HSC 1261.6]

~~**Yes No N/A**~~

☐☐☐ 2.4 Provides pharmacy services through an AUDS in **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** 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 dangerous devices to patients of the practice. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029 of the Business and Professions Code, 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 of the Business and Professions Code. 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. [BPC 4427.2(i)]

☐☐☐ 2.8 **AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room)**, as defined in section 4056 of the Business and Professions Code, is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs to outpatients: [BPC 4056(f), (g), (h), 4427.2(i)]

- ☐ 2.8.1. Only if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued.
- ☐ 2.8.2. 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 from the hospital pharmaceutical services by means of the method of transportation the patient states that they intend to use.
- ☐ 2.8.3. The quantity dispensed to any outpatient is limited to the amount necessary to maintain uninterrupted therapy during the period when the pharmaceutical services outside the hospital are not readily available or accessible and does not exceed a 72-hour supply. [BPC 4056, 4427.2(i)]

Yes No N/A

☐☐☐ 2.9 **AUDS located in the emergency room operated by a licensed hospital pharmacy**, as defined in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, 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 subdivisions (a) and (b) of section 1250 of the Health and Safety Code**, and to dispense** to an emergency room patient if: [BPC 4068, 4427.2(i), HSC 11165(a)]

- ☐ 2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 2.9.2. The drug is acquired by the hospital pharmacy.
- ☐ 2.9.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 2.9.4. The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance and dispensing information is reported to the Department of Justice pursuant to section 11165 of the Health and Safety Code.
- ☐ 2.9.5. 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 reasonably believes a

pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.

☐ 2.9.6. The quantity of drugs dispensed to any patient pursuant to this section is limited to the 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.

Note: Licensure of AUDS operated under these provisions is required.

☐☐☐ 2.10 **An AUDS may be located and operated in a facility licensed in CA with the statutory authority to provide pharmaceutical services**. [BPC 4427.65(a)(1)]

Type of Facility: _____

Statutory authority to provide pharmaceutical services (List code section): _____

Yes No N/A

☐☐☐ 2.11 **An AUDS may be located and operated in a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director**. [BPC 4427.3(b)(6), BPC 4427.65(a)(2)]

Type of Facility: _____

Statutory authority for type of Facility (List code section): _____

Please 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)]

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)]

☐ 3.4.1. Use of the ADDS is consistent with legal requirements.

☐ 3.4.2. The proposed location for installation of the ADDS meets the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.

☐ 3.4.3. The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

☐ 3.4.4. The pharmacy's policy and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law.

Yes No N/A

☐☐☐ 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), 4119.11(a)(9)]

☐☐☐ 3.7. The pharmacy is aware a replacement of an ADDS shall require notification to the board within 30 days. [BPC 4427.2(e), 4119.11(a)(9)]

☐☐☐ 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), 4119.11(a)(10)]

☐☐☐ 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), 4119.11(a)(11)]

☐☐☐ 3.10 The ADDS license~~(s)~~ is~~/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 section 4008. [BPC 4427.4(c)]

Yes No N/A

☐☐☐ 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)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2), 4427.65(c)(5)(D), HSC 1261.6(f)(4)]

☐☐☐ 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), BPC 4427.65(c)(5)(E), BPC 4119.11(f), HSC 1261.6(f)(5)]

☐☐☐ 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 of the Business and Professions Code, and, upon retrieval of the dangerous drugs and dangerous 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), 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 An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license. [CCR 1711(d), CCR 1711(f)]

~~❑❑❑ 3.24 The PIC of EACH ADDS completes a self-assessment of the pharmacy's compliance with federal and state pharmacy law and is performed [CCR 1715.1(a), (b)]:~~

- ~~Before July 1 of every odd-numbered year.~~
- ~~Within 30 days whenever a new ADDS licensed has been issued.~~
- ~~Within 30 days when there is a change in PIC.~~
- ~~When there is a change in the licensed location of an ADDS to a new address.~~

~~❑❑❑ 3.25 The PIC of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1/22) entitled "Automated Drug Delivery System Self-Assessment." [CCR 1715.1(c)]~~

~~❑❑❑ 3.26 The PIC responds "yes", "no", or "not applicable" about whether the ADDS is, at the time of the self-assessment, in compliance with laws and regulations that apply to that pharmacy setting. [CCR 1715.1(c)(2)]~~

