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

Legislation and Regulation Committee Report

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The Board will review a summary of the committee's work at its April 29, 2021 meeting, as well as updates for discussion and action as necessary.

a. Discussion and Consideration of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019)

Attachment 1

Background
As included in the Board's Sunset Background Paper, in 2019, the enactment of Assembly Bill 5 (Gonzalez, Chapter 296, Statutes of 2019) effectively codified the Dynamex decision's ABC test used to determine an individual's employment status, while providing for clarifications and carve-outs for certain professions. Specifically, physicians and surgeons, dentists, podiatrists, psychologists, and veterinarians were among those professions that were allowed to continue operating under the previous framework for independent contractors. However, pharmacists were not included in the bill. As part of its response to the background question the Board noted in its response that it was aware that some pharmacists act as consultants for skilled nursing facilities and hospitals and such individuals may be negatively impacted by the exclusion of pharmacists from the new law.

For Committee Discussion and Consideration
More recently, a request was received to place on an agenda discussion of the issue. Included in the correspondence was a request for the Board to consider the list of health care professionals included in Labor Code section 2783(b) to determine if it is appropriate to include pharmacists.

Should the committee agree that such a change is necessary the following motion could be used:

> Recommend to the Board, sponsorship of an amendment to Labor Code section 2783, to include pharmacists among the list of health care professions currently exempt from the provisions of the Dynamex decision under the specified conditions.

Attachment 1 includes a copy of the request received.

b. 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. During the meeting members will have the opportunity to discuss each measure and determine if the Board should take a formal position on each measure.

Several legislative deadlines are approaching.

- April 30, 2021: Last day for policy committees to hear and report to fiscal committees, bill introduced in their house.
- May 7, 2021: Last day for policy committees to hear and report to the Floor non-fiscal bills introduced in their house.
- May 14, 2021: Last day for policies committees to meet prior to June 7, 2021.
- June 4, 2021: Last day for bills to be passed out of the house or origin.

1. Assembly Bill 2 (Fong) Regulations: Legislative Review: Regulatory Reform

Version: As introduced December 7, 2020
Status: Referred to Assembly Accountability and Administrative Review Committee
Committee Analysis: None on file
Summary: Requires each state agency to review its regulations, identify any regulations that are duplicative, overlapping, inconsistent, or out of date and revise those identified regulations, and report to the Legislature and Governor
Recommended Position: Oppose, for the reasons cited below.
Comments: This measure is author sponsored and is similar to Assembly Bill 312 (Cooley) introduced in the 2019-20 Legislative Session. Specifically, as part of the regulation process, the public has the opportunity to participate. The law requires the Board to consider each comment received in response to a proposed change. Further, as part of the rulemaking process, the Board is required to identify potential cost impacts, including to small businesses. Further, several control agencies must approve various provisions of the rulemaking package, most notably the Office of Administrative Law (OAL). As required under the Government Code, as part of its review, OAL must assess for several standards including:

- Consistency
- Clarity
- Nonduplication
- Necessity

Fiscal Impact: Staff estimates the need for two 2-year limited term attorney positions and 2-year limited term AGPA to perform all of the necessary requirements of this measure.

2. Assembly Bill 29 (Cooper) State Bodies: Meetings

Version: As introduced December 7, 2020
Status: Assembly Appropriations Committee hearing, April 21, 2021
Committee Analysis: Assembly Committee on Governmental Organization Analysis
Summary: Requires that the notice of a meeting of a state board include all writings or materials provided for the noticed meeting to a member of the state body by staff of the state agency, board, or commissions, or another member of the state board that are in connection with a matter subject to discussion or consideration at the meeting. The measure would also require the board, upon written request to send copies of such materials the same day they are disseminated to a board member or at 72 hours before the meeting whichever is earlier.
Recommended Position: Oppose Unless Amended
Comments: This measure is similar to Assembly Bill 2028 (Aguiar-Curry) introduced in the 2019-20 Legislative Session. The Board established an OUA position on that measure as well. This measure seeks to ensure transparency and public participation in public meetings. The Board values transparency as reflected in its Strategic Plan and routinely provides opportunities for public comment both before and throughout Board and Committee meetings.

Staff have identified several technical challenges with the measure that could negatively impact full consideration of information by the Board and inadvertently impede public comment.

1. There are documents and materials that cannot be made ADA accessible. If a document is not ADA accessible, the Board cannot post it on its website.
2. The file size for Board materials many times exceeds e-mail file size limitations making it difficult to comply with the requirements to provide the information via email. The volume of materials provided to members is significant. Requiring the Board to provide paper copies and mailing at that same time materials are released to members would delay the release and posting of materials due to resource limitations. The measure appears to provide that the meeting materials must be provided on the same day; however, differing delivery methods, electronic versus paper, makes this very problematic.
3. Regulation comment periods may end near or immediately before a Board meeting. Compiling the comments, making them ADA accessible and providing them at least 72 hours in advance may not always be possible and could delay implementation of needed regulations.
4. It is fairly common for the Board to receive written comments after publicly posting meeting materials. When time permits, these comments are provided to members and posted on the website; however, depending on the timing of the receipt of the comments, it may be impossible to meet the requirement to provide at the same time or within 72 hours of the meeting.
5. The measure also does not appear to recognize that there are times when information is disseminated during a meeting e.g., statistical information, supplemental materials, etc. It is unclear if the measure would preclude this practice moving forward.

6. It would appear the measure does not contemplate emergency meetings, which only require 48 hours' notice. Should the provisions of the measure apply to emergency board meetings, from a practical stand point, the Board would never be able to avail itself of the emergency meeting provisions.
7. This measure does not appear to contemplate meetings convened for purposes of considering petitions through an administrative hearing. In such cases, members are providing materials; however, the information does not become public, rather during the course of the public hearing documents are submitted into evidence.

Fiscal Impact: The fiscal impact on this measure could be significant should the Board receive a significant number of individuals that request paper copies of meeting materials. These costs would include staff resource time, materials and postage.

3. Assembly Bill 69 (Kiley) State of Emergency: Termination After 60 Days

Version: As introduced December 7, 2020
Status: Referred to Committee on Emergency Management
Committee Analysis:
Summary: Requires a state of emergency to terminate 60 days after the Governor's proclamation of the state of emergency unless the Legislature extends it by a concurrent resolution. Prohibits a concurrent resolution from extending a state of emergency by more than 60 days.
Recommended Position: Oppose unless amended.
Comments: The Board has relied heavily on the provisions included in BPC 4062 and the declaration of emergency to respond to the pandemic. Limiting the duration of a state of emergency could impede the Board's ability to waive provisions of Pharmacy Law that will aid in the protection of the public health or the provisions of patient case. The Board has issued numerous waivers during the pandemic to address many challenges created. Under this measure, an emergency declaration would expire in either 60 or 120 days. Such defined parameters would have crippled the Board's ability to ensure provisions of patient care. Should the committee agree with the staff recommendation, it is recommended that amendments offered to provide flexibility to either the Governor or the Legislature to extend a state of emergency as necessary to respond to the issue in the best interest of Californians.
Fiscal Impact: Undetermined

4. Assembly Bill 107 (Salas) Licensure: Veterans and Military Spouses

Version: As Amended April 20, 2021
Status: Assembly Military and Veterans Affairs Committee hearing, April 27, 2021
Committee Analysis: Assembly Committee on Business and Professions Analysis
Summary: Expands the requirement to issue temporary licenses to practice a profession or vocation to include licenses issued by any board with the Department of Consumer Affairs, except as provided. Specifically, would require a board to issue a temporary license within 30 days of receiving the required documentation if the results of a criminal background check do not show grounds for denial for an application married to, or in a domestic partnership or

other legal union with, an active duty member of the Armed Forces who is stationed in California. Temporary licenses would expire 12 months after issuance, upon issuance of a standard license, or upon issuance of an expedited license, whichever occurs first.
Recommended Position: Oppose Unless amended
Comments: This measure is similar to the provisions of AB 2549 (Salas) introduced in the 2019-2020 Legislative Session. The Board established an OUA position on that measure because of some consumer protection concerns with the measure, including noting that legal requirements and practice standards for pharmacists vary between jurisdictions. Amendments to be offered could include a requirement to pass the CPJE prior to issuing a temporary pharmacist license. Further it is unclear if other jurisdictions would release to the Board information confirming that the applicant is the subject of an unresolved complaint, review procedure, or disciplinary proceeding being conducted in another jurisdiction.
Fiscal Impact: The Board believes a ½ AGPA position would be necessary to implement the provisions of the measure, including promulgation of necessary regulations, and perform the ongoing workload associated.

5. Assembly Bill 225 (Gray) Department of Consumer Affairs: Veterans: Spouses

Version: As Amended April 20, 2021
Status: Assembly Military and Veterans Affairs Committee hearing, April 27, 2021
Committee Analysis: Assembly Committee on Business and Professions Analysis
Summary: Requires the Board to issue temporary licenses to honorably discharged veterans similar to Assembly Bill 107. Requires specified temporary licenses to expire 18 months after issuance and would expand eligibility for a temporary license to an applicant that meets specified criteria and who supplies evidence satisfactory to the board that the applicant is a veteran of the Armed Forces as specified. Requires board not responsible for the licensure and regulation of healing arts licensees and not subject to temporary licensing provisions to issue licenses to an applicant if the applicant meets specified requirements, including that the applicant supplies evidence satisfactory to the board that the applicant is an honorably discharged veteran of the Armed Forces of the United States or is involved, as specified.
Recommended Position: Oppose Unless Amended
Comments: The staff notes the same concerns for this bill as for Assembly Bill 107 related to the inability of the Board to assess for minimum competency prior to issuing a temporary license.
Fiscal Impact: The Board believes a ½ AGPA position would be necessary to implement the provisions of the measure and perform the workload associated.

6. Assembly Bill 527 (Wood) Controlled Substances

Version: As Amended March 15, 2021
Status: Assembly Consent Calendar
Committee Analysis: Assembly Committee on Business and Professions Analysis
Summary: This bill would exempt from Schedule III specific compounds, mixtures,

or preparations that contain a nonnarcotic controlled substance in combination with a derivative of barbituric acid or any salt thereof that are listed in the federal Table of Exempted Prescription Products and have been exempted pursuant to federal law or regulation. The bill would exempt from Schedule IV specific compounds, mixtures, or preparations that contain a nonnarcotic controlled substance in combination with a chlordiazepoxide or phenobarbital that are listed in the federal Table of Exempted Prescription Products and have been exempted from scheduling under federal law or regulation. Further, would expand the provisions authorizing the prescription, furnishing, dispensing, transportation, possession, or use of cannabidiol products in accordance with federal law, upon the specified changes made to federal law to include all products with cannabinoids.
Recommended Position: Support (contains Board-sponsored provisions)
Comments: This measure includes provisions approved by the Board during the January 2021 Meeting.
Fiscal Impact: Minor and absorbable

7. Assembly Bill 646 (Low) Department of Consumer Affairs: Boards: Convictions

Version: As Amended April 14, 2021
Status: Assembly Appropriations Committee hearing, April 21, 2021
Committee Analysis: Assembly Business and Professions Committee Analysis
Summary: Would require professional licensing boards under the Department of Consumer Affairs that post information on their internet website about a revoked license due to a criminal conviction to update or remove information about the revoked license should the board receive an expungement order related to the conviction, as specified.
Recommended Position: None
Comments: This measure appears to build upon the policy goals of AB 2138 (Statutes of 2018) which restricted a licensing board from denying an application based on some criminal convictions and required licensing boards to amend substantial criteria regulations and regulations defining rehabilitative efforts. According to the author, this bill is intended to reduce employment barriers for people with previously criminal records who have been rehabilitated and whose conviction has been dismissed, or expunged, through the judicial process.
Fiscal Impact: Board staff believe a ¼ Information Technology Association position would be necessary to implement the provisions of this measure.

8. Assembly Bill 657 (Cooper) State Civil Service System: Personal Services Contracts: Professionals

Version: As Amended April 21, 2021
Status: Referred to Assembly Public Employment and Retirement Committee
Committee Analysis: None
Summary: As amended this measure no longer applies to the Board.

9. Assembly Bill 671 (Wood) Medi-Cal: Pharmacy Benefits

Version: As revised March 25, 2021

Status: Referred to Assembly Appropriations Committee
Committee Analysis: Assembly Health Committee Analysis
Summary: Would require the Department of Health Care Services (DHCS) to provide a disease management or similar payment to a pharmacy for specified costs and activities that are associated with dispensing specialty drugs in an amount necessary to ensure beneficiary access as determined based on result of a DHCS-contracted survey, as specified.
Recommended Position: None
Comments: According to the author, this bill will address an issue with Medi-Cal FFS pharmacy reimbursement that exists as a result of a new federally required AAC drug reimbursement cost change. This bill would ensure the availability of high cost specialty drugs and the viability of pharmacies that dispense those drugs to Medi-Cal beneficiaries by providing a disease management payment for high cost specialty medications, such as for mental health and HIV treatment and prevention that includes recognition of the costs of the additional services certain pharmacies provide in dispensing these medications. Certain high-cost brand name prescription drugs used to treat multiple sclerosis (MS), serious mental health conditions, and to treat and prevent HIV are reimbursed by Medi-Cal FFS near or below the cost at which certain community pharmacies acquired the drug. For example, a recent DHCS-contracted report found the brand drug acquisition costs were below reimbursement for MS drugs, and the average dollar amount margin for other brand name drugs for HIV, cystic fibrosis, and to treat serious mental illnesses was very low. The report additionally, identified 15 drugs as examples of "at-risk" that are under-reimbursed by the existing Medi-Cal rate compared to pharmacies' AAC, thereby reducing the availability of these medications and jeopardizing the financial viability of the pharmacies dispensing these medications to patients enrolled in the Medi-Cal program. To the extent this measure would expand access to necessary specialty drugs for Medic-Cal patients, it may be appropriate to consider supporting the measure.
Fiscal Impact: Minor and absorbable

10. Assembly Bill 864 (Low) Controlled Substances: CURES Database
Version: As Amended March 4, 2021
Status: Referred to Assembly Business and Professions Committee
Committee Analysis: None
Summary: Would establish the intent of the Legislature to enact legislation to transfer maintenance and operation of CURES from the Department of Justice to the State Department of Public Health no later than January 2, 2023.
Comments: Staff has been advised the measure has become a two-year bill. As such, staff recommends that the committee not offer a position on this measure.

11. Assembly Bill 1064 (Fong) Pharmacy Practice: Vaccines: Independent Initiation
Version: As Amended March 15, 2021
Status: Assembly Business and Professions Committee hearing, April 27, 2021
Committee Analysis: None

Summary: This bill would authorize a pharmacist to independently initiate and administer any vaccine approved or authorized by the United States Food and Drug Administration for persons 3 years of age and older.
Recommended Position: Support
Comments: Under current law a pharmacist may initiate and administer any COVID-19 approved or authorized vaccine or any vaccine included on the routine immunization schedule recommended by the federal Advisory Committee on Immunization Practices (ACIP)The measure would expand the authority for pharmacist to provide any vaccine as specified. Expansion to all vaccines creates an important access point for Californian's who may not otherwise have ready access to vaccination services. This measure is similar to a version of AB 1710 (Statutes of 2020) that was ultimately amended to expand pharmacist vaccine authority to COVID-19 vaccinations only. The Board had established a support position on the measure.
Fiscal Impact: Minor and absorbable

12. Assembly Bill 1236 (Ting) Healing Arts: Licensees: Data Collections
Version: As Amended April 15, 2021
Status: Assembly Business and Professions Committee hearing, April 27, 2021
Committee Analysis: None
Summary: This bill would require all boards that oversee healing arts licensees to request at the time of electronic application for a license and license renewal, or at least biennially, specified demographic information from its licensees and, if designated by the board, its registrants and to post the information on the internet websites that they each maintain. The bill would specify that licensees and registrants shall not be required to provide the requested information.
This bill would also require each board, or the Department of Consumer Affairs on its behalf, to provide the information annually to the Office of Statewide Health Planning and Development. The bill would require these boards to maintain the confidentiality of the information they receive from licensees an registrants and to release information only in deidentified aggregate from, as specified.
Recommended Position: Oppose Unless Amended
Comments: The Board should only collect information that is necessary for purposes of exercising its authority. The measure in its current form, would require the Board to serve as a collection and repository agency for data to be used by the Office of Statewide Health Planning (OSHPD). Amendments could be offered to require OSHPD to develop and collect information for its purposes. The Board could provide information at the time of renewal, information about the OSHPD survey and encourage participation by licensees.
Fiscal Impact: This measure could have significant cost impacts to the Board as the Board cannot currently accept electronic applications. With that understanding, the Board would require a full-time Research Program Specialist or other equivalent classification to identify a scientifically selected random sample of licensees for purposes of conducted the survey, collect and report the data consistent with provisions of the measure. Further the Board would require IT

support to facilitate collection and management of the IT solution and development of a reporting and posting mechanism.

13. Assembly Bill 1328 (Irwin) Clinical Laboratory Technology and Pharmacists

Version: As Amended April 21, 2021
Status: Assembly Business and Professions Committee hearing, April 20, 2021
Committee Analysis: Assembly Business and Professions Committee Analysis
Summary: Would amend several provisions of the Business and Professions Code to expand the authority for pharmacists to perform CLIA-waived tests either approved or authorized by the FDA upon patient request or hospital authorization provided that there is a valid and respective CLIA certificate of waiver and laboratory license, with some exceptions. Exceptions include CLIA waived tests that are used for surgery, diagnosis or treatment of heart failure, female fertility, or ovulation prediction. Further would require a pharmacist to notify the patient's primary care provider, or other appropriate physician and surgeon, of any abnormal test results. In the event the patient refuses consent or does not have a primary care provider, the pharmacist shall provide the patient a list of physicians, clinics or other health care service providers to contact for ongoing patient care. Further, would amend Pharmacy Law to declare that pharmacy practice is a patient and public health-oriented health service that is continually evolving to include more sophisticated and comprehensive patient care and public health activities.
Recommended Position: None
Comments: This measure seeks to expand testing authority for pharmacists by amending provisions of Pharmacy Law as well as other provisions of the BPC under the jurisdiction of the California Department of Public Health, Laboratory Field Services. This measure is broader than the Board's current statutory proposal and takes a different approach than the statutory proposal offered by the Board.
Fiscal Impact: Undetermined

14. Assembly Bill 1430 (Arambula) Pharmacy: Dispensing Controlled Substances

Version: As Amended April 21, 2021
Status: Referred to Assembly Appropriations Committee
Committee Analysis: Assembly Judiciary Committee Analysis
Summary: Would create the California Safe Dispensing Act within Pharmacy Law. Part of the Act, would require a pharmacist who dispenses a schedule II drug to do so in a lockable vial and require the pharmacist to provide a copy of an Opioid Factsheet for Patients published by the federal Centers for Disease Control and Prevention and include the appropriate passcode in any patient notes maintain in the pharmacy's' system, as specified. Further would establish conditions under which such dispensing is not required include for dispensing that occurs in a hospital or the patient or patient's agent requests that the medication not be dispensed in a lockable vial. The Act would also establish a funding mechanism for pharmacies to seek reimbursement for the cost of the lockable vials from the manufacturer of a controlled substance. The Board

would be charged with assessing a civil penalty in the event a manufacturer is delinquent in reimbursing the pharmacy.

Recommended Position: None

Comments: This measure appears to build upon Assembly Bill 2859 (Statutes of 2018) which required specified pharmacist that dispense schedule II-IV controlled substances to display safe storage devices. The Board had a neutral position on that measure.

Fiscal Impact: The board will require one ½ APGA to initiate investigations and coordinating civil actions brought.

The Board anticipates the need for ½ Inspector to address an increase in inspection and investigation workload, to monitor for compliance and conduct investigations when noncompliance is identified as part of an inspection as well as to conduct consumer complaints alleging violations of the provisions.

15. Assembly Bill 1533 (Assembly Business and Professions Committee) Pharmacy

Version: As Amended April 19, 2021

Status: Assembly Business and Professions Committee hearing, April 27, 2021

Committee Analysis: None

Summary: As recently amended, this measure would extend the operations of the Board until January 1, 2026. Further, several technical and several substantive changes are also included. Detailed below are several of the substantive changes identified.

1. Update the membership composition of the Board to include a compounding pharmacy specializing in human drug preparations
2. Require the Board to hire its own counsel.
3. Amend a pharmacist scope of practice to include initiating, adjusting or discontinuing drug therapy under a collaborative practice agreement as well authority to provide nonopioid medication-assisted treatment pursuant to a state protocol.
4. Expand existing conditions for an advanced practice pharmacist to initiate, adjust or discontinue drug therapy.
5. Extend the cease and desist appeal hearing timelines to reflect five business days.
6. Create an alternative pathway to licensure for nonresident third-party logistics providers.
7. Provide authority for the Board to deny an application for licensure if the conviction or other underlying conduct would be grounds for denial of a federal registration to distribute controlled substances.
8. Realign the advanced practice pharmacist licensure requirements.
9. Require completions of a CE course on the risks of addiction associated with the use of Schedule II drugs for pharmacists who prescribe such substances.
10. Require the Board to convene a workgroup to evaluate moving to a standard of care enforcement model and report the findings to the Legislature.
11. Provide the Board with authority to bring action for civil penalties for violations of pharmacy law by one or more pharmacies operating under common

ownership or management under specified conditions.
12. Expand locations where an automated unit dose system may be used under specified conditions.

Recommended Position: Support

Comments: This is the Board's Sunset measure. The provisions included in the pending legislation include several of the issues identified by the Board and stakeholders.

Fiscal Impact: Undetermined

16. Senate Bill 306 (Pan) Sexually Transmitted Disease: Testing

Version: As Amended March 24, 2021

Status: Referred to Senate Appropriations Committee

Committee Analysis: Senate Business, Professions and Economic Development Committee Analysis

Summary: Would make several legislative findings and declarations related to sexually transmitted diseases and its impact on Californians. Further, it would define existing authority for prescribers who diagnose a sexually transmitted infection to also prescriber antibiotic drugs to the patient's sexual partner(s) as the practice of "expedited partner therapy (EPT). As it relates to Pharmacy Law, would allow a pharmacist to dispense a drug prescribed pursuant to EPT provisions without an individual name if the prescription includes either "expedited partner therapy" or EPT. Further the section provides that a pharmacist would not be liable in, and not subject to a civil, criminal, or administration action if the use of EPT was done in compliance with the law, unless otherwise specified.

Recommended Position: None

Comments: Typically, the dispensing of prescriptions envisioned an awareness of the patient's medical history, either through a patient profile, medical record, etc. It may be appropriate for members to consider if sufficient consumer protections are in place to reduce or minimize the risk of contraindications that could occur when a pharmacist does not have access to such information. Further, should this measure be enacted, the Board will need to complete a review of several provisions of Pharmacy Law and its regulations to determine if conforming changes are necessary.

Fiscal Impact: The Board will require one full time/limited term AGPA to facilitate enactment of the legislation.

17. Senate Bill 362 (Newman) Community Pharmacies: Quotas

Version: As Introduced February 10, 2021

Status: Senate Appropriations Suspense File

Committee Analysis: Senate Appropriations Committee Analysis

Summary: This bill would prohibit a community pharmacy from establishing a quota, defined as a fixed number or formula related to the duties for which a pharmacist or pharmacy technician license is required to complete, or against which the community pharmacy or its agent measures or evaluates the pharmacist or pharmacy technician's performance of those duties in the community pharmacy. The bill would also prohibit a community pharmacy,

through employees, contractors, or third parties, from communicating the existence of quotas to pharmacists or pharmacy technicians who are its employees or with whom it contracts. For an initial violation of this provision, the bill would require the community pharmacy to be assessed a fine not exceeding one million dollars and a 30-day suspension of the licenses of its pharmacies in the state. For a second violation, the bill would require the revocation of the licenses of its pharmacies in the state. The bill would provide that a community pharmacy is not subject to these penalties if it demonstrates by clear and convincing evidence that the violation was contrary to its policy.
Recommended Position: None
Comments: In its current form, the measure would require the Board to issue a fine and a suspension of the licenses of pharmacies in the state owned or controlled by the community pharmacy for 30 days. It may be appropriate for the Board to consider if such a suspension could result in delays in therapy for patients impacted by the closures or other potential negative outcome.
Fiscal Impact: Undetermined, but significant revenue could be possible depending on the fines issued should the Board conduct an investigation and substantiate a violation of the provisions.

18. Senate Bill 409 (Caballero) Pharmacy Practice: SARS-CoV-2 and Influenza Testing

Version: As introduced February 12, 2021
Status: Assembly
Committee Analysis: Senate Floor Analyses
Summary: This bill would also authorize a pharmacist or a pharmacy to perform, under specified conditions, any aspect of any FDA-approved or authorized point-of-care test for the presence of SARS-CoV-2, the virus that causes COVID-19, or influenza that is classified as waived under CLIA. The bill would also make conforming changes in provisions related to clinical laboratories to authorize that testing and include pharmacist-in-charge, as specified, in the definition of a laboratory director. The bill would require a pharmacy and a pharmacist-in-charge to maintain documents related to testing and compliance in a specified manner.
Recommended Position: Board sponsored
Comments: In general, this measure has enjoyed support; however, some comments indicate that the measure should be expanded to include additional tests as well as should further be expanded to make permanent the provisions of the DCA Director's waiver allowing pharmacists to perform specimen collection. The Licensing Committee will be discussing the measure and possible expansion of the current policy statement approved by the Board to facilitate the legislation.
Fiscal Impact: Minor and absorbable

19. Senate Bill 524 (Skinner) Health Care Coverage: Patient Steering

Version: As Amended April 19, 2021
Status: Senate Health Committee hearing, April 28, 2021
Committee Analysis: Senate Business, Professions and Economic Development

Analysis

Summary: Would prohibit a health care service plan or a health insurer, including a self-insured employer plan, or the agent of a health care service plan or health insurer from engaging in patient steering, as specified. The bill would define "patient steering" to mean:

1. Communicating to an enrollee or insured that they are required to have a prescription dispensed at, or pharmacy services provided by, a particular pharmacy, as specified
2. Offering or including in contract or policy designs for purchasers for group health care cover provisions that limited enrollee's access to only those pharmacy providers that are owner or operated by the health care service plan or plan's agent, or are owned or operated by a corporate affiliate of the health care service plan or plan's agent.

Further, explicitly exempts from the definition of patient steering, directing an enrollee to a specific pharmacy for a specific prescription due to the need for special handling or clinical requirements that cannot be performed by other pharmacies in the provider network of health care service plan.

The bill would provide that these provisions do not apply to a "fully integrated delivery system," and would also make related findings and declarations.

Recommended Position: None

Comments: The measure includes legislative findings and concludes that it is necessary to limit the practice of "patient steering," used by some health care service plans and health insurers, and their contracted pharmacy benefits managers, to those situation when it is used for established clinical or logistical reasons, and not for financial benefit to the plan or insurer, or their agents. Staff notes that during the Enforcement and Compounding Committee's Informational Meeting on White Bagging, concern was expressed about the practice and possible negative impacts to patient care. Should the Board conclude that the practice of White Bagging places patients at risk, it may be appropriate to support this measure.

Fiscal Impact: Undetermined

20. Senate Bill 731 (Durazo) Criminal Records: Relief

Version: As Amended April 20, 2021

Status: Referred to Senate Appropriations Committee

Committee Analysis: Senate Committee on Public Safety Analysis

Summary: Under existing law, effective July 1, 2022, the Department of Justice is required to review arrest records on a monthly basis to identify arrest and conviction records that are eligible for record relief under specified conditions. This measure would make the current provisions, effective for arrests that occurred on or after January 1, 2021 and would expand many of the provisions to include any felony arrest or conviction under specified conditions. Further, the measure would prohibit state or federal summary criminal history information from including records of arrest or convictions that were granted relief, unless the records require the record-holder to register as a sex offender or other conditions.

Recommended Position: None

Comments: As a consumer protection agency, the Board must have access to full information to evaluate an individual's background prior to making a licensing decision. The Board's authority to take action on various types of past criminal or arrest has been limited over the past several years. This measure appears to place additional limits on the information the Board receives as part of its investigation and evaluation of an applicant prior to licensure, and could encompass more serious felonies that should have a bearing on a licensure.
Fiscal Impact: Minor and absorbable.

c. Board Adopted Regulations Approved by the Office of Administrative Law

Attachment 2

1. Proposed Regulation to Amend Title 16, Sections 1702, 1702.1, 1702.2, 1702.5, Renewal Requirements

Summary of Regulation: This proposal updates the renewal requirement language to include all licensing programs and reduce the administrative workload associated that would otherwise be required when new licensing programs are established.

Status: Approved by OAL on March 1, 2021 with a quarterly effective date. The regulation will be effective on July 1, 2021.

2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

Summary of Regulation: This proposal establishes the regulatory framework for third-party logistics providers.

Status: Approved by OAL on February 22, 2021 with a quarterly effective date. The regulation became effective on April 1, 2021.

d. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

Attachment 3

1. Proposed Regulation to Amend Title 16, Section 1707, Off-Site Storage

Summary of Regulation: This proposal amends the board's regulations regarding the waiver requirements for off-site storage of records to allow those entities previously cited for a records violation to be eligible for a waiver to store records off-site.

Status: Formal review by OAL began on December 10, 2020. (Review deadline extended to May 28, 2021 - Pursuant to Governor Newsom's executive order,

OAL's review may be extended in 60-day increments; however, only two 60-day extensions are permitted).

2. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

   Summary of Regulation: This proposal establishes regulatory requirements for automated refill programs.

   Status: Formal review by OAL began on March 30, 2021.

3. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

   Summary of Regulation: This proposal will require submission of quality assurance records to the Board, update the Board regulations with respect to the use of an APDS, and identify the specific requirements for the annual completion of the ADDS self-assessment form.

   Status: Formal review by OAL began on April 7, 2021.

e. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumer Affairs (DCA) or the Business, Consumer Services and Housing Agency

Attachment 4

1. Proposed Permanent Regulation to Add and Amend Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

   Summary of Regulation: This proposal, on a permanent basis, establishes the criteria for training programs to meet in order to be offered to pharmacists so that the pharmacists may independently initiate and furnish preexposure and postexposure prophylaxis.

   Status: Formal review by DCA began on March 18, 2021.

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

Attachment 5

Provided below is a summary of each of the regulations currently undergoing pre-notice review. As there are many steps included in the pre-review process, the status is detailed below. Members have previously requested that regulations without action for over 30 days be highlighted. As such, regulations with inactivity for over 30

days are indicated below in **red**. The full timelines for each of the regulation are included in **Attachment 5**.

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements, and Section 1793.65 Related to the Pharmacy Technician Certification Programs

   Summary of Regulation:
   This proposal establishes the training requirements and certification programs and updates the application for licensure for pharmacy technicians.

   Status: Returned to DCA on April 13, 2021.

2. Proposed Regulation to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Summary of Regulation: This proposal amends the board's regulations regarding ownership to include provisions relating to trust ownership of pharmacies.

   Status: Returned to DCA on April 16, 2021.

3. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

   Summary of Regulation: This proposal updates the Self-Assessment forms 17M-13 (rev. 10/16) and 17M-14 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1715. Additionally, this regulation updates section 1715 with clarifying language as to the completion and certification requirements of the self-assessment forms.

   Status: Returned to DCA on April 12, 2021.

   The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

4. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   Summary of Regulation: This proposal updates the Self-Assessment form 17M-26 (rev. 10/16) as incorporated by reference in Title 16 CCR section 1784. Additionally, this regulation updates section 1784 with clarifying language as to the completion and certification requirements of the self-assessment form.

   Status: Returned to DCA on April 12, 2021.

The Board approved self-assessment forms can be found on the Board's website: https://www.pharmacy.ca.gov/licensees/facility/self_assess.shtml

5. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

   Summary of Regulation: This proposal amends and clarifies the requirements for the completion of the inventory reconciliation report.

   Status: Returned to DCA on April 14, 2021.

6. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

   Summary of Regulation: This proposal amends the drug loss reporting requirements to further define when drug losses must be reported and to increase clarity for the regulated public.

   Status: Returned to DCA on March 24, 2021.

7. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification

   Summary of Regulation: This proposal amends the board's regulations regarding the requirements for a licensee to maintain a current electronic mail address with the board, should the licensee have one.

   Status: Submitted for DCA review on February 11, 2021.

8. Proposed Regulation to Add Title 16 CCR Section 1708.1 Related to the Temporary Closure of Facilities

   Summary of Regulation: This proposal establishes the notification requirement for the temporary closure of licensed facilities.

   Status: Submitted for DCA review on February 11, 2021.

g. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

Attachment 6

1. Proposed Regulation to Amend Title 16 CCR Section 1735.2 to Update the Compounding Self-Assessment Form 17M-39

Summary of Regulation: This proposal updates the Self-Assessment form 17M-39 (rev. 02/12) as incorporated by reference in Title 16 CCR section 1735.2.

Status: Adopted by Board in January 2021. Staff drafting rulemaking documents to be submitted in May 2021.

h. Future Committee Meeting Dates

The committee will meet on the following dates:

- July 15, 2021
- October 27, 2021

Attachment 1

March 15, 2021

From: Larry R.Reis RPh, BCGP California Lic # 27114

551 Wrangler St, Oakdale, CA 95361

To: Anne Sodegren, Executive Officer, California State Board of Pharmacy

2720 Gateway Oaks Drive, Suite 100

Sacramento, CA 95833

I am writing to the Board of Pharmacy both as an individual consultant pharmacist (BCGP) and member of a committee representing the California Chapter of ASCP, Leah Johnson PharmD President, and California Society of Health Systems Pharmacists, Loriann De Martini CEO.

We are requesting the Board of Pharmacy to affirm B&P Code Section 4050 that declares the practice of pharmacy to be a profession, and "declares that pharmacists are health care providers who have the authority to provide health care services".

2 pieces of legislation were passed in 2020 that significantly impacted the practice of independent consultant pharmacists and others and their ability to professionally function as independent contractors. AB5 clarified and codified language dealing with determination methods of definition as employee or independent contractor. There were specific occupations who were listed to whom this would not apply and it included exception for "A physician and surgeon, podiatrist, psychologist, or veterinarian licensed by the State of California pursuant to Division 2, commencing with Section 500, of the Business and Professions code, performing professional or medical services provided to or by a health care entity."

Unfortunately, it was identified that when B&P Code Section 4050 was codified in 2014 the section was isolated and the above mentioned area in division 2, section 500, did not get updated correspondingly to include pharmacists. This created an immediate situation where some prior clinical and consulting functions provided as independent contracted consultants were eliminated, a step we believe has impacted the health and safety of California patients in health care entities, as well as limited the professional and clinical ability of pharmacists to provide those services.

Clarifying language was passed in late 2020, AB 2257 Gonzalez to "revise and recast the provisions of existing exemptions including persons providing professional services under specified circumstances".

There is additional language "This bill would create additional exemptions for various professions and occupations. In this regard, the bill would exempt from the ABC test people who provide.....consulting services.....with specialized skills as specified".

AB2257 further specifies and defines "consulting means providing substantive insight, information, advice, opinions, or analysis that requires the exercise of discretion and independent judgment and is based on an individual's knowledge or expertise of a particular subject matter or field of study." It is our belief this definition clearly outlines the characteristics of a pharmacist, in particular a consultant pharmacist providing clinical services in multiple practice settings. However, there has been some

accounting opinions that are concern the lack of codification or memorialization of consultant "pharmacists" specifically by language.

It is our hope that the Board of Pharmacy could take one of several actions. One might be to update the list of professionals in Division 2, Section 500 of the B&P code to not only include physicians and surgeons, psychologists, podiatrist, and veterinarian but to INCLIUDE PHARMACIST in this list of health care professionals as designated elsewhere in the B&P code. This would resolve this concern.

If that is not possible, if the Board of Pharmacy could implement clarifying or supporting language or resolution for the sections updated by AB2257 to clarify the "consulting" would include the practice of pharmacy.

I mentioned earlier how I believe this impacts the health and safety of residents in California long term care facilities, and other health care facilities and specialty entities. This has also drastically impacted the methods of practice by independent consulting companies, including my own. Although I know the focus of the Board is primarily to protect the health and safety of California consumers, this has impacted the practice of pharmacy significantly.

I am willing to provide verbal testimony to the Board if it is possible to be placed on an upcoming agenda. Or if the Board would desire individual statements, those can also be provided. Briefly, I can summarize that as an independent contractor, terms of agreements can be set to allow the time and professional flexibility to provide clinical services. The alternatives as an employee require meeting employer mandated productivity standards and review time and function.

My specific practice has suffered by the loss of over 50% of my prior business since the contracts reverted to the dispensing pharmacy who must hire employees and dictates the standards of service and care. As an independent contractor who can establish my own rates and fees, I can be flexible and become more directly involved in the care of my patient base. One quick example, most corporate employee consultant pharmacists, and there are many excellent consultants working in this circumstance, will have specific requirements of completing so many MRR (medication regimen reviews) within an hour. My time is based on the patient and customer clinical need. I was recently at a nursing station reviewing chart records when I could hear loud yelling coming from a resident down the hall. The nurse commented the resident "yells like this almost every morning and I have called the doctor about ordering some Risperidone or Ativan to help calm her down". I decided to go to the room to better evaluate what was causing the resident to scream. The physical therapist was leaving the room when I approached and commented how she (the resident) was calm until PT started and then when doing range of motion and other exercises she would scream. I asked the resident herself why she was screaming, and her response was "He hurts me". She was not complaining of pain otherwise, and I was able to work with the physician involved and other members of the IDT and we started pre-therapy treatment with an analgesic. This greatly resolved the issue, improved the resident willingness to work with therapy and hastened her recovery. Otherwise ,she may have been placed on an antipsychotic or benzodiazepine.

Other consultants have shared similar and other events with me. These would include the inability to bring on an independent contractor short-term to cover illness or vacation for a consultant pharmacist. There are a fixed number of MRR to be completed each month under contract, and if they cannot bring in additional help, this falls as an additional workload meaning less time, on other employee consultants.

Another consultant shares how he no longer has the time to provide the same in-depth level of service to residents/patients serviced by an employer pharmacy. He noted that in his private independent work he is able to fully review the acute hospital discharge records and in as many as 50% or more of the new admissions to LTC facilities he will find some type of irregularity, duplication, or modification in dose that should not have occurred. Some of these situations are more dramatic than others and he has offered to provide examples.

In my personal business, I was a preceptor and worked with pharmacy students to provide them exposure to long term care. I worked specifically in the past with students from UC San Francisco, Belmont University Kentucky, and in the past, University of the Pacific in Stockton. Now that my practice has been drastically reduced, and I have had to cut positions and do not have the same amount of flexibility I had in the past, I am no longer providing these services.

Pharmacists have proven to be a valuable resource in many practice settings. In the past I worked with up to 5 different pharmacies to provide services to their facilities, and most of this business is gone. Recently I was asked by my local community pharmacy if I wanted to assist with his Covid immunization services, and as an independent short-term contractor I could have done that, but I did not want to go through all the paperwork, or put him through that paperwork, of becoming an employee for a limited duration project. A project for which I commend him as a community non-chain pharmacist in providing. But we then revert again to using and stretching out existing employee pharmacist staff.