~~❑❑❑ 3.27 For each "no" response, the PIC provides 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 on the last page of the self-assessment that they are the PIC, has certified a timeframe within which any deficiency identified within the self-assessment will be corrected, and has 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)]~~

~~Yes No N/A~~

~~❑❑❑ 3.30 The ADDS owner has certified the final page of the self-assessment that they have 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 is 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 ensures the following: [CCR 1715.65(h)]~~

~~☐ 3.33.1 All controlled substances added to an ADDS are accounted for.~~
~~☐ 3.33.2 Access to the ADDS is limited to authorized facility personnel.~~
~~☐ 3.33.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.~~
~~☐ 3.33.4 Confirmed losses of controlled substance are reported to the board.~~

Yes No N/A

☐☐☐ 3.24 The pharmacy's inventory reconciliation report prepared at least once every three months for federal Schedule II controlled substances, includes the federal Schedule II controlled substances stocked in the ADDS. [CCR 1715.65(a)(1)]

☐☐☐ 3.25 The pharmacy's inventory reconciliation report prepared at least once every 12 months for alprazolam 1mg/unit, alprazolam 2mg/unit, Tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, includes these controlled substances stocked in the ADDS. [CCR 1715.65(a)(2)]

☐☐☐ 3.26 Inventory activities are performed at least once every two years from the performance of the last inventory activities for each controlled substance that is not listed as a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml and includes the controlled substances stocked in the ADDS. [CCR 1715.65(a)(3)(B)]

☐☐☐ 3.27 For any controlled substance stocked in the ADDS that is not a federal Schedule II controlled substance, alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit and promethazine/codeine 6.25mg/10mg/5ml, the pharmacy prepares an inventory reconciliation report for the identified loss of that controlled substance in the ADDS no later than three months after the discovery of the reportable loss and is completed if the loss is discovered either by the inventory activities as identified in Section 3.26 above or any other manner. [CCR 1715.65(a)(3)(A)]

☐☐☐ 3.28 A physical count, not an estimate, of the federal controlled substances in the ADDS is taken for the inventory reconciliation reports, except for an inpatient hospital pharmacy or licensed correctional pharmacy where the inventory in the ADDS may be accounted for using means other than a physical count. [CCR 1715.65(c)(1), CCR 1715.65(h)]

☐☐☐ 3.29 The PIC or the consulting pharmacist for a licensed clinic reviews all inventory activities performed and inventory reconciliation reports prepared in accordance with CCR 1715.65 and has established and maintained secure methods to prevent losses of federal controlled substances. [CCR 1715.65(b)]

☐☐☐ 3.30 The pharmacy has written policies and procedures developed for performing the inventory activities and preparing the inventory reconciliation reports in accordance with CCR 1715.65

that includes the inventory of federal controlled substances stored in the ADDS. [CCR 1715.65(b)]

☐☐☐ 3.31 The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public. [BPC 4058]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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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 pharmacy owner or hospital administrator of the ADDS shall sign the Certification Acknowledgment on page ~~33~~ 48 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)~~
- APDS located in a Medical Office~~s~~
- APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice
- APDS located at a clinic pursuant to HSC 1204, 1204.1, BPC 4180, or 4190.

☐ 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~~7:– ADDS operated by a correctional clinic pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

☐ SECTION ~~9~~8:

- Hospital Pharmacy: AUDS used for dispensing pursuant to BPC 4068 ~~(~~when the hospital pharmacy is closed and no pharmacist is available~~)~~.
- Drug Room: AUDS used for dispensing pursuant to BPC 4056.

☐ SECTION 9:

- AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (or)
- AUDS through a jail, youth detention facility, or other licensed correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2).