The Board has clearly for over 7 years acknowledged the pharmacist as a valuable professional member of the health care team. The current language in the B&P and these two pieces of legislation is restrictive of how myself, and many consultant pharmacists I know, can be utilized. I hope the Board can consider adopting, modifying this language or at least provide an affirming statement that AB2257 when referencing "consultant" would be referring to a consultant pharmacist.

If you would like statements from individual consultants I can work on obtaining those for you, and in discussions with ASCP and CSHP have agreed to provide verbal statements to the Board on behalf of the pharmacists they serve in the state of California. Thank you for your consideration.

Larry R. Reis. RPh BCGP # 27114

Larry@reisrxcare.onmicrosoft.com Mobile 559-301-2020. Mailing address above. THANK YOU

Attachment 2

Regulation Timeline

V. Board Adopted Regulations Approved by the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR Sections 1702, 1702.1, 1702.2, and 1702.5 Related to Renewal Requirements

   Timeline:
   Approved by Board: May 2, 2018
   Submitted to DCA for Pre-Notice Review: July 12, 2018
   Returned to the board: September 6, 2018
   Re-submitted to DCA for Pre-Notice Review: September 18, 2018
   Returned to the board: September 28, 2018
   Re-submitted to DCA for Pre-Notice Review: October 4, 2018
   Formal DCA Pre-Notice Review began: October 16, 2018
   Returned to the Board on: July 23, 2019
   Re-submitted to DCA for Formal Pre-Notice Review: December 18, 2019
   45-Day Comment Period: February 7, 2020 to March 23, 2020
   Adopted by the Board: May 7, 2020
   Submitted to DCA for Final Review: May 19, 2020
   Submitted to OAL for Final Review: September 5, 2020
   Approved by OAL on March 1, 2021 with a quarterly effective date. The regulation will be effective on **July 1, 2021**.

2. Proposed Regulations to Amend Title 16 CCR Sections 1780-1783 et seq., Related to Dangerous Drug Distributors and Third-Party Logistics Providers

   Timeline:
   Approved by board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: February 9, 2017
   Returned to the board on: February 28, 2017
   Re-submitted to DCA for Pre-Notice Review: October 25, 2017
   Returned to the board on: March 26, 2018
   Re-submitted to DCA for Pre-Notice Review: June 28, 2018
   Returned to the board on: August 28, 2018
   Re-submitted to DCA for Pre-Notice Review: September 6, 2018
   Returned to the board on: October 30, 2018
   Re-submitted to DCA for Pre-Notice Review: December 20, 2018
   Submitted to DCA for Formal Review: December 13, 2019
   45-Day Comment Period: May 29, 2020 to July 13, 2020
   Adopted by Board: July 27, 2020
   Submitted to DCA for Final Review: October 26, 2020
   Submitted to OAL for Final Review: January 12, 2021
   Approved by OAL on February 22, 2021 with a quarterly effective date. The regulation became effective on **April 1, 2021**.

Renewal Requirements 16 CCR §§ 1702, 1702.1, 1702.2, 1702.5

Title 16. Board of Pharmacy
Order of Adoption

Amend section 1702 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702. Pharmacist Renewal Requirements.

(a) A pharmacist applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date.

(1) A pharmacist~~s~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) A pharmacist applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license, or for restoration of a retired license, an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, a pharmacist applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty being placed on the license, such as revocation, suspension, probation or public reprimand or reproval.

(d) <u>As a condition of renewal, a pharmacist applicant shall disclose whether he or she has complied with all continuing education requirements to renew his or her pharmacist or advanced practice pharmacist license as required by section 1732.5.</u>

<u>(e)</u> Failure to provide <u>under penalty of perjury</u> all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license and shall issue the applicant an inactive pharmacist license. An inactive pharmacist license issued pursuant to this section may only be reactivated after compliance is confirmed for all licensure renewal requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4036, 4200.5, 4207, 4231, 4300, 4301, 4301.5, 4311 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Amend section 1702.1 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.1. ~~Pharmacy Technician~~ Renewal Requirements for Individual Licensees Other Than Pharmacists.

This section applies to the renewal of any license held by an individual licensee, other than an individual licensed as a pharmacist or an advanced practice pharmacist.

(a) A licensee ~~pharmacy technician applying icant~~ for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.

(1) The licensee ~~A pharmacy technician~~ shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.

(2) The licensee ~~A pharmacy technician~~ applicant for renewal shall pay the actual cost of compliance with subdivision (a).

(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).

(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).

(b) As a condition of renewal, ~~a pharmacy technician applicant~~ the licensee shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.

(c) As a condition of renewal, ~~a pharmacy technician applicant~~ the licensee shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, “disciplinary action” means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.

(d) Failure to provide under penalty of perjury all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.

Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.6, 4022.7, 4032, 4038, 4053, 4115, 4202, 4202.5, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(e), Penal Code.

Repeal section 1702.2 in Article 1 of Division 17 of Title 16 of the California Code of Regulations.

~~**1702.2. Designated Representative Renewal Requirements.**~~

~~(a) A designated representative applicant for renewal who has not previously submitted fingerprints as a condition of licensure or for whom an electronic record of the licensee's fingerprints does not exist in the Department of Justice's criminal offender record identification database shall successfully complete a state and federal level criminal offender record information search conducted through the Department of Justice by the licensee's or registrant's renewal date that occurs on or after January 1, 2018.~~

~~(1) A designated representative shall retain for at least three years as evidence of having complied with subdivision (a) either a receipt showing that he or she has electronically transmitted his or her fingerprint images to the Department of Justice or, for those who did not use an electronic fingerprinting system, a receipt evidencing that his or her fingerprints were recorded and submitted to the board.~~

~~(2) A designated representative applicant for renewal shall pay the actual cost of compliance with subdivision (a).~~

~~(3) As a condition of petitioning the board for reinstatement of a revoked or surrendered license an applicant shall comply with subdivision (a).~~

~~(4) The board may waive the requirements of this section for licensees who are actively serving in the United States military. The board may not return a license to active status until the licensee has complied with subdivision (a).~~

~~(b) As a condition of renewal, a designated representative applicant shall disclose on the renewal form whether he or she has been convicted, as defined in Section 490 of the Business and Professions Code, of any violation of the law in this or any other state, the United States, or other country, since his or her last renewal. Traffic infractions not involving alcohol, dangerous drugs, or controlled substances do not need to be disclosed.~~

~~(c) As a condition of renewal, a designated representative applicant shall disclose on the renewal form any disciplinary action against any license issued to the applicant by a government agency. For the purposes of this section, "disciplinary action" means an adverse licensure or certification action that resulted in a restriction or penalty against the license or certification such as revocation, suspension, probation or public reprimand or reproval.~~

~~(d) Failure to provide all of the information required by this section renders an application for renewal incomplete and the board shall not renew the license until the licensee demonstrates compliance with all requirements.~~

~~Note: Authority cited: Sections 4001.1 and 4005, Business and Professions Code. Reference: Sections 141, 490, 4022.5, 4022.7, 4053, 4207, 4300, 4301 and 4400, Business and Professions Code; and Sections 11105(b)(10) and 11105(c), Penal Code.~~

Amend section 1702.5 in Article 1 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1702.5. Renewal Requirements for Premises or Facilities ~~Disclosure of Discipline, Renewal, Nonresident Wholesaler or Nonresident Pharmacy~~.

This section applies to the renewal of any license held by a premises or facility.

(a) As a condition of renewal, an applicant seeking renewal of a premises or facility license ~~as a nonresident wholesaler or as a nonresident pharmacy~~ shall report to the board any disciplinary action taken by any government agency since the issuance or last renewal of the license. ~~An applicant seeking the first renewal of a license as a nonresident wholesaler or a nonresident pharmacy shall report to the board any disciplinary action taken by any government agency since issuance of the license.~~ Failure to provide information required by this section shall render an application for renewal incomplete, and the board shall not renew the license until such time as the information is provided.

(b) For purposes of this section, "disciplinary action" means any adverse licensure or certification action that resulted in a restriction or penalty against the license or certification. Such actions include revocation, suspension, probation, or public reprimand or reproval.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 141, 4021.5, 4029, 4034, 4037, 4041, 4043, 4044.3, 4107, 4112, 4161, 4300, 4301, 4302, 4303, 4303.1 and 4316, Business and Professions Code.

Third-Party Logistics Providers and Dangerous Drug Distributors
16 CCR §§ 1780-1783

Title 16. Board of Pharmacy

Order of Adoption

To Amend Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

Article 10. ~~Wholesalers~~ Dangerous Drug Distributors.

To Amend Section 1780 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1780. Minimum Standards for Wholesalers and Third-Party Logistics Providers.
The following minimum standards shall apply to all wholesale and third-party logistics provider establishments for which permits have been issued by the Board:

(a) A wholesaler and a third-party logistics provider shall store dangerous drugs in a secured and lockable area.

(b) All wholesaler and third-party logistics provider premises, fixtures and equipment therein shall be maintained in a clean and orderly condition. Wholesale and third-party logistics provider premises shall be well ventilated, free from rodents and insects, and adequately lighted. Plumbing shall be in good repair. Temperature and humidity monitoring shall be conducted to assure compliance with the standards set forth in the latest edition of the United States Pharmacopeia ~~Standards (1990, 22nd Revision)~~.

(c) Entry into areas where prescription drugs are held shall be limited to authorized personnel.
  (1) All facilities shall be equipped with an alarm system to detect entry after hours.
  (2) All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
  (3) The outside perimeter of the ~~wholesaler~~ premises shall be well-lighted.

(d) All materials must be examined upon receipt and ~~or~~ before shipment.
  (1) Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
  (2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

(e) The following procedures must be followed for handling returned, damaged and outdated prescription drugs.
  (1) Prescription drugs that are outdated, damaged, deteriorated, misbranded or adulterated shall be placed in a quarantine area and physically separated from other drugs until they are destroyed or returned to their supplier.
  (2) Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be placed in a quarantine area and physically separated from other prescription

drugs until they are either destroyed or returned to the supplier.

(3) If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality or purity, the drug shall be destroyed or returned to the supplier unless testing or other investigation proves that the drug meets the standards set forth in the latest edition of the ~~appropriate~~ United States Pharmacopeia ~~Standards (1990, 22nd Revision)~~.

(f) Policies and procedures must be written and made available upon request by the board.

(1) Each ~~W~~wholesaler and third-party logistics provider ~~drug distributors~~ shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, for correcting all errors and inaccuracies in inventories, and for maintaining records to document proper storage.

(2) The records required by paragraph (1) shall be in accordance with Title 21, Code of Federal Regulations, Section 205.50(g). These records shall be maintained for three years after disposition of the drugs.

(3) Each ~~W~~wholesaler and third-party logistics provider ~~drug distributors~~ shall establish and maintain lists of officers, directors, managers and other persons in charge of ~~wholesale~~ drug distribution, storage and handling, including a description of their duties and a summary of their qualifications.

(4) Each wholesaler and third-party logistics provider shall provide adequate training and experience to assure compliance with licensing requirements by all personnel.

(g) The board shall require an applicant for a licensed premise or for renewal of that license to certify under penalty of perjury that it meets the requirements of this section at the time of licensure or renewal.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4045, 4051, 4053, 4053.1, 4054, 4059, 4120, 4160, 4161, 4161.5 ~~and~~ 4304, and 4342 of the Business and Professions Code; Sections 109985 and 111280 of the Health and Safety Code; Section 321 of Title 21, U.S. Code; and Section 205.50 of Title 21, Code of Federal Regulations.

To Amend Section 1781 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1781. ~~Exemption Certificate~~ Pharmacist or Designated Representative on Premises and In Control.

(a) A registered pharmacist, or a designated representative certified in accordance with Section 4053 ~~or 4054~~ of the Business and Professions Code, shall be present and in control of a manufacturer's or wholesaler's licensed premises during the conduct of business.

(b) A designated representative-3PL, qualified in accordance with Section 4053.1 of the Business and Professions Code, shall be present and in control of a third-party logistics provider's licensed premises during the conduct of business.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4022.5, 4022.7, 4053, ~~and~~ 4053.1, 4160, and 4161 ~~4054~~, Business and Professions Code.

To Amend Section 1782 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1782. Reporting Sales of Drugs Subject to Abuse.

~~All~~ Each manufacturers~~,~~ ~~and~~ wholesalers~~,~~ and third-party logistics provider shall report to the Board or its designee, up to twelve (12) times a year, all sales of dangerous drugs subject to abuse as designated by the Board for reporting, in excess of amounts to be determined by the Board from time to time. Reports shall be made within thirty (30) days of the request in the form specified by the Board.

Note: Authority cited: Section 4005, Business and Professions Code~~; and Section 26692, Health and Safety Code~~. Reference: Sections 4081, 4164, 4165, and 4332, Business and Professions Code~~; and Section 26692, Health and Safety Code~~.

To Amend Section 1783 of Article 10 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

1783. Manufacturer, ~~or~~ Wholesaler, or Third-Party Logistics Provider Furnishing Drugs and Devices.

(a) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall be delivered only to the premises listed on the permit; provided that a manufacturer, ~~or~~ wholesaler, or third-party logistics provider may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer, ~~or~~ wholesaler, or third-party logistics provider if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at

the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer, ~~or~~ wholesaler, or third-party logistics provider by the next business day after the delivery to the pharmacy receiving area.

(d) A manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall not accept payment for or allow the use of an entity's credit to establish an account for the purchase of dangerous drugs or devices from any person other than: (1) the owner(s) of record, chief executive officer, or chief financial officer listed on the p~~m~~ermit for the authorized person; and (2) on an account bearing the name of the permittee.

(e) All records of dangerous drugs or devices furnished by a manufacturer, ~~or~~ wholesaler, or third-party logistics provider to an authorized person shall be preserved by the authorized person for at least three years from the date of making and shall, at all times during business hours, be open to inspection by authorized officers of the law at the licensed premises. The manufacturer, ~~or~~ wholesaler, or third-party logistics provider shall also maintain all records of dangerous drugs or devices furnished pursuant to this section for at least three years from the date of making and shall, at all times during business hours, keep them open to inspection by authorized officers of the law at the premises from which the dangerous drugs or devices were furnished.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4025, 4043, 4059, 4059.5, 4080, 4081, 4105, 4120, 4160, 4161, 4163, 4165 and 4304, Business and Professions Code; and Section 11209, Health and Safety Code.

Attachment 3

Regulation Timeline

VI. Discussion and Consideration of Board Adopted Regulations Undergoing Final Review by the Office of Administrative Law

1. Proposed Regulations to Amend Title 16 CCR Section 1707 Related to Offsite Storage

   Timeline:
   Approved by Board: January 24, 2017
   Submitted to DCA for Pre-Notice Review: April 27, 2017
   Returned to the board: January 18, 2018
   Re-submitted to DCA for Pre-Notice Review: June 25, 2018
   Returned to the board: July 3, 2018
   Re-submitted to DCA for Pre-Notice Review: July 13, 2018
   Formal DCA Pre-Notice Review began: August 20, 2018
   Returned to the board: March 19, 2019
   Re-submitted to DCA for Formal Pre-Notice Review: April 9, 2019
   45-Day Comment Period: February 7, 2020 to March 23, 2020
   15-Day Comment Period: May 19, 2020 to June 3, 2020 (No Negative Comments Received)
   Adopted per EO Delegation from May 7, 2020 Board Meeting: June 3, 2020
   Submitted to DCA for Final Review: June 15, 2020
   Submitted to OAL for Final Review: December 10, 2020
   OAL decision due by May 28, 2021
   (Pursuant to Governor Newsom's executive order, OAL's review may be extended in 60-day increments; however, only two 60-day extensions are permitted)

2. Proposed Regulations to Add Title 16 CCR Sections 1717.5 Related to Automatic Refill Programs

   Timeline:
   Approved by Board: May 3, 2017
   Submitted to DCA for Pre-Notice Review: November 7, 2017
   Returned to the board on: March 26, 2018
   Re-submitted to DCA for Pre-Notice Review: June 29, 2018
   Returned to the board on: August 20, 2018
   Re-submitted to DCA for Pre-Notice Review: September 20, 2018
   Formal DCA Pre-Notice Review began: December 5, 2018
   45-Day Comment Period: July 17, 2020 to August 31, 2020
   Comments reviewed by Board: September 17, 2020
   15-Day Comment Period: September 25, 2020 to October 10, 2020
   Adopted by the Board: October 28, 2020
   Submitted to DCA for Final Review: November 6, 2020
   Submitted to OAL for Final Review: March 30, 2021
   OAL decision due by May 12, 2021

3. Proposed Regulation to Amend Title 16 CCR Section 1711 Related to Quality Assurance Programs for ADDS, Section 1713 Related to Use of an APDS, and Add Section 1715.1 Related to the ADDS Self-Assessment Forms 17M-112

Timeline:
Approved by Board: January 30, 2019
Submitted to DCA for Pre-Notice Review: April 30, 2019
Returned to the board on: December 17, 2019
Re-submitted to DCA for Pre-Notice Review: December 20, 2019
Formal DCA Pre-Notice Review began: December 23, 2019
45-Day Comment Period: July 3, 2020 to August 17, 2020
Comments reviewed by Board: September 17, 2020
15-Day Comment Period: September 25, 2020 to October 10, 2020
Adopted by the Board: October 28, 2020
Submitted to DCA for Final Review: January 8, 2021
Submitted to OAL for Final Review: April 7, 2021
OAL decision due by May 19, 2021

Offsite Storage
16 CCR § 1707

Title 16. Board of Pharmacy
Modified Text

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

Proposed changes to the initial proposed text are shown by double underline for added language.

Proposal to Amend § 1707 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read:

§ 1707. Waiver Requirements for Off-Site Storage of Records

(a) Pursuant to subdivision (e) of Section 4105 of the Business and Professions Code and subdivision (c) of Section 4333 of the Business and Professions Code, a waiver ~~shall~~ may, on a case-by-case basis, be granted to any entity licensed by the board for ~~off-site~~ storage of the records outside the licensed area of the pharmacy described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code ~~unless the applicant has, within the preceding five years, failed to produce records pursuant to Section 4081 of the Business and Professions Code or has falsified records covered by Section 4081 of the Business and Professions Code~~. The board may consider space limitations within the pharmacy, cost, previous compliance with records requirements, ease of access to records stored outside of the licensed area, and any other factor presented by the licensee in making its determination.

(b) An entity that is granted a waiver pursuant to subdivision (a) shall:
   (1) maintain the storage area so that the records are secure, including from unauthorized access; and
   (2) be able to produce the records within two business days upon the request of the board or an authorized officer of the law.

(c) In the event that a licensee fails to comply with the conditions set forth in subdivision (b), the board may cancel the waiver without a hearing. Upon notification by the board of cancellation of the waiver, the licensee shall maintain all records at the licensed premises.

(d) A licensee whose waiver has been cancelled pursuant to the provisions set forth in subsection (c) may reapply to the board when compliance with the conditions set forth in subsection (b) can be confirmed by the board.

(e) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for non controlled substances shall be maintained on the licensed premises for a period of one year from the date of dispensing.

(f) Notwithstanding any waiver granted pursuant to subdivision (a), all prescription records for controlled substances shall be maintained on the licensed premises for a period of two years from the date of dispensing.

(g) Notwithstanding the requirements of this section, any entity licensed by the board may store the records described in subdivisions (a), (b) and (c) of Section 4105 of the Business and Professions Code in a storage area at the same address or adjoining the licensed premises without obtaining a waiver from the board if the following conditions are met:
   (1) The records are readily accessible to the pharmacist-in-charge (or other pharmacist on duty, or designated representative) and upon request to the board or any authorized officer of the law.
   (2) The storage area is maintained so that the records are secure and so that the confidentiality of any patient-related information is maintained.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081, 4105 and 4333, Business and Professions Code.