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)]

☐☐☐ 4.3 Drugs purchased and received pursuant to section 256b of Title 42 of the United States Code (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 42 USC 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]~~

Yes No N/A

☐☐☐ 4.~~9~~8 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)]~~

☐☐☐ 4.9~~13~~ The pharmacy does not have more than 15 APDS licenses for one underlying operating pharmacy under this section. [BPC 4119.11(d)(10), 4427.6(k)] List of current APDS licenses:

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

~~**Yes No N/A**~~

☐☐☐ 4.10~~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)]

Yes No N/A

☐☐☐ 4.11~~15~~ The operating pharmacy of an APDS has completed a~~n annual~~ biennial Self-Assessment pursuant to CCR 1715.1 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: _____
Reason: ☐ Biennial; ☐ 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)]~~

☐☐☐ 4.~~18~~12 The underlying operating pharmacy is solely responsible for: [BPC 4119.11(a)(5), (6)]

☐ 4.12.1 The security of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.2 The operation of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.3 The maintenance of the APDS. [BPC 4119.11(a)(5)]
☐ 4.12.4 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

☐☐☐ 4.1~~9~~3 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~~14 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~~14.1. 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~~14.2. Transportation of removeable pockets, cards, drawers or similar technology o~~O~~r 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~~14.3. 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~~15 ~~The~~ A 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~~16 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

☐ 4.16.1. All controlled substances added to the ADDS/APDS are accounted for;

☐ 4.16.2. Access to ADDS/APDS is limited to authorized facility personnel;

☐ 4.16.3. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and

☐ 4.16.4. 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~~17 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~~18 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~~19 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~~20 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐ 4.2~~7~~1.1 The pharmacy has developed, ~~and~~ implemented, and maintained~~s~~ 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)]

- ☐ 4.21.1.1 Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 4.21.1.2 Determining~~e~~ 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.
- ☐ 4.21.1.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication, including those delivered via APDS.
- ☐ 4.21.1.4 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.
- ☐ 4.21.1.5 Orienting patients on the 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.
- ☐ 4.21.1.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event that the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

☐ 4.2~~7~~1.2 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drugs and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4119.11(d)(2)]

~~Yes No N/A~~

☐ 4.2~~7~~1.3 The ~~device~~ APDS 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)(2)]

☐ 4.2~~7~~1.4 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)]

☐ 4.2~~7~~1.5 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~~s~~ contraindications and adverse drug reactions. [BPC 4119.11(d)(5)]

☐ 4.2~~7~~1.6 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 4119.11(d)(6)]

☐ 4.2~~7~~1.7 The APDS shall prominently post a notice that provides the name, address and telephone number of the pharmacy [BPC 4119.11(d)(7)]

☐ 4.2~~7~~1.8 The prescription labels on all drugs dispensed via APDS shall comply with BPC 4076 and CCR 1707.5. [BPC 4119.11(d)(8)]

~~☐☐☐ 4.27.9 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)]~~

Yes No N/A

☐☐☐ 4.2~~8~~2 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 4.2~~9~~3 Prescriptions are dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the prescriber or when requested by the purchaser. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 4.~~30~~24 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 4.~~31~~25 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 4.~~32~~26 Medication guides are provided on required medications. [~~(~~21 CFR 208.1]~~)~~

☐☐☐ 4.27 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

- ☐ 4.27.1. 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 the delivery of the prescription medication to the patient.
- ☐ 4.27.2. The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.
- ☐ 4.27.3. The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

☐ 4.27.4. Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

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~~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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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.~~36~~29 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually [BPC 4119.11(d)(1), CCR 1713(e)]:

- ☐ 4.29.1 Maintaining the security of the APDS and dangerous drugs and devices within the APDS.
- ☐ 4.29.2 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.
- ☐ 4.29.3 Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 4.29.4 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.

☐ 4.29.5 Orienting patients on use of the 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.

☐ 4.29.6 Ensuring the delivery of drugs and devices to patients expecting medications from the APDS ~~in the event~~ if the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.3~~7~~0 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)~~4105.5(c)(2)~~]

☐☐☐ 4.3~~8~~1 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~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~~ (Check the Appropriate Box)

☐ **APDS ADJACENT TO THE SECURED PHARMACY AREA ~~OR~~**

☐ **APDS LOCATED IN A MEDICAL OFFICE~~S (OR)~~**

☐ **APDS LOCATED WHERE PATIENTS ARE REGULARLY SEEN FOR PURPOSES OF DIAGNOSIS AND TREATMENT TO ONLY BE USED FOR PATIENTS OF THE PRACTICE ~~(OR).~~**

☐ **APDS LOCATED AT A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190.**

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 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.~~
- ~~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

☐☐☐ 5.2 The pharmacy uses the APDS to deliver prescription medications to patients provided: [CCR 1713(d)]

- ☐ 5.2.1. A pharmacist has determined that each patient using the APDS meets inclusion criteria for use of the APDS established by the pharmacy prior to delivery of prescription medication to the patient.
- ☐ 5.2.2. The APDS has a means of identifying each patient and only release that patient's prescription medication to the patient or patient's agent.
- ☐ 5.2.3. The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.
- ☐ 5.2.4. Any incident involving the APDS where a complaint, delivery error, or omission has occurred shall be reviewed as part of the pharmacy's quality assurance program mandated by Business and Professions Code section 4125.

~~**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)]

Yes No N/A

☐☐☐ 5.6 ~~The pharmacist shall consult patients for the first time on all prescribed drugs and devices dispensed from the APDS.~~ All prescribed drugs and devices dispensed to the patient from the APDS for the first time are accompanied by a consultation conducted by a California licensed pharmacist. 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)]

~~**Yes No N/A**~~

☐☐☐ 5.7 The ~~P~~pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- ☐ 5.7.1. All controlled substances added to the ADDS/APDS are accounted for;
- ☐ 5.7.2. Access to ADDS/APDS is limited to authorized facility personnel;
- ☐ 5.7.3. An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- ☐ 5.7.4. 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: _____~~

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~~8 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~~9 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.~~16~~10 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.~~17~~11 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)]

☐☐☐ 5.~~18~~12 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.~~19~~13 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.~~20~~14 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 5.~~21~~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]

Yes No N/A

☐☐☐ 5.~~22~~16 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 5.~~23~~17 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(c).

☐☐☐ 5.~~24~~18 Medication guides are provided on required medications. [21 CFR 208.1]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

~~☐☐ 5.25 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.~~26~~19 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.~~27~~20 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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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 5.~~28~~21 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are maintained and reviewed annually: [BPC 4427.6(a)~~= 4427.6(a)(6)~~, CCR 1713(e)]

- ☐ 5.21.1. Maintaining the security of the APDS and dangerous drug and devices within the APDS.
- ☐ 5.21.2. Determining~~e~~ and applying inclusion criteria regarding which drugs and~~,~~ devices are appropriate for placement in the APDS and for which patients.
- ☐ 5.21.3. Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS.
- ☐ 5.21.4. 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.
- ☐ 5.21.5. 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.
- ☐ 5.21.6. 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.~~29~~22 The pharmacy reports drug losses as required by law. [BPC 4104, 4427.2(d)(4)~~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~~ THAT COMPLIES WITH HSC 1261.6

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means any 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), 1250]

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~~1 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~~2 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~~3 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~~3.1. 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~~3.2. 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~~3.3. 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~~4 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~~5 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)]

☐☐☐ 6.6 A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:

☐ 6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]

- ☐ 6.6.1.1. The date the prescription was orally transmitted by the prescriber.
- ☐ 6.6.1.2. The name of the person for whom the prescription was authorized.
- ☐ 6.6.1.3. The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient.
- ☐ 6.6.1.4. The name and quantity of the controlled substance prescribed.
- ☐ 6.6.1.5. The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.1.6. The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.

☐ 6.6.2 Prior to filling a prescription for a Schedule II controlled substance that has been **electronically transmitted,** the pharmacist has produced, signed, and dated a hard copy prescription. The prescription must contain: [HSC 11167.5(a)]

- ☐ 6.6.2.1. The date the prescription was electronically transmitted by the prescriber;
- ☐ 6.6.2.2. The name of the person for whom the prescription was authorized;
- ☐ 6.6.2.3. The name and address of the licensed skilled nursing facility or licensed intermediate care facility in which the person is the patient;
- ☐ 6.6.2.4. The name and quantity of the controlled substance prescribed;
- ☐ 6.6.2.5. The directions for use, and the name, address, category of the professional licensure, license number, and federal controlled substance registration number of the prescriber.
- ☐ 6.6.2.6. The prescription is endorsed by the pharmacist with the pharmacy's name, license number, and address.
- ☐ 6.6.2.7. The prescription contains the signature of the person who received the controlled substance for the licensed skilled nursing facility or licensed intermediate care facility.