Automatic Refill Programs

16 CCR § 1717.5

California State Board of Pharmacy
Department of Consumer Affairs
California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 17. Board of Pharmacy

Proposed Modified Text

Modified changes to the proposed regulation text are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Proposal to add § 1717.5 in Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1717.5. Automatic Refill Programs.

(a) A pharmacy may offer a program to automatically refill prescription medications provided the pharmacy complies with this section.

(1) The pharmacy shall have written policies and procedures describing the program, which shall set forth, at a minimum, how the pharmacy will comply with this section~~, as well as a list of medications that may be refilled through the program~~.

(2) Before a patient enrolls, the pharmacy shall provide a written or electronic notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program. The patient or patient's agent shall enroll by written, online, or electronic informed consent to participate in the program for each prescription.

(3) The pharmacy shall keep a copy of the written or electronic informed consent to enroll on file for one year from date of dispensing.

~~(4) When a patient enrolls, the pharmacy shall provide a written notice summarizing the program to the patient or patient's agent. Such notice shall include, at a minimum, instructions about how to withdraw a prescription medication from refill through the program or to disenroll entirely from the program.~~

(~~5~~ 4) The pharmacy shall complete a drug regimen review for each prescription refilled through the program at the time of refill.

(~~6~~ 5) Each time a prescription is refilled through the program, the pharmacy shall provide a written or electronic notification to the patient or patient's agent confirming that the prescription medication is being refilled through the program.

(~~7~~ 6) The patient or patient's agent shall at any time be able to withdraw a prescription medication from automatic refill or to disenroll entirely from the program. The

pharmacy shall document and maintain such withdrawal or disenrollment for one year from the date of withdrawal or disenrollment and shall provide confirmation to the patient or patient's agent.

(~~8~~ 7) The pharmacy shall provide a full refund to the patient, patient's agent, or payer for any prescription medication refilled through the program if the pharmacy ~~is~~ was notified that the patient did not want the refill, regardless of the reason, ~~and~~ or the pharmacy had been notified of withdrawal or disenrollment from the program prior to dispensing the prescription.

(~~9~~ 8) A pharmacy shall make available any written or electronic notification required by this section in alternate languages as required by state or federal law.

(b) A licensed health facility, as defined in Health and Safety Code section 1250, that automatically refills prescription medications for its patients need not comply with the provisions of this section.

(c) Pharmacies automatically refilling prescription medications for inmates of an adult correctional facility or a juvenile detention facility need not comply with the provisions of this section if the facility has written policies and procedures describing how a patient may request that a medication be automatically refilled and how a patient may refuse the medication.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4001.1, 4005, 4063 and 4076.6, Business and Professions Code and Section 1250, Health and Safety Code.

Automated Drug Delivery Systems (ADDS) 16 CCR §§ 1711, 1713, and 1715.1

California State Board of Pharmacy
Department of Consumer Affairs
California Code of Regulations
Title 16. Professional and Vocational Regulations
Division 17. Board of Pharmacy
Proposed Regulation

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

Modified changes to the current proposed regulation text are shown by ~~double strikethrough~~ for deleted language and double underline for added language.

Amend section 1711 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1711. Quality Assurance Programs.

(a) Each pharmacy shall establish or participate in an established quality assurance program ~~which~~ that documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, “medication error” means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. 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. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy. The record shall contain at least the following:

(1.) t The date, location, and participants in the quality assurance review;

(2.) t The pertinent data and other information relating to the medication error(s) reviewed and documentation of any patient contact required by subdivision (c);

(3.) t The findings and determinations generated by the quality assurance review; and,

(4.) r Recommend changes to pharmacy policy, procedure, systems, or processes, if any.

The pharmacy shall inform pharmacy personnel of changes to pharmacy policy, procedure, systems, or processes made as a result of recommendations generated in the quality assurance program.

(f) The record of the quality assurance review, as provided in subdivision (e) shall be immediately retrievable in the pharmacy for at least one year from the date the record was created. Further, a Any quality assurance record related to the use of an licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review and any facility with an unlicensed automated drug delivery system must report the quality assurance review to the Board at the time of annual renewal.

(g) The pharmacy's compliance with this section will be considered by the board as a mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or otherwise arranging for the provision of personnel or other resources, by a third party or administrative offices, with such skill or expertise as the pharmacy believes to be necessary to satisfy the requirements of this section.

Note: Authority cited: Section 4005, Business and Professions Code; and Section 2 of Chapter 677, Statutes of 2000. Reference: Sections 4125, and 4427.7, Business and Professions Code.

Amend section 1713 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1713. Receipt and Delivery of Prescriptions and Prescription Medications Must be To or From Licensed Pharmacy

(a) Except as otherwise provided in this Division, no licensee shall participate in any arrangement or agreement, whereby prescriptions, or prescription medications, may be left at, picked up from, accepted by, or delivered to any place not licensed as a retail pharmacy.

(b) A licensee may pick up prescriptions at the office or home of the prescriber or pick up or deliver prescriptions or prescription medications at the office of or a residence designated by the patient or at the hospital, institution, medical office or clinic at which the patient receives health care services. In addition, the Board may, in its sole discretion, waive application of subdivision (a) for good cause shown.

(c) A patient or the patient's agent may deposit a prescription in a secure container that is at the same address as the licensed pharmacy premises. The pharmacy shall be responsible for the security and confidentiality of the prescriptions deposited in the container.

(d) A pharmacy may use an automated patient dispensing system (APDS) ~~delivery device~~ to deliver ~~previously dispensed~~ prescription medications to patients provided:

~~(1) Each patient using the device has chosen to use the device and signed a written consent form demonstrating his or her informed consent to do so.~~

~~(2)~~(1) A pharmacist has determined that each patient using the ~~device~~ APDS meets inclusion criteria for use of the APDS ~~device~~ established by the pharmacy prior to delivery of prescription medication to that patient.

~~(3)~~(2) The APDS ~~device~~ has a means to identify each patient and only release that patient's prescription medications to the patient or patient's agent.

~~(4) The pharmacy does not use the device to deliver previously dispensed prescription medications to any patient if a pharmacist determines that such patient requires counseling as set forth in section 1707.2(a)(2).~~

~~(5)~~(3) The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

~~(6) The device is located adjacent to the secure pharmacy area.~~

~~(7) The device is secure from access and removal by unauthorized individuals.~~

~~(8) The pharmacy is responsible for the prescription medications stored in the device.~~

~~(9)~~(4) Any incident involving the APDS ~~device~~ 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.

~~(10) The pharmacy maintains written policies and procedures pertaining to the device as described in subdivision (e).~~

(e) Any pharmacy making use of an APDS ~~automated delivery device as permitted by subdivision (d)~~ shall maintain, and on an annual basis review, written policies and procedures providing for:

(1) Maintaining the security of the APDS ~~automated delivery device~~ and the dangerous drugs within the APDS ~~device~~.

(2) Determining and applying inclusion criteria regarding which medications are appropriate for placement in the APDS ~~device~~ and for which patients, including when consultation is needed.

(3) Ensuring that patients are aware that consultation with a pharmacist is available for any prescription medication, including for those delivered via the APDS ~~automated delivery device~~.

(4) Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filing procedures for the APDS ~~automated delivery device~~.

(5) Orienting participating patients on use of the APDS ~~automated delivery device~~, notifying patients when expected prescription medications are not available in the APDS ~~device~~, and ensuring that patient use of the APDS ~~device~~ does not interfere with delivery of prescription medications.
(6) Ensuring the delivery of medications to patients in the event the APDS ~~device~~ is disabled or malfunctions.

(f) Written policies and procedures shall be maintained at least three years beyond the last use of an APDS ~~automated delivery device~~.

~~(g) For the purposes of this section only, "previously-dispensed prescription medications" are those prescription medications that do not trigger a non-discretionary duty to consult under section 1707.2(b)(1), because they have been previously dispensed to the patient by the pharmacy in the same dosage form, strength, and with the same written directions.~~

Note: Authority cited: Sections 4005, 4075, and 4114, Business and Professions Code. Reference: Sections 4005, 4017.3, 4052, 4116, ~~and~~ 4117, 4427, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.6, 4427.7, and 4427.8, Business and Professions Code

Add section 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 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 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 12/18) 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 completed the self-assessment of the automated drug delivery system of which he or she is the pharmacist-in-charge. The pharmacist-in-charge shall also certify a timeframe within which any deficiency identified within the self-assessment will be corrected and acknowledge that all responses are subject to verification by the Board of Pharmacy. The certification shall be made under penalty of perjury of the laws of the State of California that the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form.

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

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

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

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

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

AUTOMATED DRUG DELIVERY SYSTEM SELF-ASSESSMENT

Business and Professions Code (BPC) section 4427.7(a) requires the pharmacy holding an automated drug delivery system (ADDS) license complete an annual self-assessment, performed pursuant to section 1715.1 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 annually **before July 1 of every year** by the pharmacist-in-charge of each pharmacy under section 4029 (Hospital Pharmacy) or section 4037 (Pharmacy). The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new automated drug delivery system permit has been issued, or (2) there is a change in the pharmacist-in-charge and becomes the new pharmacist-in-charge of an automated drug delivery system, or (3) there is a change in the licensed location of an automated drug delivery system to a new address. The primary purpose of the self-assessment is to promote compliance through self-examination and education. All information regarding operation, maintenance, compliance, error, omissions, or complaints pertaining to the ADDS shall be included in this Self-Assessment.

All references to Business and Professions Code (BPC) are to Chapter 9, Division 2; California Code of Regulations (CCR) are to Title 16; and Code of Federal Regulations (21 CFR) to Title 21 unless otherwise noted.

The self-assessment must be completed and retained in the pharmacy for three (3) years after performed.

Please mark the appropriate box for each item. If "NO", enter an explanation and timeframe when the deficiency will be completed on the "CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE" lines at the end of the section. If more space is needed, you may add additional sheets.

Pharmacy Name: _____
Address: _____
City: _____
Phone: _____
Fax number: _____
Website: _____
Pharmacy License #: _____
Expiration Date: _____
DEA Registration #: _____
DEA Expiration Date: _____
DEA Inventory Date: _____
Last C2 Inventory Reconciliation Date (CCR 1715.65(c)): _____
Pharmacy Hours: M-F: _____ **Saturday**_____ **Sunday**_____

PIC: _____**RPH#**_____
ADDS License #: _____
ADDS Expiration Date:_____
ADDS Address: _____
City: _____
ADDS Hours: **M-F:** _____**Saturday**_____ **Sunday**_____
Please explain if the ADDS hours are different than the pharmacy:
_____

FOR ALL TYPES OF ADDS: COMPLETE SECTIONS 1, 2 AND 3

SECTION 1: DEFINITIONS/TYPE OF ADDS DEVICE USED

An **ADDS – "Automated drug delivery system**," a mechanical system that performs operations or activities other than compounding or administration, relative to storage, dispensing, or distribution of drugs. An ADDS, shall collect, control and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4119.11(b)(1), 4017.3(a)]

IDENTIFY THE TYPE OF ADDS DEVICE USED

Yes No N/A

☐☐☐ 1.1. The pharmacy uses an **APDS – "Automated PATIENT dispensing system**," an ADDS for storage and dispensing of prescribed drugs directly to the patients pursuant to prior authorization by a pharmacist. [BPC 4119.11(b)(2), 4017.3(c)]

☐☐☐ 1.2 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration to patient by persons authorized to perform these functions. [BPC 4119.11(b)(3), 4017.3(b)]

☐☐☐ 1.3 The pharmacy uses an **AUDS – "Automated UNIT DOSE system**," an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a drug room or hospital emergency room when the pharmacy is closed. [BPC 4427.2(i), BPC 4056, BPC 4068]

SECTION 2: LOCATION OF DEVICES

Yes No N/A

☐☐☐ 2.1 Provides pharmacy services to the patient of **covered entities**, as defined that are eligible for discount drug programs under federal law as specified through the use of an APDS as defined. The APDS need not be at the same location as the underlying operating pharmacy if all the specific conditions are met. "Covered entity" as defined by section 256b of Title 42 of United Sates Code. [BPC 4119.11(a)-(a)(11)]

☐☐☐ 2.2 Provides pharmacy services through an ADDS **adjacent to the secured pharmacy area** of the pharmacy holding the ADDS license. [BPC 4427.3(b)(1)]

Yes No N/A

☐☐☐ 2.3 Provides pharmacy services through an ADDS in **a health facility** licensed pursuant to section 1250 of the Health and Safety Code (Long Term Care (LTC)) that complies with section 1261.6 of the Health and Safety Code. [BPC 4427.3(b)(2)]

☐☐☐ 2.4 Provides pharmacy services through **a clinic** licensed pursuant to section 1204 or 1204.1 of the Health and Safety Code, or section 4180 or 4190 of Business and Professions Code. [BPC 4427.3(b)3)]

☐☐☐ 2.5 Provides pharmacy services through a **correctional clinic**. [BPC 4187.1, 4427.3(b)(4)]

☐☐☐ 2.6 Provides pharmacy services through a **medical office**. [BPC 4427.3(b)(5), 4427.6(j)]

☐☐☐ 2.7 **AUDS operated by a licensed hospital pharmacy**, as defined in section 4029, and is used solely to provide doses administered to patients while in a licensed general acute care hospital facility or a licensed acute psychiatric hospital facility, as defined in subdivision (a) and (b) of section 1250 of the Health and Safety Code, shall be exempt from the requirement of obtaining an ADDS license, if the licensed hospital pharmacy owns or leases the AUDS and owns the dangerous drugs and dangerous devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS in Article 25. The licensed hospital pharmacy shall maintain a list of the locations of each AUDS it operates and shall make the list available to the board upon request. [BPC4427.2(i)]

Note: An ADDS license is not required for technology, installed **within the secured licensed premises area of a pharmacy,** used in the selecting, counting, packaging, and labeling of dangerous drugs and dangerous devices. [BPC 4427.2(j)]

SECTION 3: GENERAL REQUIREMENTS FOR ALL TYPES OF ADDS

(Answer N/A if licensure not required)

Yes No N/A

☐☐☐ 3.1 The ADDS is installed, leased, owned, or operated in California and is licensed by the board. [BPC 4427.2(a), 4427.4(a)]

☐☐☐ 3.2 The ADDS license was issued to a holder of a current, valid, and active pharmacy license of a pharmacy located and licensed in California. [BPC 4427.2(b)]

☐☐☐ 3.3 Each ADDS has a separate license. [BPC 4427.2(c)]

☐☐☐ 3.4 The licensed ADDS meets the following conditions: [BPC 4427.2(d)]

- Use of the ADDS is consistent with legal requirements.
- The proposed location for installation of the ADDS met the requirements of section 4427.3 and the ADDS is secure from access and removal by unauthorized individuals.
- The pharmacy's policies and procedures related to the ADDS include appropriate security measures and monitoring of the inventory to prevent theft and diversion.

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

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)]

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

☐☐☐ 3.8 The pharmacy is aware the ADDS license will be canceled by operation of law if the underlying pharmacy license is not current, valid, and active. Upon reissuance or reinstatement of the underlying pharmacy license, a new application for an ADDS license is submitted to the board. [BPC 4427.2(f)]

☐☐☐ 3.9 The pharmacy is aware the holder of an ADDS license will advise the board in writing within 30 days if use of an ADDS is discontinued. [BPC 4427.2(g)]

☐☐☐ 3.10 The ADDS license(s) was/were renewed annually, and the renewal date is the same as the underlying pharmacy license. [BPC 4427.2(h)]

☐☐☐ 3.11 The ADDS is placed and operated inside an enclosed building, with a premises address, at a location approved by the board. [BPC 4427.3(a)]

☐☐☐ 3.12 Prior to installation, the pharmacy holding the ADDS license and the location where the ADDS is placed pursuant to subdivision (b) of Business and Professions Code section 4427.3, jointly developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS, as well as quality, potency, and purity of the drugs and devices. The policies and procedures are maintained at the location of the ADDS and at the pharmacy holding the ADDS license. [BPC 4427.3(c)]

☐☐☐ 3.13 Each ADDS is operated under the supervision of the pharmacy holding the ADDS license. [BPC 4427.4(b)]

Yes No N/A

☐☐☐ 3.14 The ADDS is considered an extension and part of the pharmacy holding the ADDS license, regardless of the ADDS location, and is subject to inspection pursuant to BPC 4008. [BPC 4427.4(c)]

☐☐☐ 3.15 Drugs and devices stored in an ADDS will be deemed part of the inventory and the responsibility of the pharmacy holding the ADDS license, and the drugs and devices dispensed from the ADDS shall be considered to have been dispensed by the pharmacy. [BPC 4427.4(d)]

☐☐☐ 3.16 The stocking and restocking of an ADDS is performed by a pharmacist, or by a pharmacy technician or intern pharmacist under the supervision of a pharmacist, except for an ADDS located in a health facility pursuant to HSC 1250, where the stocking and restocking of the ADDS may be performed in compliance with HSC 1261.6. [BPC 4427.4(e)(1)]

☐☐☐ 3.17 Access to the ADDS is controlled and tracked using an identification or password system or biosensor. [BPC 4427.4(e)(2)]

☐☐☐ 3.18 The ADDS makes a complete and accurate record of all transactions including all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3)]

☐☐☐ 3.19 Are drugs or devices not immediately transferred into an ADDS upon arrival at the ADDS location, stored for no longer than 48 hours in a secured room within the ADDS location approved by the board under section 4427.3 and upon retrieval of the dangerous drugs and devices from the secured storage is an inventory taken to detect any losses or overages? [BPC 4427.4(f)]

☐☐☐ 3.20 Prior to installation, and annually thereafter, the pharmacy holding the ADDS license provides training on the operation and use of the ADDS to the pharmacy personnel and to personnel using the ADDS at the location where the ADDS is placed pursuant to BPC 4427.3(b). [BPC 4427.5]

☐☐☐ 3.21 The pharmacy complies with all recordkeeping and quality assurance requirements established in pharmacy law and regulations, and maintains records within the licensed pharmacy holding the ADDS license and separate from other pharmacy records. [BPC 4427.7(b)]

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 owner of the ADDS shall sign the Certification Acknowledgment on page 33 after completing the assessment.

- ☐ SECTION 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity.
- ☐ SECTION 5 – ADDS adjacent to the secured pharmacy area ~~and~~ or located in Medical Offices.
- ☐ SECTION 6 – ADDS in a health facility pursuant to HSC 1250 that complies with HSC 1261.6 ~~(LTC).~~
- ☐ SECTION 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190.
- ☐ SECTION 8 – ADDS operated by a correctional clinic.
- ☐ SECTION 9 - AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (when the hospital pharmacy is closed and no pharmacist is available).