☐ 6.6.3 An original Schedule II prescription is written on a form that complies with Health and Safety Code section 11162.1. [HSC 11164(a)]

☐ 6.6.4 An original Schedule II prescription is written with the "11159.2 exemption" for the terminally ill. [HSC 11159.2]

☐ 6.6.5 In an emergency where failure to issue the prescription may result in loss of life or intense suffering, a Schedule II controlled substance may be dispensed from a prescription transmitted orally or electronically by a prescriber or written on a form not as specified in HSC 11162.1, subject to the following: [HSC 11167(a)-(c)]

- ☐ 6.6.5.1. The order contains all information required by subdivision (a) of Section 11164.

☐ 6.6.5.2. If the order is written by the prescriber, the prescription is signed, and dated by the prescriber in ink.

☐ 6.6.5.3. If the prescription is orally or electronically transmitted, it must be reduced to hard copy prior to dispensing the controlled substance.

☐ 6.6.5.4. The prescriber provides a written prescription on a controlled substance prescription form that meets the requirements of HSC 11162.1 by the seventh day following the transmission of the initial order.

☐ 6.6.6. An electronic prescription (e-script) for controlled substances that is received from the prescriber and meets federal requirements. [21 CFR 1306.08, 21 CFR 1311]

Yes No N/A

☐☐☐ 6.~~8~~7 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.~~

☐☐☐ 6.~~10~~8 The pharmacy operating the ADDS has completed a~~n~~ biennial Self-Assessment pursuant to BPC 4427.7(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~~9 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), HSC 1261.6(c), (g)]

~~☐☐☐ 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)]~~

~~Yes No N/A~~

☐☐☐ 6.~~13~~10 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~~11 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~~12 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~~13 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~~14 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~~15 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~~16 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~~17 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)]~~

Yes No N/A

☐☐☐ 6.~~23~~18 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~~19 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~~20 If the ADDS allows licensed personnel to have access to multiple drugs and ~~are~~ is not patient specific in its~~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)]~~)~~.

Please Note: A skilled nursing facility or intermediate care facility using an ADDS that allows licensed personnel to have access to multiple drugs and are not patient specific in their design, is required to contact the California Department of Public Health, Licensing, and Certification in writing prior to utilizing this type of ADDS. [HSC 1261.6(f)(7)(A)]

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)]~~

☐☐☐ 6.~~27~~21 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)]

Yes No N/A

☐☐☐ 6.22 Records of inspections completed by the pharmacist are kept for at least three years. [22 CCR 70263(f)(3)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.~~23~~23 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.~~24~~24 The ADDS policies and procedures define access to the ADDS and limits to access to equipment and drugs. [HSC 1261.6(d)(1)]

☐☐☐ 6.~~25~~25 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.~~26~~26 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~~27 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 Drugs removed from the ADDS shall be provided to the patient by a health professional licensed pursuant to BPC 4186(b).

☐☐☐ 7.4 The clinic is responsible for the review of the drugs contained within, and the operation and maintenance of, the ADDS. [BPC 4186(d)]

☐☐☐ 7.5 Drugs dispensed from the clinic ADDS shall comply with labeling requirements in BPC 4076 with CCR 1707.5. [BPC 4186(g), 4426.7(h)]

☐☐☐ 7.6 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)]

☐☐☐ 7.7 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)]

☐☐☐ 7.8 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)]

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule II 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 II controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule II 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.

Yes No N/A

☐☐☐ 7.10 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)]

☐☐☐ 7.11 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)]

☐☐☐ 7.12 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)]

☐☐☐ 7.13 The federal warning label prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ 7.14 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]

☐☐☐ 7.15 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ 7.16 The pharmacy provides patients with Black Box Warning Information in conformance with 21 CFR 201.57(e).