SECTION 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 USC shall be segregated from the pharmacy's other drug stock by physical or electronic means. [BPC 4126(b)]

☐☐☐ 4.4 All records of acquisition and disposition of these drugs shall be readily retrievable in a form separate from the pharmacy's other records. [BPC 4126(b)]

☐☐☐ 4.5 The drugs shall be returned to the distributor from which the drugs were obtained if drugs to be dispensed to patient of a covered entity pursuant to section 256b of Title 42USC cannot be distributed because of a change in circumstances of the covered entity or the pharmacy. [BPC 4126(c)]

☐☐☐ 4.6 A licensee that participates in a contract to dispense preferentially priced drugs pursuant to this section shall not have both a pharmacy and a wholesaler license. [BPC 4126(d)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. UNDERLYING OPERATING PHARMACY

Yes No N/A

☐☐☐ 4.7 The operating pharmacy has obtained a license from the Board to operate the APDS which includes the address of the APDS location and the identity of the covered entity or affiliated site. [BPC 4119.11(a)(1)]

☐☐☐ 4.8 A separate license was obtained for each APDS location and has been renewed annually concurrent with the pharmacy license. (Note: The Board may issue a license for operation of an APDS at an address for which the Board has issued another site license.) [BPC 4119.11(a)(1), 4119.11(a)(8), 4107]

☐☐☐ 4.9 A prelicensure inspection of the proposed APDS location was conducted by the Board within 30 days after Board receipt of the APDS application before Board approval. [BPC 4119.11(a)(9)]

Date of Inspection: _____

☐☐☐ 4.10 The pharmacy will submit a new APDS licensure application for Board approval if the current APDS is relocated. [BPC 4119.11(a)(9)]

☐☐☐ 4.11 The pharmacy will notify the Board within 30 days of replacement of an APDS or discontinuing an APDS. [BPC 4119.11(a)(9), 4119.11(a)(11)]

☐☐☐ 4.12 A new APDS licensure application will be submitted if original APDS is cancelled due to the underlying operating pharmacy's permit being cancelled, not current, not valid, or inactive. (Once cancelled, a new APDS license can only be issued if the underlying pharmacy's permit is reissued or reinstated.) [BPC 4119.11(a)(10)]

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

1._____ 2. _____

3._____ 4. _____

5._____6. _____

7._____8. _____

9._____10._____

11. _____ 12._____

13._____14. _____

15. _____

Yes No N/A

☐☐☐ 4.14 The operating pharmacy will maintain the written APDS policies and procedures for 3 years after the last date of use for that APDS. [BPC 4119.11(d)(11)]

☐☐☐ 4.15 The operating pharmacy of an APDS has completed an annual Self-Assessment pursuant to CCR 1715 or BPC 4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4119.11(i)]

Date of Last Self-Assessment: _____

☐☐☐ 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 The underlying operating pharmacy is solely responsible for:

- The security of the APDS. [BPC 4119.11(a)(5)]
- The operation of the APDS. [BPC 4119.11(a)(5)]
- The maintenance of the APDS. [BPC 4119.11(a)(5)]
- The training regarding the operation and use of the APDS for both the pharmacy and covered entity personnel using system. [BPC 4119.11(a)(6)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 4.19 The operation of the APDS is under the supervision of a licensed pharmacist acting on behalf of the operating pharmacy. [BPC 4119.11(a)(7)]. Note: The pharmacist need not be physically present at the site of the APDS and may supervise the system electronically.

☐☐☐ 4.20 The pharmacist performs the stocking of the APDS or if the APDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking of the APDS may be done outside of the facility if the following conditions are met: [BPC 4119.11(g)]

☐☐☐ 4.20.1 A pharmacist, intern pharmacist or pharmacy technician working under the supervision of the pharmacist may place drugs into the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers. [BPC 4119.11(g)(1)]

☐☐☐ 4.20.2 Transportation of removeable pockets, cards, drawers or similar technology or unit of use or single dose container between the pharmacy and the facility are in a tamper-evident container. [BPC 4119.11(g)(2]

☐☐☐ 4.20.3 There are policies and procedures to ensure the removeable pockets, cards, drawers, similar technology, or unit of use or single dose containers are properly placed into the APDS. [BPC 4119.11(g)(3)]

☐☐☐ 4.21 The pharmacist conducts a monthly review of the APDS including a physical inspection of the drugs contained within, operation, maintenance, and cleanliness of the APDS, and a review of all transaction records in order to verify the security and accountability of the APDS. [BPC 4119.11(h)]

Date of Last Review: _____

☐☐☐ 4.22 The Pharmacist-in-charge of the offsite ADDS/APDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENTS

Yes No N/A

☐☐☐ 4.23 Access to the APDS is controlled and tracked using an identification or password system or biosensor. Systems tracked via password shall include a camera that records a picture of the individual accessing the APDS and the picture must be maintained for a minimum of 180 days. [BPC 4119.11(e)]

☐☐☐ 4.24 The APDS makes complete and accurate records of all transactions including users accessing system and drugs added and removed from the APDS. [BPC 4119.11(f)]

☐☐☐ 4.25 The APDS will collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of APDS. [BPC 4119.11(c)(1)]

☐☐☐ 4.26 The APDS will maintain transaction information in a readily available in downloadable format for review and inspection by authorized individuals for a minimum of 3 years. [BPC 4119.11(c)(2)]

☐☐☐ 4.27 The APDS may dispense medications **DIRECTLY** to the patient if **all** the following are met: [BPC 4119.11(d)]

☐☐☐ 4.27.1 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [BPC 4119.11(d)(1) – (d)(1)(F)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

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

Yes No N/A

☐☐☐ 4.27.3 The device shall have a means to identify each patient and only release the identified patient's drugs and devices to the patient or the patient's agent. [BPC 4119.11(d)(3)]

☐☐☐ 4.27.4 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)]

☐☐☐ 4.27.5 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 potentials contraindication and adverse drug reactions. [BPC 4119.11(d)(5)]

☐☐☐ 4.27.6 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)]

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

☐☐☐ 4.27.8 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)]

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

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

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

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

☐☐☐ 4.32 Medication guides are provided on required medications. (21 CFR 208.1)

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 4.33 The operating pharmacy has complied with all recordkeeping and quality assurance requirements pursuant to BPC 4119.11 and those records shall be maintain within the pharmacy holding the APDS and separately from the other pharmacy records. [BPC 4119.11(j)]

☐☐☐ 4.34 The operating pharmacy will maintain records of acquisition and disposition of dangerous drugs stored in the APDS separate from other pharmacy records. [BPC 4119.11(a)(4)]

☐☐☐ 4.35 Any records maintained electronically must be maintained so that the pharmacist-in-charge, or the pharmacist on duty if the pharmacist-in-charge is not on duty, must, at all times during which the licensed premises are open for business, be able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically. [BPC 4105(d)(1)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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F. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 4.36 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually:

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.

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

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 4.37 The pharmacy has policies and procedures for security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4105.5(c)(2)]

☐☐☐ 4.38 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 5: ADDS ADJACENT TO THE SECURED PHARMACY AREA ~~AND~~OR LOCATED IN MEDICAL OFFICES.

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)]

☐☐☐ 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

☐☐☐ 5.3 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. 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)]

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

- All controlled substances added to the ADDS/APDS are accounted for;
- Access to ADDS/APDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

☐☐☐ 5.8. The pharmacy operating the APDS has completed an annual Self-Assessment pursuant to CCR 1715 evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS. [BPC 4427.7(a)]

Date of Last Self-Assessment: _____

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)]

Yes No N/A

☐☐☐ 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)]

☐☐☐ 5.14 The APDS may only be used for patients who have signed a written consent demonstrating their informed consent to receive prescribed drug and devices from the APDS. Attach a copy of the consent form to the back of the self-assessment. [BPC 4427.6(b)]

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

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

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

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

☐☐☐ 5.24 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 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 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 The pharmacy has developed and implemented written policies and procedures with respect to all the following and the policies are reviewed annually: [4427.6(a) – 4427.6(a)(6)]

- Maintaining the security of the APDS and dangerous drug and devices within the APDS
- Determine and apply inclusion criteria regarding which drugs, devices are appropriate for placement in the APDS and for which patients.
- Ensuring patients are aware that consultation with a pharmacist is available for any prescription medication including those delivered via APDS
- Describing assignment of responsibilities and training of pharmacy personnel and other personnel using the APDS at that location regarding maintenance and filling procedures for the APDS.
- Orienting patients on use of APDS and notifying patients when expected medications are not available in the APDS. The pharmacy must ensure the use of the APDS does not interfere with the delivery of drugs and devices.
- Ensuring the delivery of drugs and devices to patients expecting medications from the APDS in the event the APDS is disabled or malfunctions.

Date of Last Policy Review: _____

Yes No N/A

☐☐☐ 5.29 The pharmacy reports drug losses as required by law. [BPC 4104, 4105.5(c), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 6: ADDS IN A HEALTH FACILITY PURSUANT TO HSC 1250 – LONG TERM CARE FACILITIES

A. GENERAL REQUIREMENTS

For purposes of this section, "FACILITY" means a health facility licensed pursuant to subdivision (c), (d), or (k) of section 1250 of the Health and Safety Code that has an ADDS provided by a pharmacy. [HSC 1261.6(a)(2)]

For purposes of this section, "PHARMACY SERVICES" means the provision of both routine and emergency drugs and biologicals to meet the needs of the patient, as prescribed by a physician. [HSC 1261.6 (a)(3)]

Yes No N/A

☐☐☐ 6.1 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6 (d)(1)]

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

☐☐☐ 6.3 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.4 The pharmacy is responsible for review of drugs contained within the ADDS and the operation and maintenance of the ADDS. [HSC 1261.6(h)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. PHARMACIST RESPONSIBILITIES:

Yes No N/A

☐☐☐ 6.5 The stocking of the ADDS is performed by a pharmacist or if the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers are used, the stocking system may be done outside the facility and be delivered to the facility if the following conditions are met: [HSC 1261.6 (g)]

☐☐☐ 6.5.1 The task of placing drugs into the removeable pockets, cards, drawers, or unit or use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician under the direct supervision of a pharmacist. [HSC 1261.6 (g)(1)]

☐☐☐ 6.5.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container. [HSC 1261.6 (g)(2)]

☐☐☐ 6.5.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.6 Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs. [HSC 1261.6 (c)]

☐☐☐ 6.7 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.8 The review of the drugs contained within the ADDS and the operation and maintenance of the ADDS is conducted, on a monthly basis, by a pharmacist. The review includes a physical inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [HSC 1261.6 (h)]

Date of Last Review: _____

☐☐☐ 6.9 The Pharmacist-in-charge of the offsite ADDS has ensured the following: [CCR 1715.65(h)]

- All controlled substances added to the ADDS are accounted for;
- Access to ADDS is limited to authorized facility personnel;
- An ongoing evaluation of discrepancies or unusual access associated with controlled substance is performed; and
- Confirmed losses of controlled substances are reported to the Board.

Yes No N/A

☐☐☐ 6.10 The pharmacy operating the ADDS has completed an annual Self-Assessment pursuant to BPC4427.7(a) evaluating the pharmacy's compliance with pharmacy law relating to the use of the APDS (BPC 4427.7(a)).

Date of Last Self-Assessment: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. DEVICE REQUIREMENTS:

Yes No N/A

☐☐☐ 6.11 The stocking and restocking of the ADDS is performed in compliance with section 1261.6 of the Health and Safety Code. [BPC 4427.4(e)(1)]

☐☐☐ 6.12 Drugs and devices not immediately transferred into an ADDS upon arrival at the ADDS location are stored for no longer than 48 hours in a secured room within the ADDS location. Upon retrieval of these drugs and devices from secured storage, an inventory is taken to detect any losses or overages. [BPC 4427.4(f)]

☐☐☐ 6.13 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

☐☐☐ 6.14 The information required by BPC section 4076 and HSC 111480 is readily available at the time of drug administration if unit dose packaging or unit of use packaging is used. Unit dose packaging, for purposes of this section, includes blister pack cards. [HSC 1261.6(i)]

When the ADDS is used as an emergency pharmaceutical supplies container, drugs removed from the ADDS are limited to the following [HSC 1261.6(e)]:

Yes No N/A

☐☐☐ 6.15 A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drug is retrieved only upon the authorization of a pharmacist and after the pharmacist has reviewed the prescriber's order and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6(e)(1)]

☐☐☐ 6.16 Drugs that a prescriber has ordered for a patient on an as-needed basis, if the utilization and retrieval of those drugs are subject to ongoing review by a pharmacist. [HSC 1261.6(e)(2)]

☐☐☐ 6.17 Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs are retrieved from the

ADDS pursuant to the order of a prescriber for emergency or immediate administration to a patient of the facility and reviewed by a pharmacist within 48 hours. [HSC 1261.6(e)(3)]

When the ADDS is used to provide pharmacy services pursuant to BPC 4017.3, the ADDS is subject to the following requirements [HSC 1261.6 (f)]:

Yes No N/A

☐☐☐ 6.18 Drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages. [HSC 1261.6(f)(1)]

☐☐☐ 6.19 A pharmacist reviews and approves all orders prior to a drug being removed from the ADDS for administration to a patient. The pharmacist reviews the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions. [HSC 1261.6 (f)(2)]

☐☐☐ 6.20 The pharmacy controls access to the drugs stored in the ADDS. [HSC 1261.6 (f)(3)]

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

☐☐☐ 6.22 The ADDS makes a complete and accurate record of all transactions that includes all users accessing the system and all drugs added to, or removed from, the system. [BPC 4427.4(e)(3), HSC 1261.6(f)(5)]

☐☐☐ 6.23 After the pharmacist reviews the prescriber's order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. [HSC 1261.6(f)(6)]

☐☐☐ 6.24 When the prescriber's order requires a dosage variation of the same drug, licensed personnel only have access to the drug ordered for that scheduled time of administration. [HSC 1261.6 (f)(6)]

☐☐☐ 6.25 If the ADDS allow licensed personnel to have access to multiple drugs and are not patient specific in their design, the ADDS has electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient (HSC 1261.6 (f)(7)).

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 6.26 The pharmacy complies with all recordkeeping and quality assurance requirements, established in pharmacy law and regulation, and maintains those records within the licensed pharmacy holding the ADDS license and separate from the other pharmacy records. [BPC 4427.7 (b)]

☐☐☐ 6.27 Transaction information from the ADDS will be made readily available in a written format for review and inspection by individuals authorized by law and maintained in the facility for a minimum of three years. [HSC 1261.6(b)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 6.28 The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the ADDS as well as quality, potency, and purity of the stored drugs and devices. [BPC 4427.3(c), HSC 1261.6(d)(1)]

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

☐☐☐ 6.30 All ADDS policies and procedures are maintained at the pharmacy and the location where the ADDS is being used. [HSC 1261.6(d)(2), BPC 4427.3(c)]

☐☐☐ 6.31 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS. [HSC 1261.6(g)(3)]

☐☐☐ 6.32 The pharmacy has policies and procedures that include appropriate security measures and monitoring of the inventory to prevent theft and diversion. [BPC 4427.2(d)(3)]

☐☐☐ 6.33 The pharmacy's policies and procedures include provisions for reporting to the board drug losses from the ADDS inventory, as required by law. [BPC 4104, 4427.2(d)(4), CCR 1715.6, 21 CFR 1301.76]

Last Reported Drug Loss: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 7: APDS THROUGH A CLINIC PURSUANT TO HSC 1204 OR 1204.1 OR BPC 4180 OR 4190

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 7.1 The ADDS is located inside an enclosed building with a premises address, at a location approved by the Board [BPC 4427.3 (a)]. The clinic has a current Board of Pharmacy Clinic license pursuant to BPC 4180 or BPC 4190? or the clinic is licensed pursuant to HSC 1204 or 1204.1. [BPC 4427.3(b)(3)]

License number: _____Expiration Date: _____

☐☐☐ 7.2 The clinic has developed and implemented written policies and procedures that ensure the safety, accuracy, accountability, security and patient confidentiality. Additionally, the policies and procedures shall ensure the maintenance of the quality, potency and purity of the drugs. **The policies and procedures shall be maintained at the location where the ADDS is being used.** [BPC 4186(a)]

☐☐☐ 7.3 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)]

Yes No N/A

☐☐☐ 7.9 The clinic shall compile an inventory reconciliation report of all **federal Schedule ll controlled substance** at least every three months. [CCR 1715.65(c)] The compilation requires:

- A physical count (not estimate) of all quantities of all **federal Schedule ll controlled substances.**
- A review of all acquisition and disposition records of **federal Schedule ll controlled substances** since that last inventory reconciliation report:

Date of last inventory_____

- A comparison of (1) and (2) to determine if there are any variances.
- All records used to compile each inventory reconciliation report shall be maintained at clinic for 3 years in a readily retrievable form.
- Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report.

☐☐☐ 7.10 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(c).

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

Yes No N/A

☐☐☐ 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: _____

Yes No N/A

☐☐☐ 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)]

☐☐☐ 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_____

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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: ADDS OPERATED BY A CORRECTIONAL CLINIC

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 8.1 The pharmacy uses an "automated drug delivery system" used in a correctional clinic, meaning a mechanical system controlled remotely by a pharmacist that performs operations or activities, other than compounding or administration, relative to the storage, dispensing, or distribution of prepackaged dangerous drugs or dangerous devices. An automated drug delivery system shall collect, control, and maintain all transaction information to accurately track the movement of drugs into and out of the system for security, accuracy, and accountability. [BPC 4187.5(h)]

☐☐☐ 8.2 The ADDS is located in a "correctional clinic," a primary care clinic, as referred to in subdivision (b) of section 1206 of the Health and Safety Conde, conducted, maintained, or operated by the state to provide health care eligible patients of the Department of Corrections and Rehabilitation (BPC 4187).

Yes No N/A

☐☐☐ 8.3 The correctional clinic licensed by the board obtains the drugs from a licensed correctional pharmacy, the Department of Correction and Rehabilitation's Central Fill Pharmacy, or from another correctional clinic licensed by the board within the same institution for the administration or dispensing of drugs or devices to patients eligible for care at the correctional facility if under either: [BPC 4187.1(a)]

- The directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe.
- An approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures.