☐☐☐ 7.17 Medication guides are provided on required medications. [21 CFR 208.1]

☐☐☐ 7.18 Is the APDS located and operated only used to dispense dangerous drugs and dangerous devices to patients of the clinic? [BPC 4427.6j)]

☐☐☐ 7.19 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

☐☐☐ 7.20 The pharmacist performs the stocking of the ADDS. [BPC 4186(c)]

☐☐☐ 7.21 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)]

☐☐☐ 7.22 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: _____

☐☐☐ 7.23 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)]

Yes No N/A

☐☐☐ 7.24 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)]

☐☐☐ 7.25 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)]

☐☐☐ 7.26 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)]

☐☐☐ 7.27 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. [BPC 4186(e)]

☐☐☐ 7.28 The pharmacist operating the ADDS shall be located in California. [BPC 4186(f)]

☐☐☐ 7.29 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_____

C. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 7.32 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)]

- 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: _____

Yes No N/A

~~☐☐☐ 7.33 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)]~~

~~☐☐☐ 7.34 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)]~~

~~☐☐☐ 7.35 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)]~~

~~☐☐☐ 7.36 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)]~~

SECTION ~~8~~7: ADDS OPERATED BY A CORRECTIONAL CLINIC PURSUANT TO BPC 4187.1, 4427.3(b)(6), or 4427.65(a)(2)

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7~~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)]

☐☐☐ 7~~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 Co~~n~~de, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation. ~~(~~[BPC 4187(a)~~)~~].

~~Yes No N/A~~

☐☐☐ 7~~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 direction~~s~~ 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.

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~8~~.7 The correctional clinic has obtained a license from the board. [BPC 4187.1(d)(1)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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)]

☐☐☐ 7~~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

☐☐☐ 7~~8~~.1~~2~~1 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)]

☐☐☐ 7~~8~~.1~~3~~2 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)]

☐☐☐ 7~~8~~.1~~4~~3 The chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services. [BPC 4187.2(b)(1)]

☐☐☐ 7~~8~~.1~~5~~4 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 502~~4~~4~~2~~.2 of the Penal Code and the ~~statewide Inmate Medical Services~~ California Correctional Health Care Services ~~Policies and Procedures~~ Health Care Department Operations Manual in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

Yes No N/A

☐☐☐ 7~~8~~.1~~6~~5 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)]

☐☐☐ 7~~8~~.1~~7~~6 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]

☐☐☐ 7~~8~~.1~~8~~7 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~~ California Correctional Health Care Services Health Care Department Operations Manual ~~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)]

☐☐☐ 7~~8~~.1~~9~~8 All policies and procedures are maintained either in an electronic form or paper form at the location where the ~~automated drug system~~ ADDS 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

☐☐☐ 7~~8~~.~~20~~19 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 7~~8~~.~~21~~20 Drugs removed from the ~~automated drug system~~ ADDS ~~is~~ are 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,~~ Where administration of the drug is necessary before a pharmacist has reviewed the prescription and if, in the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the ~~automated drug delivery system~~ ADDS 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~~ California Correctional Health Care Services Health Care Department Operations Manual. Any removal of the medication from an ~~automated drug delivery~~ ADDS ~~system~~ is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

Yes No N/A

☐☐☐ 7~~8~~.~~22~~21 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~~ ADDS, an inspection of the ~~automated drug delivery system~~ ADDS 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

☐☐☐ 7~~8~~.~~23~~22 Drugs removed from the ADDS ~~is~~ are 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)]

☐☐☐ 7~~8~~.~~24~~23 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)]

☐☐☐ 7~~8~~.~~25~~24 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)]

☐☐☐ 7~~8~~.~~26~~25 Drugs from the ADDS in the correctional clinic are removed by a person authorized to stock the ADDS, or 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

☐☐☐ 7~~8~~.~~27~~26 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~~ are 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~~8:

- ☐ **HOSPITAL PHARMACY: AUDS USED FOR DISPENSING PURSUANT TO BPC 4068 (WHEN THE HOSPITAL PHARMACY IS CLOSED AND NO PHARMACIST IS AVAILABLE.**
- ☐ **DRUG ROOM: AUDS ~~used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)~~ USED FOR DISPENSING PURSUANT TO BPC 4056**

Please Note: Hospital pharmacies and drug rooms must also complete Section 6 for ADDS used for administration. This section addresses additional requirements for hospital pharmacies and drug rooms operating an ADDS used for dispensing.