☐☐☐ 8.4 The dispensing or administering of drugs in the correctional clinic is performed pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.1(b)]

☐☐☐ 8.5 Medications dispensed to patients that are kept on the patient's person for use shall meet the labeling requirements of section 4076 and all record keeping requirements of chapter 9 division 2 of the Business and Professions Code. [BPC 4187.1(b)]

☐☐☐ 8.6 The correctional clinic keeps records of the kind and amounts of drugs acquired, administered, transferred, and dispensed. The records must be readily available and maintained for a minimum of three years for inspection by all properly authorized personnel. [BPC 4187.1(c)]

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

☐☐☐ 8.8 A separate license was obtained for each correctional clinic location where an APDS is located and is not to be transferrable. [BPC 4187.1(d)(2)]

☐☐☐ 8.9 The correctional clinic's location and address is identified by the correctional institution and building within the correctional institution. [BPC 4187.1(d)(3)]

☐☐☐ 8.10 The correctional clinic will notify the board in advance of any change in the clinic's address on a form furnished by the board. [BPC 4187.1(d)(4)]

☐☐☐ 8.11 The ADDS is secured from access and removal by unauthorized individuals. [BPC 4427.2(d)(2)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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B. POLICIES AND PROCEDURES

Yes No N/A

☐☐☐ 8.12 The policies and procedures to implement the laws and regulations of this article within the correctional clinic was developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5024.2 of the Penal Code. [BPC 4187.2(a)]

☐☐☐ 8.13 Prior to the issuance of the correctional clinic license by the board, an acknowledgment of the policies and procedures was signed by the correctional facility pharmacist-in-charge servicing the institution, the pharmacist-in-charge for the California Department of Correction and Rehabilitation's Central Fill Pharmacy, and the correctional clinic's chief medical executive, supervising dentist, chief nurse executive, and chief executive officer. [BPC 4187.2(a)]

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

☐☐☐ 8.15 The pharmacist-in-charge of the correctional facility shall implement the policies and procedures developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in section 5042.2 of the Penal Code and the statewide Inmate Medical Services Policies and Procedures in conjunction with the chief executive officer, the chief medical executive, the supervising dentist, and the chief nurse executive. [BPC 4187.2(b)(1)]

☐☐☐ 8.16 The licensed correctional clinic will notify the board within 30 days of any change in the chief executive officer on a form furnished by the board. [BPC 4187.2(b)(2)]

☐☐☐ 8.17 Schedule II, III, IV or V controlled substances may be administered by health care staff of the licensed correctional clinic lawfully authorized to administer pursuant to a chart order, as defined in section 4019, a valid prescription consistent with chapter 9 division 2 of the Business and Professions Code, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. [BPC 4187.3]

☐☐☐ 8.18 The ADDS located in a licensed correctional clinic has implemented the statewide Correctional Pharmacy and Therapeutics Committee's policies and procedures and the statewide Inmate Medical Services Policies and Procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of drugs. [BPC 4187.5(a)]

☐☐☐ 8.19 All policies and procedures are maintained either in an electronic form or paper form at the location where the automated drug system is being used. [BPC 4187.5(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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C. PHARMACIST RESPONSIBILITIES

Yes No N/A

☐☐☐ 8.20 A correctional facility pharmacist inspects the clinic at least quarterly. [BPC 4187.2(c)]

☐☐☐ 8.21 Drugs removed from the automated drug delivery system is removed upon authorization by a pharmacist after the pharmacist has reviewed the prescription and the patient profile for potential contraindications and adverse drug reactions. If the correctional pharmacy is closed, and if, the prescriber's professional judgment, a delay in therapy may cause patient harm, the medication may be removed from the automated drug delivery system and administered or furnished to the patient under the direction of the prescriber. Where the drug is otherwise unavailable, a medication may be removed and administered or furnished to the patient pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Any removal of the medication from an automated drug delivery system is documented and provided to the correctional pharmacy when it reopens. [BPC 4187.5(b)]

☐☐☐ 8.22 The review is conducted on a monthly basis by a pharmacist and shall include a physical inspection of the drugs in the automated drug delivery system, an inspection of the automated drug delivery system machine for cleanliness, and a review of all transaction records in order to verify the security and accountability of the system. [BPC 4187.5(e)]

Date of Last Review: _____

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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D. DEVICE REQUIREMENT

Yes No N/A

☐☐☐ 8.23 Drugs removed from the ADDS is provided to the patient by a health professional licensed pursuant to division 2 of the Business and Professions Code who is lawfully authorized to perform the task. [BPC 4187.5(c)]

☐☐☐ 8.24 The review of the drugs contained within, and the operation and maintenance of, the ADDS shall be the responsibility of the correctional clinic. [BPC 4187.5(e)]

☐☐☐ 8.25 The ADDS is operated by a licensed correctional pharmacy. Any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS. [BPC 4187.5(f)]

☐☐☐ 8.26 Drugs from the ADDS in the correctional clinic are removed by a person lawfully authorized to administer or dispense the drugs. [BPC 4187.5(g)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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E. RECORD KEEPING REQUIREMENTS

Yes No N/A

☐☐☐ 8.27 All records of manufacture and of sale, acquisition, receipt, shipment, or disposition of dangerous drugs or dangerous devices, at all times during business hours, are open for inspection by authorized officer of the law and is preserved for at least three years from the date of making. A current inventory is kept by the licensed correctional clinic. [BPC 4081(a)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

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SECTION 9: AUDS used for dispensing pursuant to BPC 4056 (Drug Room) or BPC 4068 (Hospital Pharmacy is closed and no pharmacist is available)

A. GENERAL REQUIREMENTS

Yes No N/A

☐☐☐ 9.1 The licensed drug room does not employ a full-time pharmacist and the AUDS is used for administration and dispensation by a physician to persons registered as inpatients of the hospital, to emergency cases under treatment in the hospital, or to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius by means of the method of transportation the patient states he/she intend to use. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply. [BPC 4056(a),(f)]

Yes No N/A

☐☐☐ 9.2 The prescriber in a hospital emergency room dispenses drug from the AUDS when the hospital pharmacy is closed and there is no pharmacist available in the hospital. The drugs is acquired by the hospital pharmacy. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens. The hospital pharmacy retains the dispensing information. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the prescriber reasonable believes that a pharmacy located outside the hospital is not available at the time of dispensing to the patients. The quantity dispensed is limited to the amount necessary to maintain uninterrupted therapy when pharmacy services outside the hospital are not readily available or accessible, and shall not exceed a 72-hour supply. [BPC 4068(a)(1)(2)(3)(4)(5)(6)]

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

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

☐☐☐ 9.5 The prescription drug is dispensed in a new and child-resistant container, or senior-adult ease-of-opening tested container, or in a non-complying package only pursuant to the request of the prescriber or patient. [15 USC 1473(b), 16 CFR 1700.15, CCR 1717]

☐☐☐ 9.6 The hospital pharmacy or drug room reports the dispensing information of a Schedule II, III or IV controlled substance to the Dept of Justice pursuant to HSC 11165 as soon as reasonably possible, but not more than seven days after the date a controlled substance is dispensed. [BPC 4069(a)(4), HSC 11165(d)]

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

☐☐☐ 9.8 The hospital has written policies and procedures to ensure each patient receive information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions. [BPC 4074(e)]

CORRECTIVE ACTION OR ACTION PLAN AND COMPLETION DATE_____

_____

_____

_____

_____

CERTIFICATION ACKNOWLEDGMENT

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____Date _____

CERTIFICATION OF COMPLETED ACTION PLAN

PHARMACIST-IN-CHARGE CERTIFICATION:

I, (please print)_____, RPH #_____ hereby certify that I have completed deficiencies identified in the self-assessment of this automated drug delivery system of which I am the pharmacist-in-charge. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information that I have provided in this self- assessment form is true and correct.

Signature _____Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OF ADDS:

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

Signature _____Date _____

Attachment 4

Regulation Timeline

VII. Discussion and Consideration of Board Adopted Regulations Undergoing Formal Review by the Department of Consumers Affairs or the Business, Consumer Services and Housing Agency

1. Proposed Permanent Regulation to Add Title 16 CCR Section 1747 Related to Independent HIV Preexposure and Postexposure Prophylaxis Furnishing

Timeline:
Approved by Board: January 29, 2020
Submitted to DCA for Pre-Notice Review: February 7, 2020
Submitted to Agency for Review: October 9, 2020
45-Day Comment Period: January 29, 2021 to March 15, 2021
Adopted by the Board: March 18, 2021
Submitted to DCA for Final Review: March 18, 2021

Independent HIV Preexposure and Postexposure Prophylaxis Furnishing
16 CCR § 1747 (Permanent)

Title 16. Board of Pharmacy
Proposed Text

Changes to the adopted emergency regulation text are as follows: underline for added text and ~~strikethrough~~ for deleted text.

Proposal to Add Section 1747 to Title 16 of the California Code of Regulations, to read as follows:

§ 1747. Independent HIV Preexposure and Postexposure Prophylaxis Furnishing.

(a) Prior to independently initiating and furnishing HIV preexposure and/or postexposure prophylaxis to a patient pursuant to Business and Professions Code sections 4052.02 and 4052.03, a pharmacist shall successfully complete a training program approved by the board, ~~or~~ provided by a provider accredited by an approved accreditation agency, or as part of an equivalent curriculum-based training program completed from a recognized school of pharmacy. The training program shall satisfy the following criteria:

(1) Each training program shall be specific to the use of HIV preexposure and postexposure prophylaxis, and include at least 1.5 hours of instruction covering, at a minimum, the following areas:
(A) HIV preexposure and postexposure prophylaxis pharmacology.
(B) Requirements for independently initiating and furnishing HIV preexposure and postexposure prophylaxis contained in Business and Professions Code sections 4052.02 and 4052.03.
(C) Patient counseling information and appropriate counseling techniques, including at least, counseling on sexually transmitted diseases and sexual health.
(D) Patient referral resources and supplemental resources for pharmacists.
(E) Financial assistance programs for preexposure and postexposure prophylaxis, including the Office of AIDS' PrEP Assistance Program (PrEP-AP).
(F) Clinical eligibility recommendations provided in the federal Centers for Disease Control and Prevention (CDC) guidelines defined in Business and Professions Code sections 4052.02(c) and 4052.03(c).

(2) The training program shall require the passing of an assessment based on the criteria of (a)(1) with a score of 70% or higher to receive documentation of successful completion of the training program.

(b) A pharmacist who independently initiates or furnishes HIV preexposure and/or postexposure prophylaxis pursuant to Business and Professions Code sections 4052.02 and 4052.03 shall maintain documentation of their successful completion of the training program for a period of four (4) years. Training obtained as part of an equivalent curriculum-based training program, as identified in (a), can be documented by written certification from the registrar or training

director of the educational institution or program from which the licensee graduated stating that the training is included within the institution's curriculum required for graduation at the time the pharmacist graduated, or within the coursework that was completed by the pharmacist. Documentation maintained pursuant to this subdivision must be made available upon request of the board.

Note: Authority cited: Sections 4005, 4052.02, and 4052.03, Business and Professions Code. Reference: Sections 4052, 4052.02, and 4052.03, Business and Professions Code; Section 120972, Health and Safety Code.

Attachment 5

Regulation Timeline

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

1. Proposed Regulations to Amend Title 16 CCR Section 1793.5 Related to the Pharmacy Technician Application, Section 1793.6 Related to the Pharmacy Technician Training Requirements and Section 1793.65 Related to the Pharmacy Technician Certification Programs

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: January 23, 2017
   Returned to the Board: March 28, 2017
   Re-submitted to DCA for Pre-Notice Review: August 21, 2017
   Returned to the Board: February 24, 2018
   Modified language approved by Board: March 27, 2018
   Re-submitted to DCA for Pre-Notice Review: July 11, 2018
   Returned to the Board: August 20, 2018
   Re-submitted to DCA for Pre-Notice Review: October 26, 2018
   Returned to the Board: December 13, 2019
   Re-submitted to DCA for Pre-Notice Review: July 10, 2020
   Returned to the Board: September 3, 2020
   Modified language approved by Board: March 18, 2021
   Returned to DCA for Pre-Notice Review: April 13, 2021

2. Proposed Regulations to Amend Title 16 CCR Section 1709 Related to Pharmacy Ownership, Management, and Control, Including Through Trusts

   Timeline:
   Approved by Board: October 26, 2016
   Submitted to DCA for Pre-Notice Review: January 26, 2017
   Returned to the board on: March 28, 2017
   Re-submitted to DCA for Pre-Notice Review: May 24, 2018
   Returned to the board: August 6, 2018
   Re-submitted to DCA for Pre-Notice Review: August 16, 2018
   Returned to the board: November 2, 2018
   Re-submitted to DCA for Pre-Notice Review: December 20, 2018
   Returned to the board: January 3, 2020
   Re-submitted to DCA for Pre-Notice Review: January 14, 2020
   Returned to the Board: April 22, 2020
   Re-submitted to DCA for Pre-Notice Review: October 21, 2020
   Returned to the Board: November 16, 2020
   Re-submitted to DCA for Pre-Notice Review: December 3, 2020
   Returned to the Board: March 2, 2021
   Re-submitted to DCA for Pre-Notice Review: April 16, 2021

3. Proposed Regulations to Amend Title 16 CCR Section 1715 to Update Self-Assessment Forms 17M-13 and 17M-14

   Timeline:
   Approved by Board: November 8, 2017
   Submitted to DCA for Pre-Notice Review: February 2, 2018
   Returned to the Board on: April 17, 2018
   Re-submitted to DCA for Pre-Notice Review: July 23, 2018
   Returned to the Board on: November 13, 2018
   Re-submitted to DCA for Pre-Notice Review: December 24, 2018
   Returned to the Board: November 23, 2020
   Re-submitted to DCA for Pre-Notice Review: January 6, 2021
   Returned to the Board: February 24, 2021
   Re-submitted to DCA for Pre-Notice Review: April 12, 2021

4. Proposed Regulations to Amend Title 16 CCR Section 1784 to Update the Wholesaler/3PL Self-Assessment Form 17M-26

   Timeline:
   Approved by Board: November 8, 2017
   Submitted to DCA for Pre-Notice Review: December 26, 2018
   Returned to the Board: October 6, 2020
   Re-submitted to DCA for Pre-Notice Review: January 6, 2021
   Returned to the Board: February 24, 2021
   Re-submitted to DCA for Pre-Notice Review: April 12, 2021

5. Proposed Regulation to Amend Title 16 CCR Section 1715.65 Related to Inventory Reconciliation

   Timeline:
   Approved by Board: January 29, 2020
   Submitted to DCA for Pre-Notice Review: May 11, 2020
   Submitted to DCA Budgets for Review: December 2, 2020
   Returned to the Board: February 23, 2021
   Re-submitted to DCA for Pre-Notice Review: April 14, 2021

6. Proposed Regulation to Amend Title 16 CCR Section 1715.6 Related to Drug Losses

   Timeline:
   Approved by Board: January 29, 2020
   Submitted to DCA for Pre-Notice Review: June 3, 2020
   Submitted to DCA Budgets for Review: October 27, 2020
   Returned to the Board: March 1, 2021
   Re-submitted to DCA for Pre-Notice Review: March 24, 2021

7. Proposed Regulation to Amend Title 16 CCR Section 1704 Related to Address Change Notification

   Timeline:
   Approved by Board: July 29, 2020
   Submitted to DCA for Pre-Notice Review: February 11, 2021

8. Proposed Regulation to Add Title 16 CCR Section 1708.1 Related to the Temporary Closure of Facilities

   Timeline:
   Approved by Board: July 29, 2020
   Submitted to DCA for Pre-Notice Review: February 11, 2021

Pharmacy Technician

16 CCR § 1793.5, 1793.6, and 1793.65

Title 16. Board of Pharmacy

Proposed Regulation Text

Changes to the adopted emergency regulation text are as follows: underline for added text and ~~strikethrough~~ for deleted text.

Amend §1793.5 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.5. Pharmacy Technician Application.

The "Pharmacy Technician Application" (Form 17A-5 (Rev. ~~1/2021~~ 2/2021)), incorporated by reference herein, required by this section is available from the Board of Pharmacy upon request.

(a) Each application for a pharmacy technician license shall include:

(1) Information sufficient to identify the applicant.
(2) A description of the applicant's qualifications and supporting documentation for those qualifications.
(3) A criminal background check that will require submission of fingerprints in a manner specified by the board and the fee authorized in Penal Code section 11105(e).
(4) A sealed, original Self-Query from the National Practitioner Data Bank (NPDB) dated no earlier than 60 days of the date an application is submitted to the board.

(b) The applicant shall sign the application under penalty of perjury and shall submit it to the Board of Pharmacy.

(c) The board shall notify the applicant within 30 days if an application is deficient; and what is needed to correct the deficiency. Once the application is complete, and upon completion of any investigation conducted pursuant to section 4207 of the Business and Professions Code, the board will notify the applicant within 60 days of a license decision.

(d) Before expiration of a pharmacy technician license, a pharmacy technician must renew that license by payment of the fee specified in subdivision (r) of section 4400 of the Business and Professions Code.

Note: Authority cited: Sections ~~163.5,~~ 114.5, 115.4, 115.5, 4005, ~~4007, 4038,~~ 4115, and 4202, ~~4207 and 4400,~~ Business and Professions Code. Reference: Sections 144, 144.5, 163.5, 4005, 4007, 4038, 4115, 4202, 4207, 4400 and 4402 ~~and 4400~~, Business and Professions Code; and Section 11105, Penal Code.

Amend §1793.6 of Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.6. Training Courses Specified by the Board.

A course of training that meets the requirements of Business and Professions Code section 4202(a)(2) is:

(a) Any pharmacy technician training program accredited by the American Society of Health-System Pharmacists,

(b) Any pharmacy technician training program provided by a branch of the federal armed services for which the applicant possesses a certificate of completion, or

(c)(1) Any other course that provides a training period of at least 240 hours of instruction covering at least the following:

(~~1~~A) Knowledge and understanding of different pharmacy practice settings.

(~~2~~B) Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to other pharmacy personnel and knowledge of standards and ethics, laws and regulations governing the practice of pharmacy.

(~~3~~C) Knowledge and ability to identify and employ pharmaceutical and medical terms, abbreviations and symbols commonly used in prescribing, dispensing and record keeping of medications.

(4D) Knowledge of and the ability to carry out calculations required for common dosage determination, employing both the metric and apothecary systems.

(~~5~~E) Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms and storage requirements.

(~~6~~F) Knowledge of and ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions.

(~~7~~G) Knowledge of and ability to perform procedures and techniques relating to manufacturing, packaging, and labeling of drug products.

(2) In addition to the content of coursework specified in subdivision (c)(1), the course of training must also satisfy all of the following:

(A) Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall conduct a criminal background check on the applicant that is consistent with the criminal background check required for a pharmacy technician license per Business and Professions Code section 4202(c). If the criminal background check reveals the applicant has committed acts that would constitute grounds for denial of licensure, the administrator or instructor shall counsel applicants about the negative impact to securing licensure.

(B) Prior to enrollment in any classes or admission into the course of training, an administrator or instructor shall inform applicants that the course of training includes practical training at a pharmacy which may require the applicant to undergo drug screening for illicit drug use. The administrator or instructor shall counsel applicants about the negative impact of a positive drug screen, including eligibility to continue the course of training and eligibility for licensure.

(C) Require students to be at least 18 years of age prior to enrolling in any course work involving practical training, such as an externship or any other training equivalent to pharmacy technician trainee placement as defined by Business and Professions Code section 4038, 4115, 4115, and 4115.5.

(D) Require a final examination that demonstrates students' understanding and ability to perform or apply each subject area identified in subdivision (1) above.

Authority cited: Sections 4005, ~~4007, 4038, 4115,~~ and 4202, Business and Professions Code. Reference: Sections 4005, 4007, 4038, 4115, 4115.5, and 4202, Business and Professions Code.

Add §1793.65 to Article 11 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1793.65 Pharmacy Technician Certification Programs Approved by the Board.

(a) Pursuant to Business and Professions Code section 4202(a)(4), the board approves the pharmacy technician certification program offered by:

(1) The Pharmacy Technician Certification Board, and
(2) The National Healthcareer Association.

(b) Approval of these programs is valid through December 31, 2024.

Note: Authority cited: Sections 4005 and 4202, Business and Professions Code. Reference: Sections 4038 and 4202, Business and Professions Code.

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

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

PHARMACY TECHNICIAN APPLICATION

Please read the application instructions before you complete the application. Failure to provide the requested information ~~will~~ may result in the application being considered incomplete. Attach additional sheets on paper if necessary.

TAPE A COLOR PASSPORT STYLE 2"X2" PHOTO TAKEN WITHIN 60 DAYS OF THE FILING OF THIS APPLICATION

NO POLAROID OR SCANNED IMAGES

PHOTO MUST BE ON PHOTO QUALITY PAPER

_____ **Military** (Are you currently serving in the United States military?)
_____ **Veteran** (Have you ever served in the United States military?)

MILITARY EXPEDITE (Please check one of the following, if applicable)

_____**Veteran** (Have you served as an active duty member of the United States military and been honorably discharged?)

_____**Active Duty Military Spouse or Domestic Partner** (Are you married to, or in a domestic partnership or other legal union with, an active duty member of the United States military who is assigned to a duty station in California under official active duty military orders and do you hold a current license in another state, district, or territory of the United States in the profession for which you seek licensure?)

REFUGEE EXPEDITE (Please check one of the following, if applicable)

_____ Refugee pursuant to section 1157 of title 8 of the United States Code;
_____ Refugee granted asylum by the Secretary of Homeland Security or the Attorney General of the United States pursuant to section 1158 of title 8 of the United States Code; or,
_____ Refugee with a special immigrant visa that has been granted a status pursuant to section 1244 of Public Law 110-181, Public Law 109-163, or section 602(b) of title VI of division F of Public Law 111-8.

Applicant Information - Please Type or Print

_____ _____ _____
Full Legal Name - Last Name First Name Middle Name

_____
Previous Names (AKA, Maiden Name, Alias, etc.)

_____
*Official Mailing/Public Address of Record (Street Address, PO Box #, etc.) City State Zip Code

_____
Residence Address (If different from above) Street City State Zip Code

_____ _____ _____
Home # Cell # Work #

_____ _____
Driver's License Number State Email Address

_____ _____
Date of Birth (Month/Day/Year) **US Social Security # or Individual Tax ID #

THIS SECTION IS FOR BOARD USE ONLY

App Fee: ___ Enf. Check: ___ Photo: ___ Qualify Code: ____ School Code: _____	FP Card/Fee: ___ LS: ___ DOJ Date__ FBI Date __	**Issuance**	**CASHIERING ONLY**	
		License #	*APPLICATION FEE*	
		Date Issued	Receipt #:	
		Date Expires	Date Cashiered:	
			Amount:	

Mandatory Education
Please indicate how you satisfy the education requirement in Business and Professions Code section 4202(a).

_____ High school graduate or foreign equivalent.
Attach an official embossed transcript or notarized copy of your high school transcript, or certificate of proficiency, or foreign secondary school diploma along with a certified translation of the diploma.

_____ Completed a general education development certificate equivalent.
Attach an official transcript of your test results or certificate of proficiency.

Pharmacy Technician Qualifying Method (check one box)
Please check one of the boxes below indicating how you qualify in order to apply for a pharmacy technician license pursuant to section 4202(a)(1)(2)(3)(4) of the Business and Professions Code.

_____ Attached Affidavit of Completed Coursework or Graduation for: Associate degree in Pharmacy Technology, Training Course, or Graduate of a school of pharmacy

_____ Attached is a ~~certified~~ copy of PTCB or ExCPT certificate ~~— Date certified: _____~~

_____ Attached is a ~~certified~~ copy of military training DD214

List all state(s) where you hold or held a license as a pharmacy technician, pharmacist, intern pharmacist, and/or ~~pharmacy technician and or~~ another health care professional license, including California. Attach an additional sheet if necessary.

State	Registration Number	Active or Inactive	Issued Date	Expiration Date
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

Self-Query Report by the National Practitioner Data Bank (NPDB)
_____ Attached is the original sealed envelope containing my Self-Query Report from NPDB. (This must be submitted with your application.)

~~**You must provide a written explanation for all affirmative answers indicated below. Failure to do so may result in this application being deemed incomplete and being withdrawn.**~~

~~**1.** Do you have a mental illness or physical illness that in any way impairs or limits your ability to practice your profession with reasonable skill and safety without exposing others to significant health or safety risks?~~
~~Yes _____ No_____ If "yes," attach a statement of explanation. If "no," proceed to #2.~~

~~Are the limitations caused by your mental illness or physical illness reduced or improved because you receive ongoing treatment or participate in a monitoring program?~~
~~Yes _____ No_____ If "yes," attach a statement of explanation.~~
~~If you do receive ongoing treatment or participate in a monitoring program, the board will make an individualized assessment of the nature, the severity and the duration of the risks associated with an ongoing mental illness or physical illness to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether you are not eligible for license.~~

~~**2.** Have you previously engaged in the illegal use of controlled substances?~~
~~Yes _____ No_____ If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you in order to assure that you are not engaging in the illegal use of controlled dangerous substances? Yes _____ No_____ If Yes, attach a statement of explanation.~~

~~**3.** Do you currently participate in a substance abuse program or have previously participated in a substance abuse program in the past five years?~~
~~Yes _____ No_____ If "yes," are you currently participating in a supervised substance abuse program or professional assistance program which monitors you to ensure you are maintaining sobriety?~~
~~Yes _____ No_____ Attach a statement of explanation.~~

~~**4.** Has disciplinary action ever been taken against your designated representative, pharmacist, intern pharmacist and/or pharmacy technician license in this state or any other state?~~
~~Yes _____ No_____ If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.~~

~~**5.** Have you ever had an application for a designated representative, pharmacist, intern pharmacist and/or pharmacy technician license denied in this state or any other state?~~
~~Yes _____ No_____ If "yes," attach a statement of explanation to include circumstances, type of action, date of action and type of license, registration or permit involved.~~

~~**6.** Have you ever had a pharmacy license, or any professional or vocational license or registration, denied, suspended, revoked, placed on probation or had other disciplinary action taken by this or any other government authority in California or any other state?~~
~~Yes _____ No_____ If "yes," provide the name of company, type of permit, type of action, year of action and state.~~

~~**7.** Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator or medical director on a permit to conduct a pharmacy, wholesaler, medical device retailer or any other entity licensed in this state or any other state?~~
~~Yes _____ No_____ If "yes," provide company name, type of permit, permit number and state where licensed.~~

APPLICANTS MUST ANSWER THE FOLLOWING QUESTIONS.

Ownership Information - For any affirmative answer, attach a statement of explanation including company name, type of license, license number, and identify the state, territory, foreign country, or other jurisdiction where licensed.

1. Are you currently or have you previously been listed as a corporate officer, partner, owner, manager, member, administrator, or medical director on a license to conduct a pharmacy, wholesaler, third-party logistics provider, or any other entity licensed in any state, territory, foreign country, or other jurisdiction?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #2.

Disciplinary History - The following questions pertain to a license sought or held in any state, territory, foreign country, or other jurisdiction. For any affirmative answer, attach a statement of explanation including type of license, license number, type of action, date of action, and identify the state, territory, foreign country, or other jurisdiction.

2. Have you ever had an application for pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration denied?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #3.

3. Have you ever had a pharmacy technician, intern pharmacist, pharmacist, any type of designated representative, and/or any other professional or vocational license or registration suspended, revoked, placed on probation, or had other disciplinary action taken against it?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #4.

4. Have you ever had a pharmacy, wholesaler, third-party logistics provider, and/or any other entity license denied, suspended, revoked, placed on probation, or had other disciplinary action taken?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #5.

Practice Impairment or Limitation

The board will make an individualized assessment of the nature, the severity, and the duration of the risks associated with any identified condition to determine whether an unrestricted license should be issued, whether conditions should be imposed, or whether the applicant is not qualified for licensure. If the board is unable to make a determination based on the information provided, the board may require an applicant to be examined by one or more physicians or psychologists, at the board's cost, to obtain an independent evaluation of whether the applicant is able to safely practice despite the mental illness or physical illness affecting competency. A copy of any independent evaluation would be provided to the applicant.

5. Have you ever been diagnosed with an emotional, mental, or behavioral disorder that may impair your ability to practice safely?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #6.

6. Have you ever been diagnosed with a physical condition that may impair your ability to practice safely?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #7.

7. Do you have any other condition that may in any way impair or limit your ability to practice safely?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #8.

8. Have you ever participated in, been enrolled in, or required to enter into any drug, alcohol, or other substance abuse recovery program?
   Yes No If "yes," attach a statement of explanation. If "no," proceed to #9.

9. If you answered "Yes" to questions 5 through 8 above, have you ever received treatment or participated in any program that improves your ability to practice safely?
   Yes No N/A If "yes," attach a statement of explanation.

APPLICANT AFFIDAVIT

Provide a written explanation for all affirmative answers. Failure to do so ~~will~~ may result in this application being deemed incomplete. Falsification of the information on this application may constitute ground for denial or revocation of the license.

All items of information requested in this application are mandatory. Failure to provide any of the requested information may result in the application being deemed as incomplete and a deficiency notice being issued. An applicant who fails to complete all application requirements within 60 days after being notified by the board of deficiencies in his or her file may be deemed to have abandoned the application and may be required to file a new application, fee (as required by 16 CCR section 1749), and meet all the requirements in effect at the time of reapplication.

Collection and Use of Personal Information. The California State Board of Pharmacy of the Department of Consumer Affairs collects the personal information requested on this form pursuant to ~~as authorized by~~ Business and Professions Code Sections 30 and 4400 and following and California Code of Regulations title 16, division 17.~~4200 and 4202 and Title 16 California Code of Regulations Section 1793.5 and 1793.6.~~ The California State Board of Pharmacy uses this information principally to identify and evaluate applicants for licensure, issue and renew licenses, and enforce licensing standards set by law and regulation.

~~**Mandatory Submission.** Submission of the requested information is mandatory. The California State Board of Pharmacy cannot consider your application for licensure or renewal unless you provide all of the requested information.~~

Access to Personal Information. You may review the records maintained by the California State Board of Pharmacy that contain your personal information, as permitted by the Information Practices Act. The official responsible for maintaining records is the Executive Officer at the board's address listed on the application. Each individual has the right to review the files or records maintained by the board, unless confidential and exempt by law. ~~Civil Code Section 1798.40.~~

Possible Disclosure of Personal Information. We make every effort to protect the personal information you provide us. The information you provide, however, may be disclosed in the following circumstances:

- In response to a Public Records Act request (Government Code Section 6250 and following), as allowed by the Information Practices Act (Civil Code Section 1798 and following);
- To another government agency as required or permitted by state or federal law; or
- In response to a court or administrative order, a subpoena, or a search warrant.

***Address of Record:** Once you are licensed with the board, the address of record you enter on this application is considered public information pursuant to the Information Practices Act (Civil Code section 1798 and following ~~et seq.~~) and the Public Records Act (Government Code Section 6250 and following ~~et seq.~~) and will be ~~placed~~ available on the Internet. This is where the board will mail all correspondence. If you do not wish your residence address to be available to the public, you may provide a post office box number or a personal mail box (PMB). However, if your address of record is not your residence address,

you must also provide your residence address to the board, in which case your residence will not be available to the public.

****Disclosure of your U.S. social security ~~account~~ number or individual taxpayer identification number is mandatory**. Section 30 of the Business and Professions Code, Section 17520 of the Family Code, and Public Law 94-455 (42 USC § 405(c)(2)(C)) authorize collection of your social security ~~account~~ number or individual taxpayer identification number. Your social security ~~account~~ number or individual taxpayer identification number will be used exclusively for tax enforcement purposes, for purposes of compliance with any judgment or order for child or family support in accordance with section 17520 of the Family Law Code, or for verification of license or examination status by a licensing or examination entity which utilizes a national examination and where licensure is reciprocal with the requesting state. If you fail to disclose your social security ~~account~~ number or individual taxpayer identification number, your application will not be processed and you may be reported to the Franchise Tax Board, which may assess a $100 penalty against you.

NOTICE: The State Board of Equalization and the Franchise Tax Board may share taxpayer information with the board. You are obligated to pay your state tax obligation. This application may be denied or your license may be suspended if your state tax obligation is not paid.

MANDATORY REPORTER

Under California law, each person licensed by the California State Board of Pharmacy is a "mandated reporter" for both child and elder abuse or neglect laws.~~purposes.~~ California Penal Code Section 11166 and Welfare and Institutions Code Section 15630 require that all mandated reporters make a report to an agency specified in Penal Code Section 11165.9 and Welfare and Institutions Code Section 15630(b)(1) [generally law enforcement, state and/or county adult protective services agencies, etc.] whenever the mandated reporter, in his or her professional capacity or within the scope of his or her employment, has knowledge of or observes a child, elder and/or dependent adult whom the mandated reporter knows or reasonably suspects has been the victim of child abuse or elder abuse or neglect. The mandated reporter must contact by telephone immediately or as soon as possible, to make a report to the appropriate agency(ies) or as soon as practicably possible. The mandated reporter must prepare and send a written report thereof within two working days or 36 hours of receiving the information concerning the incident.

Failure to comply with the requirements of ~~Section 11166 and Section 15630~~ the laws above is a misdemeanor, punishable by up to six months in a county jail, by a fine of one thousand dollars ($1,000), or by both that imprisonment and fine. For further details about these requirements, ~~consult~~ refer to Penal Code Section 11164 and Welfare and Institutions Code Section 15630, and ~~subsequent~~ following sections.

APPLICANT AFFIDAVIT

~~(must be signed and dated by the applicant)~~ Must be signed and dated by the applicant. Must be received by the Board within 60 days

I, _____ , hereby attest to the fact that I am the
(Print full Legal Name)

applicant whose signature appears below. I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of all statements, answers and representations made in this

application, including all supplementary statements. I understand that my application may be denied, or any license disciplined, for fraud or misrepresentation.

_____ _____

Original Signature of Applicant Date

(please sign and date within 60 days of board receipt of the application)

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

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

AFFIDAVIT OF COMPLETED COURSEWORK OR GRADUATION FOR PHARMACY TECHNICIAN

Instructions: The Director, Registrar, or Pharmacist must complete and sign this form certifying the identified individual has met the specified requirements in section 4202 of the Business and Professions Code and, if applicable, board regulations. ~~This form must be completed by the university, college, school, or pharmacist (The person who must complete this form will depend on how the applicant is qualifying).~~ All dates must include the month, day, and year ~~in order~~ for the form to be accepted.

This is to certify that _____ has
Print Full Name of Applicant

_____ Completed a pharmacy technician training program accredited by the American Society of Health-System Pharmacists (ASHP) as specified in Title 16, California Code of Regulations, Section 1793.6(a) on _____/_____/_____
(completion date must be included)

_____ Completed a training course that provided at least 240 hours of instruction as specified in Title 16, California Code of Regulations, Section 1793.6(c) on _____/_____/_____
(completion date must be included)

_____ Completed an Associate Degree in Pharmacy Technology and was conferred on ~~her/him on~~ _____/_____/_____
(graduation date must be included)

_____ Graduated from a school of pharmacy accredited or granted candidate status by the Accreditation Council for Pharmacy Education (ACPE). The degree of Bachelor of Science in Pharmacy or the degree of PharmD was conferred on _____/_____/_____
(graduation date must be included)

I hereby certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the above:
Signed _____ Title _____ Date_____

Name of Pharmacy Technician Training Program or School of Pharmacy _____
Address_____ Phone Number _____
Print Name of Director, Registrar, or Pharmacist _____
Email _____

Affix school seal here or Attach a business card of the pharmacist who provided the training pursuant to section 1793.6(c) of Title 16, California Code of Regulations here. The pharmacist's license number shall be listed.

Pharmacy Ownership, Management, and Control, Including Through Trusts
16 CCR § 1709

Title 16. Board of Pharmacy
Proposed Text

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

§1709. ~~Names of Owners and Pharmacist In Charge~~ Disclosure and Notification Requirements

(a) Each ~~permit~~ license issued by the board to operate a pharmacy shall reflect ~~show~~ the name and address of the pharmacy, the form of ownership ~~(individual, partnership or corporation)~~ and the pharmacist-in-charge. Each pharmacy shall, in its initial application and on the annual renewal form, report the name of the pharmacist-in-charge, the names of all owners and the names of the corporate officers (if a corporation). Any changes in the pharmacist-in-charge, or the owners, or corporate officers shall be reported to the ~~B~~board within 30 days.

(b) Any transfer, in a single transaction or in a series of transactions, of 10 percent or more of the beneficial interest in a business entity licensed by the board to a person or entity who did not hold a beneficial interest at the time the original ~~permit~~ license was issued, shall require written notification to the board within 30 days.

(c) A license issued by the board shall not be transferred from one owner to another. The following shall constitute a change of ownership ~~transfer of permit~~ and shall require a new application for ~~a change of ownership~~ licensure:

(1) any transfer of a beneficial interest in a business entity licensed by the board, in a single transaction or in a series of transactions, to any person or entity, which transfer results in the transferee's holding 50% or more of the beneficial interest in that license. A change of ownership application shall be filed with the board in advance of the proposed transaction taking place.

(d) If any beneficial interest of the pharmacy is held in trust, the applicant, licensee, or any person with management or control of the pharmacy, shall do the following:

(1) In addition to the requirements in subdivision (a), as part of their application and annual renewal, report the name of any other person in any position with management or control of the pharmacy.

(2) As part of the application, disclose the full name of the trust, and provide to the board a complete copy of, and any amendments to the trust document. A trust document and any related amendments shall be considered confidential financial documents by the board.

(3) As part of the renewal, provide to the board a complete copy of any amendments to the trust document made after submission of the original application.

(4) Include in the application and the annual renewal, the name, address and contact information for each grantor, settlor, trustee, and trust protector, as applicable.

(5) The application and annual renewal shall also include the name, address, and contact information for each named beneficiary of the trust, who is age 18 or older.

(6) Notify the board in writing within 30 days of all the following:

(A) A change in trustee, protector or any other person with management or control of the pharmacy.

(B) Any change in the beneficiaries of the trust, where the beneficiary is age 18 or older.

(C) The revocation of the trust.

(D) The dissolution of the trust.

(E) Any amendment to the trust since the original application.

(F) Any change in the character of the trust, including, but not limited to, the trust changing from revocable to irrevocable.

(e) An application may be denied, or a license may be suspended or revoked based on the failure of any individual required to be disclosed to the board to qualify pursuant to the provisions of sections 4302, 4307 and 4308 of the Business and Professions Code.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4035, 4058, 4110, 4111, 4112, 4113, 4120, ~~4124~~, ~~4130~~, ~~4133~~, ~~4141~~, ~~4149~~, ~~4160~~, ~~4161~~, ~~4196~~, 4201, 4302, ~~4304,~~ 4305, 4307, 4308, and 4330, Business and Professions Code.

Self-Assessment Forms
16 CCR § 1715
17M – 13
17M – 14

Title 16. Board of Pharmacy
Proposed Regulation

Proposal to amend §1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations to read as follows:

§ 1715. Self-Assessment of a Pharmacy by the Pharmacist-in-Charge.

(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. The assessment shall be performed before July 1 of every odd-numbered year. The 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 pharmacy permit has been issued, or

(2) There is a change in the pharmacist-in-charge, and he or she becomes the new pharmacist-in-charge of a pharmacy.

(3) There is a change in the licensed location of a pharmacy to a new address.

(c) A pharmacist-in-charge of a community pharmacy shall use ~~The~~ the components of this assessment ~~shall be~~ on Form 17M-13 (Rev. 10/~~14~~ 16) entitled "Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment." Form 17M-13 shall be used for all pharmacies serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall use the components of this assessment ~~and~~ on Form 17M-14 (Rev. 10/~~14~~ 16) entitled "Hospital Pharmacy Self-Assessment." ~~which are~~ Both forms are hereby incorporated by reference ~~to evaluate compliance with federal and state laws and regulations~~.

(1) The pharmacist-in-charge shall provide identifying information about the pharmacy including

(A) Name and license number of the pharmacy

(B) Address, phone number, and website address, if applicable, of the pharmacy

(C) DEA registration number, expiration date and date of most recent DEA inventory

(D) Hours of operation of the pharmacy

(2) The pharmacist-in-charge shall list the name of each licensed staff person working in the pharmacy, the person's license type and number, and the expiration date for each license.

(3) The pharmacist-in-charge shall respond "yes", "no" or "not applicable" (N/A) about whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting.

(4) For each "no" response, the pharmacist-in-charge shall provide a written corrective action or action plan to come into compliance with the law.

(5) The pharmacist-in-charge shall initial each page of the self-assessment form.

(6) The pharmacist-in-charge shall provide a certification on the final page of the self-assessment that affirms he or she has completed the self-assessment of the pharmacy of which he or she is the pharmacist-in-charge. The certification shall also provide a timeframe within which any deficiency identified within the self-assessment will be corrected and 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.

(7) The pharmacy owner or hospital administrator shall provide a certification on the final page of the self-assessment that affirms that he or she has read and reviewed the completed self-assessment and that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be completed in its entirety and kept on file in the pharmacy for three years after it is performed.

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

Note: Authority cited: Sections 4005 and 4127, Business and Professions Code. Reference: Sections 4019, 4021, 4022, 4029, 4030, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4081, 4101, 4105, 4110, 4113, 4115, 4119, 4120, 4127, 4201, 4301, 4305, 4330, 4332 and 4333, Business and Professions Code.

Self-Assessment Form
16 CCR § 1784
17M – 26

Proposal to Amend 16 CCR Amend § 1784

§ 1784. Self-Assessment of a Wholesaler/Third Party Logistics Provider by the Designated Representative-In- Charge or Responsible Manager.

(a) ~~The designated representative-in-charge of~~ Eeach wholesaler and third-party logistics provider, as defined under section 4160 of the Business and Professions Code, shall complete a self-assessment of ~~the wholesaler's~~ its compliance with federal and state pharmacy law. The assessment shall be performed by the designated representative-in-charge of the wholesaler, or by the responsible manager of the third-party logistics provider, 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 designated representative-in-charge or responsible manager shall complete a self-assessment within 30 days whenever:

(1) A new ~~wholesaler permit~~ license is issued, ~~or~~

(2) There is a change in the designated representative-in-charge or responsible manager. The new designated representative-in-charge of a wholesaler or responsible manager of a third-party logistics provider is responsible for compliance with this subdivision.