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8~~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 they ~~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)]

☐☐☐ ~~8~~9.2 ~~The~~ Where the prescriber in a hospital emergency room dispenses a dangerous drug, including a controlled substance, from the AUDS to an emergency room patient, the following conditions apply [BPC 4068(a)]:

- ☐ 8.2.1 ~~when t~~The hospital pharmacy is closed and there is no pharmacist available in the hospital.
- ☐ 8.2.2 The drugs ~~is~~are acquired by the hospital pharmacy.
- ☐ 8.2.3 The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
- ☐ 8.2.4 The hospital pharmacy retains the dispensing information and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code.
- ☐ 8.2.5 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 and accessible at the time of dispensing to the patients.
- ☐ 8.2.6 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)(1-6)]~~
- ☐ 8.2.7 The prescriber ensures that the label on the drug contains all the information required by BPC section 4076.

Yes No N/A

☐☐☐ 8.3 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]

~~**Yes No N/A**~~

☐☐☐ ~~9.3~~8.4 The prescriber ensures the label on the drug contains all the information required by BPC 4076 and~~,~~ CCR 1707.5.

☐☐☐ ~~9.4~~8.5 The federal warning label~~s~~ prohibiting transfer of controlled substances is on the prescription container. [21 CFR 290.5]

☐☐☐ ~~9.5~~8.6 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~~8.7 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 4068(a)(4), HSC 11165(d)]

☐☐☐ ~~9.7~~8.8 Patient package inserts are dispensed with all estrogen medications. [21 CFR 310.515]

☐☐☐ ~~9.8~~8.9 The hospital has written policies and procedures to ensure each patient receives 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)]

~~☐☐☐ 9.9 The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location. [BPC 4427.2(i)]~~

~~Yes No N/A~~

☐☐☐ 8.10 Medication guides are provided on required medications. [21 CFR 208.24]

☐☐☐ 8.11 Boxed warning "Black Box" information is in conformance with 21 CFR 201.57(c).

☐☐☐ 8.12 Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug 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 AND COMPLETION DATE_____
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SECTION 9 – AUDS THROUGH A FACILITY LICENSED IN CALIFORNIA WITH STATUTORY AUTHORITY TO PROVIDE PHARMACEUTICAL SERVICES (OR) AUDS THROUGH A JAIL, YOUTH DETENTION FACILITY, OR OTHER LICENSED CORRECTIONAL FACILITY WHERE DRUGS ARE ADMINISTERED WITHIN THE FACILITY UNDER THE AUTHORITY OF THE MEDICAL DIRECTOR PURSUANT TO BPC 4187.4, 4427.3(b)(6), or 4427.65(a)(2).

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS. [BPC 4427.65(c)(7)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____
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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 9.2 The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all the following conditions are met: [BPC 4427.65(c)(6)]

- ☐ 9.2.1. The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
- ☐ 9.2.2. 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.
- ☐ 9.2.3. 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.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 9.4 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [BPC 4427.65(c)(2)]

For Sections 9.5-9.7: When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [BPC 4427.65(c)(4)]:

☐☐☐ 9.5 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 drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(4)(A)]

☐☐☐ 9.6 Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist. [BPC 4427.65(c)(4)(B)]

☐☐☐ 9.7 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to

the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist. [BPC 4427.65(c)(4)(C)]

For Sections 9.8-9.12: When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3 and Article 25 in Chapter 9, Division 2 of the BPC, the ADDS is subject to the following requirements [BPC 4427.65(c)(5)]:

☐☐☐ 9.8 The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [BPC 4427.65(c)(5)(A)]

☐☐☐ 9.9 The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [BPC 4427.65(c)(5)(B)]

Yes No N/A

☐☐☐ 9.10 The pharmacy providing services to the facility pursuant to Article 25 in Chapter 9, Division 2 of the BPC controls the access to the drugs stored in the ADDS. [BPC 4427.65(c)(5)(C)]

☐☐☐ 9.11 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. When the prescriber's order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration. [BPC 4427.65(c)(5)(F)]

☐☐☐ 9.12 ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient. [BPC 4427.65(c)(5)(G)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 9.13 Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years. [BPC 4427.65(c)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 9.14 The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the AUDS. [BPC 4427.65(b)]

☐☐☐ 9.15 The facility and the pharmacy have developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs. [BPC 4427.5(c)(3)(A)]

☐☐☐ 9.16 All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used. [BPC 4427.5(c)(3)(B)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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)

ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~(please print)~~ _____ [print name and title], hereby certify under penalty of perjury under ~~of~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~read and reviewed this completed self-assessment.~~ Further, I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____Date _____
(Owner or Administrator)

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have corrected the 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)

ACKNOWLEDGMENT BY OWNER OF THE PHARMACY OR ADMINISTRATOR OPERATING THE ~~OF~~ ADDS:

I, ~~(please print)~~ _____ [print name and title], hereby certify under penalty of perjury under ~~of~~ the laws of the State of California that I have full authority, without any limitations to provide this certification, that I am the Owner of the Pharmacy or the Administrator Operating the ADDS and that I have reviewed this form, and acknowledge that all facts and information stated herein are true, correct, and complete. ~~read and reviewed this completed self-assessment.~~ Further, I understand that failure to correct any deficiency identified in this self-assessment could result in the revocation of the automated drug delivery system's license issued by the California State Board of Pharmacy.

Signature _____Date _____
(Owner or Administrator)

Outsourcing Facilities
16 CCR § 1750

Title 16. Board of Pharmacy

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

Article 6.5 Outsourcing Facilities

1750 Outsourcing Facility Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(E) Hours of operation of the licensee.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Outsourcing Facility Self-Assessment

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

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

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

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

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

Facility Name: _____

Address: _____ Phone: _____

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

Other ☐ (please specify) _____

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

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

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

Hours: Weekdays _____ Sat_____ Sun. _____ 24 Hours _____

Website address (optional): _____

_____
Initials

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

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

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Initials

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

Section I
Prescription Specific Regulations

Duties of a pharmacist in an Outsourcing Facility filling patient specific prescriptions
1. A pharmacist:

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

2. Patient Consultation

Yes No N/A

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

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

Yes No N/A

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Initials

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Prescription Requirements

Yes No N/A

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

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Initials

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

4. Refill Authorization

Yes No N/A

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

5. Medication Errors related to a patient specific prescription

Yes No N/A

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

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

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

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

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

Yes No N/A

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

_____
Initials

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

6. Erroneous or Uncertain prescriptions

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

7. Labeling for a patient specific prescription

Yes No N/A

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

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

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

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

_____
Initials

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

_____

8. Furnishing and Dispensing

Yes No N/A

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

Yes No N/A

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

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

_____
Initials

(21 CFR 310.515)

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

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

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

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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9. Confidentiality of Prescriptions

Yes No N/A

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

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

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

Yes No N/A

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

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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10. Record Keeping Requirements in addition to compliance with cGMP

Yes No N/A

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

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Section II

Code of Federal Regulation Part 211 for all Outsourcing Facilities

Quality Systems, validation control, facility control and training

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

Yes No N/A

☐ ☐ ☐ 12.1 Compliance with sections 211.22 through 211.34 in their entirety

Facility

13. CFR Part 211, Subpart C Buildings and Facilities

Yes No N/A

☐ ☐ ☐ 13.1 Compliance with Sections 211.42 through 211.58 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Equipment

14. CFR Part 211, Subpart D Equipment

Yes No N/A

☐ ☐ ☐ 14.1 Compliance with sections 211.63 through 211.72 in their entirely.

CORRECTIVE ACTION OR ACTION PLAN: _____

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Compounding and manufacture of the product

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

Yes No N/A

☐ ☐ ☐ 15.1 Compliance with sections 211.80 through 211.94 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

☐ ☐ ☐ 11.1 Compliance with sections 211.100 through 211.115 in their entirety.

CORRECTIVE ACTION OR ACTION PLAN: _____

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Distribution, storage,

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

Yes No N/A

☐ ☐ ☐ 19.1 Compliance with sections 211.142 through 211.150

CORRECTIVE ACTION OR ACTION PLAN: _____

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Release of product for sale

19. CFR Section 211, Subpart I—Laboratory Controls

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Record keeping

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Returns

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

Yes No N/A

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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Section III

DEA Controlled Substances Inventory, as applicable to your facility

22. Inventory:

Yes No N/A

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

Yes No N/A

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

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

CORRECTIVE ACTION OR ACTION PLAN: _____

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DESIGNATED QUALITY CONTROL PERSONNEL CERTIFICATION:

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

Signature _____ Date _____
(Designated Quality Control Personnel)

ACKNOWLEDGEMENT BY FACILITY OWNER OR OFFICER:

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

Signature _____ Date _____
(Outsourcing Facility Owner or Officer)

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

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

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