(3) There is a change in the licensed location of a wholesaler or third-party logistics provider to a new address.

(c) ~~The components of this assessment shall be on Form 17M-26 (Rev. 10/14) entitled "Wholesaler Dangerous Drugs & Dangerous Devices Self-Assessment" which is hereby incorporated by reference to evaluate compliance with federal and state laws and regulations~~. Each wholesaler and third-party logistics provider conducting business in California, through its designated representative-in-charge or responsible manager, shall complete "Wholesaler/Third Party Logistics Provider Self-Assessment," Form 17M-26 (Rev. 10/17) which is hereby incorporated by reference. The form shall include the information required by this section.

(1) The designated representative-in-charge or responsible manager shall provide identifying information about the wholesaler or third-party logistics provider including:

(A) Name and license number of the premises;

(B) Address, phone number, website address, if applicable, and type of ownership;

(C) DEA registration number and expiration date and date of most recent DEA; inventory;

(D) Verified-Accredited Wholesale Distributor accreditation number and expiration date, if applicable; and

(E) Hours of operation of the licensee.

(2) The designated representative-in-charge or responsible manager shall list the name of each Board-licensed staff person currently employed by the licensee in the facility at the time the self-assessment is completed, the person's license type and number, and the expiration date for each license.

(3) The designated representative-in-charge or responsible manager 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 representative-in-charge or responsible manager shall provide a corrective action or action plan to come into compliance with the law.

(5) The designated representative-in-charge or responsible manager shall initial each page of the self-assessment form.

(6) The designated representative-in-charge or responsible manager shall certify, under penalty of perjury, on the final page of the self-assessment that:

(A) He or she has completed the self-assessment of the licensed premises for which he or she is responsible;

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

(C) He or she understands that all responses are subject to verification by the Board of Pharmacy; and

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

(7) The licensed premises owner, partner or corporate officer shall certify on the final page of the self-assessment that he or she has read and reviewed the completed self-assessment and understands that failure to correct any deficiency identified in the self-assessment

could result in the revocation of the license issued by the board. This certification shall be made under penalty of perjury of the laws of the State of California.

(d) Each self-assessment shall be kept on file in the licensed ~~wholesale~~ premises for three years after it is completed.

(e) The wholesaler or third-party logistics provider is jointly responsible with the designated representative-in-charge or responsible manager, respectively, for compliance with this section.

(f) Any identified areas of noncompliance shall be corrected as specified in the certification.

Authority: Business and Professions Code §4005. Reference: Business and Professions Code §4022.5, §4043, §4053, §4044.5, §4045, §4059, §4120, §4160, §4161, §4201, §4301 and §4305.5.

Inventory Reconciliation

16 CCR § 1715.65

Title 16. Board of Pharmacy
Proposed Text

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

Amend Section 1715.65 to Title 16 of the California Code of Regulations, to read as follows:

§ 1715.65. Inventory Activities and Inventory Reconciliation Reports of Controlled Substances.

(a) Every pharmacy, and every clinic licensed under sections 4180 or 4190 of the Business and Professions Code, shall perform periodic inventory activities and prepare inventory reconciliation ~~functions~~ reports to detect and prevent the loss of federal controlled substances. Except as provided in subdivisions (f) and (g), inventory reconciliation reports shall be prepared on the following ongoing basis:
(1) For federal Schedule II controlled substances, at least once every three months.
(2) For products containing the following substances in the following strengths per tablet, capsule, other unit, or specified volume, at least once every 12 months:
(A) Alprazolam, 1 milligram/unit.
(B) Alprazolam, 2 milligrams/unit.
(C) Tramadol, 50 milligrams/unit.
(D) Promethazine/codeine, 6.25 milligrams of promethazine and 10 milligrams of codeine per 5 milliliters of product.
(3)(A) For any controlled substance not covered by paragraph (1) or (2), no later than three months after any loss of that controlled substance is discovered either by the inventory activities required by subparagraph (B), or in any other manner. The report shall cover the period from the last physical count of the controlled substance before the loss was discovered through the date of discovery.
(B) Inventory activities for each controlled substance not covered by paragraph (1) or (2) shall be performed at least once every two years from the performance of the last inventory activities. For purposes of this section, "inventory activities" means inventory and all other functions necessary to identify losses of the controlled substance.

(b) The pharmacist-in-charge of a pharmacy or ~~consultant~~ consulting pharmacist for a clinic shall review all inventory activities performed and inventory reconciliation reports ~~taken~~ prepared pursuant to this section, and establish and maintain secure methods to prevent losses of federal controlled ~~drugs~~ substances. Written policies and procedures shall be developed for performing the inventory activities and preparing the inventory reconciliation reports required by this section.

(c) ~~A pharmacy or clinic shall compile an~~ An inventory reconciliation report ~~of all federal Schedule II controlled substances at least every three months. This compilation~~ prepared pursuant to this section shall ~~require~~ include all of the following:

(1) A physical count, not an estimate, of all quantities of ~~federal Schedule II~~ each federal controlled ~~substances~~ substance covered by the report that the pharmacy or clinic has in inventory, except as provided in subdivision (h). The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section. An individual who performs the inventory required by this paragraph shall sign and date the inventory or the report in which it is included as provided in subdivision (e)(1);

(2) A review of all acquisitions and dispositions of each federal ~~Schedule II~~ controlled ~~substances~~ substance covered by the report since the last inventory reconciliation report covering that controlled substance;

(3) A comparison of (1) and (2) to determine if there are any variances;

(4) ~~All~~ Identification of all records used to compile ~~each inventory reconciliation~~ the report, which shall be maintained in the pharmacy or clinic ~~for at least three years in a readily retrievable form~~ pursuant to subdivision (e)(2); ~~and~~

(5) Identification of each individual involved in preparing the report; and

~~(5)~~ (6) Possible causes of overages ~~shall be identified in writing and incorporated into the inventory reconciliation report~~.

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

(e)(1) ~~The~~ An inventory reconciliation report shall be dated and signed by ~~the individual(s) performing the inventory, and countersigned by~~ the pharmacist-in-charge or professional director (if a clinic) ~~and~~, in addition to any signature required by subdivision (c)(1). An individual may use a digital or electronic signature or biometric identifier in lieu of a physical signature under this section if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file pursuant to paragraph (2).

(2) The report, and all records used to compile the report, shall be readily retrievable in the pharmacy or clinic for three years. ~~A countersignature is not required if the pharmacist-in-charge or professional director personally completed the inventory reconciliation report.~~

(f) A new pharmacist-in-charge of a pharmacy shall complete an inventory reconciliation report ~~as identified in subdivision (c)~~ for all federal controlled substances described in paragraphs (1) and (2) of subdivision (a) within 30 days of becoming pharmacist-in-charge. Whenever possible an outgoing pharmacist-in-charge should also complete an inventory reconciliation report ~~as required in subdivision (c)~~ for those controlled substances.

(g) ~~For~~ Notwithstanding the periodic reporting requirements specified in paragraphs (1) and (2) of subdivision (a), inpatient hospital pharmacies~~,~~ shall prepare an inventory reconciliation

report or reports covering the federal controlled substances described in paragraphs (1) and (2) of subdivision (a) on a ~~separate~~ quarterly ~~inventory reconciliation report shall be required for federal Schedule II~~ basis. The report or reports shall include controlled substances stored within the pharmacy ~~and for~~, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control.

(h) ~~The pharmacist in charge of~~ If an inpatient hospital pharmacy ~~or of a pharmacy servicing onsite or offsite~~ uses an automated drug delivery ~~systems~~ system (ADDS), inventory in the ADDS may be accounted for under subdivision (c)(1) using means other than a physical count. ~~shall ensure that:~~

~~(1) All controlled substances added to an automated drug delivery system are accounted for;~~

~~(2) Access to automated drug delivery systems is limited to authorized facility personnel;~~

~~(3) An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and~~

~~(4) Confirmed losses of controlled substances are reported to the board.~~

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4008, 4037, 4080, 4081, 4101, 4104, 4105, 4105.5, 4110, 4113, 4119.1, 4180, 4181, 4182, 4186, 4190, 4191, 4192 and 4332, Business and Professions Code; and Section 1261.6, Health and Safety Code.

Drug Losses
16 CCR § 1715.6

§ 1715.6. Reporting Drug Loss.

(a) The owner shall submit ~~report~~ to the Board a report containing the information in subdivision (b) ~~within~~ no later than thirty (30) days after the date of discovery of the following:

(1) ~~any~~ Any loss of ~~the~~ a controlled substance~~s, including their~~ in one of the following categories that causes the aggregate amount of unreported losses discovered in that category on or after the same day of the previous year to equal or exceed:

(A) For tablets, capsules, or other oral medication, 99 dosage units.

(B) For single-dose injectable medications, lozenges, film, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers.

(2) Any loss of a controlled substance, regardless of the amount, attributed to employee theft.

(3) Any other ~~substantial~~ significant loss as determined by the pharmacist-in-charge.

(b) All reports under this section shall specify the identity, amount~~s~~ and strength~~s~~ of each controlled substance lost, and date of discovery of the loss, for all losses that have made the report necessary.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4081 and 4332, Business and Professions Code.

Address Change Notification
16 CCR § 1704

Title 16. Board of Pharmacy
Proposed Text

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

Amend Section 1704 to Title 16 of the California Code of Regulations, to read as follows:

§ 1704. ~~Change of~~ Providing Addresses.

(a) Each person holding a certificate, license, permit, registration or exemption to practice or engage in any activity in the State of California under any and all laws administered by the Board shall file a proper and current residence address with the Board at its office in Sacramento and shall within 30 days notify the Board at its said office of any and all changes of residence address, giving both the old and new address.

(b) Each applicant and person holding a certificate, license, permit, or registration who has an electronic mail address shall provide to the Board that electronic mail address and shall maintain a current electronic mail address, if any, with the Board.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Sections 4003 and 4100, Business and Professions Code.

Temporary Closure of Facilities 16 CCR § 1708.1

Title 16. Board of Pharmacy
Proposed Text

Add Section 1708.1 to Title 16 of the California Code of Regulations, to read as follows:

§ 1708.1. Notification of Temporary Closure.

A permit holder shall notify the board of any temporary closure of a facility as soon as any closure exceeds three consecutive calendar days. Closure dates will be public information.

Note: Authority cited: Section 4005, Business and Professions Code. Reference: Section 4312, Business and Professions Code.

Attachment 6

Regulation Timeline

IX. Discussion and Consideration of Board Approved Text to Initiate Rulemaking – Staff Drafting Documents for Pre-Notice Review by the Department of Consumer Affairs and the Business, Consumer Services and Housing Agency

1. Proposed Regulation to Amend Title 16 CCR Section 1735.2 to Update the Compounding Self-Assessment Form 17M-39

   Timeline:
   Approved by Board: January 28, 2021

Self-Assessment Form
16 CCR § 1735.2
17M – 39

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

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

Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment

The California Code of Regulations section 1735.2 requires the pharmacist-in-charge of each pharmacy licensed under section 4037 or 4029 of the Business and Professions Code that compounds drug preparations to complete a self-assessment of the pharmacy's compliance with federal and state pharmacy law. **The assessment shall be performed before July 1 of every odd-numbered year. The pharmacist-in-charge must also complete a self-assessment within 30 days whenever; (1) a new pharmacy permit has been issued, or (2) there is a change in the pharmacist-in-charge; or (3) there is a change in the licensed location of the pharmacy. The primary purpose of the self-assessment is to promote compliance through self-examination and education.**

The self-assessment must be completed in its entirety and may be completed online, printed, readily retrievable and retained in the pharmacy. Do not copy a previous assessment.

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

Pharmacy Name: _____

Address: _____ Phone: _____

Fax: _____

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

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

Licensed Sterile Compounding License # _____ Expiration: _____

Accredited by: _____ From: _____ To: _____

Centralized Hospital Packaging License #: _____ Exp. Date: _____

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

PIC: _____ RPH # _____ Exp. Date: _____

Website address (optional): _____

_____
PIC Initials

Pharmacy Staff (pharmacists, intern pharmacists, pharmacy technicians assigned to compounding duties):
(Please use an additional sheet if necessary)

1. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
2. _____ RPH # _____ Exp. Date: _____
   APP # _____ Exp. Date: _____
3. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
4. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
5. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
6. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
7. _____ RPH # _____ Exp. Date: _____
   APH # _____ Exp. Date: _____
8. _____ INT # _____ Exp. Date: _____
9. _____ INT # _____ Exp. Date: _____
10. _____ INT # _____ Exp. Date: _____
11. _____ TCH # _____ Exp. Date: _____
12. _____ TCH # _____ Exp. Date: _____
13. _____ TCH # _____ Exp. Date: _____
14. _____ TCH # _____ Exp. Date: _____
15. _____ TCH # _____ Exp. Date: _____

_____
PIC Initials

COMPOUNDING SELF-ASSESSMENT

All references to the California Code of Regulations (CCR) are to Title 16 unless otherwise noted. Please mark the appropriate box for each question. If "NO", enter an explanation on "CORRECTIVE ACTION OR ACTION PLAN" lines at the end of the section. If more space is needed, you may add additional sheets.

ALL COMPOUNDING Complete Sections 1 through 10.

1. Definitions (CCR 1735 and 1735.1)

Yes No N/A

☐☐☐ 1.1 The pharmacy compounds as defined in CCR 1735(a).

☐☐☐ 1.2 Each pharmacist involved with compounding understands the definitions in CCR 1735.1.

2. Compounding Limitations and Requirements (CCR 1735.2)

Yes No N/A

☐☐☐ 2.1 The pharmacy does not compound drug preparations prior to receipt of a valid prescription unless under the following conditions as allowed in CCR 1735.2 (b-c) (CCR 1735.2(a)). See sections 2.2 and 2.3

☐☐☐ 2.2 The pharmacy prepares and stores a limited quantity of a compounded drug preparation in advance of receipt of a patient specific prescription solely in such quantity as is necessary to ensure continuity of care of an identified population as defined in CCR 1735.2(b).

☐☐☐ 2.3 The pharmacy compounds a reasonable quantity of drug preparation which is furnished to a prescriber for office use upon prescriber order as allowed in CCR 1735.2(c) and under all of the following requirements:

- 2.3.1 Is ordered by the prescriber or the prescribers' agent on a purchase order or other documentation received by the pharmacy prior to furnishing that lists the number of patients seen or to be seen in the prescriber's office for whom the drug is needed or anticipated, and the quantity for each patient sufficient for office administration; (CCR 1735.2[c][1]) **AND**
- 2.3.2 Is delivered to the prescriber's office and signed for by the prescriber or the prescriber's agent; (CCR 1735.2[c][2]) **AND**
- 2.3.3 Is sufficient for administration or application to patients in the prescriber's office or for distribution of not more than a 120-hour supply for veterinary medical practices; (CCR 1735.2[c][3]) **AND**
- 2.3.4 The pharmacist has a credible basis for concluding it is a reasonable quantity for office use considering the intended use of the compounded preparation and the nature of the prescriber's practice; (CCR 1735.2[c][4]) **AND**
- 2.3.5 Is an amount which the pharmacy is capable of compounding in compliance with pharmaceutical standards for integrity, potency, quality and strength of the compounded drug preparation; (CCR 1735.2[c][5]) **AND**
- 2.3.6 Does not exceed an amount the pharmacy can reasonably and safely compound. (CCR 1735.2[c][6])

☐☐☐ 2.4. The pharmacy does NOT compound drug preparations that: (CCR 1735.2[d])

- 2.4.1 Are classified by the FDA as demonstrably difficult to compound; (CCR 1735.2[d][1])

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2.4.2 Appear on an FDA list of drugs that have been withdrawn or removed from the market; (CCR 1735.2[d][2]) or

2.4.3 Are copies or essentially copies of one or more commercially available drug products. (CCR 1735.2[d][3])

Yes No N/A

☐☐☐ 2.5 The pharmacy does not compound drug preparations until it has prepared a written master formula document that includes the following elements: (CCR 1735.2[e][1-8])

- 2.5.1 Active ingredients used.
- 2.5.2 Equipment to be used.
- 2.5.3 Beyond use date (BUD).
- 2.5.4 Inactive ingredients used.
- 2.5.5 Specific and essential compounding steps.
- 2.5.6 Quality reviews required at each step.
- 2.5.7 Post-compounding process or procedures, if required.
- 2.5.8 Instructions for storage and handling.

☐☐☐ 2.6 The master formula for a drug preparation not routinely compounded by the pharmacy may be recorded on the prescription document itself. (CCR 1735.2[f])

☐☐☐ 2.7 The pharmacists performing or supervising compounding understand they are responsible for the integrity, potency, quality, and labeled strength of a compounded drug preparation until the beyond use date indicated on the label, so long as label instructions for storage and handling are followed after the preparation is dispensed. (CCR 1735.2[g])

☐☐☐ 2.8 All chemicals, bulk drug substances, drug preparations and other components used for drug compounding are stored and used according to compendia and other applicable requirements to maintain their integrity, potency, quality and labeled strength. (CCR 1735.2[h])

☐☐☐ 2.9 Every compounded drug preparation is given a beyond use date representing the date or date and time beyond which the compounded drug preparation should not be used, stored, transported or administered, and is determined based on the professional judgment of the pharmacist performing or supervising the compounding. (CCR 1735.2[i])

2.9.1 For non-sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][1][A-F])

- 2.9.1.1 The shortest expiration date or beyond use date of any ingredient in the compounded drug preparation,
- 2.9.1.2 The chemical stability of any one ingredient in the compounded drug preparation;
- 2.9.1.3 The chemical stability of the combination of all ingredients in the compounded drug preparation,
- 2.9.1.4 for non-aqueous formulations, 180 days or an extended date established by the pharmacist's research, analysis, and documentation,
- 2.9.1.5 for water-containing oral formulations, 14 days or an extended date established by the pharmacist's research, analysis, and documentation, and
- 2.9.1.6 for water-containing topical/dermal and mucosal liquid and semisolid formulations, 30 days or an extended date established by the pharmacist's research, analysis, and documentation.
- 2.9.1.7 The pharmacist, using his or her professional judgment establishes an extended date as provided in (D), (E), and (F), if the pharmacist researched(s) by consulting and applying drug-specific and general stability documentation and literature; analyzes such documentation and literature as well as the other factors set forth in this subdivision, and maintains documentation of the research, analysis and conclusion. The factors pharmacist analyzed included: i) the nature of the drug and its degradation mechanism, (ii) the dosage form and its components, (iii) the potential for microbial proliferation in the preparation, (iv)the container in which it is packaged, (v) the expected storage conditions,

and (vi) the intended duration of therapy. Documentation of the pharmacist's research and analysis supporting an extension must be maintained in a readily retrievable format as part of the master formula.

2.9.2 For sterile compounded drug preparations, the beyond use date does not exceed any of the following: (CCR 1735.2[i][2][A-D])

2.9.2.1 The shortest expiration date or beyond use date of any ingredient in the sterile compounded drug preparation,

2.9.2.2 The chemical stability of any one ingredient in the sterile compounded drug preparation,

2.9.2.3 The chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and

2.9.2.4 The beyond use date assigned for sterility in CCR 1751.8.

2.9.3 For sterile compounded drug preparations, extension of a beyond use date is supported by the following: (CCR 1735.2[i][3][A-C])

2.9.3.1 Method Suitability Test,

2.9.3.2 Container Closure Integrity Test, and

2.9.3.3 Stability Studies.

2.9.4 The finished drugs or compounded drug preparations tested and studied are compounded using the same identical components or ingredients, specific and essential compounding steps, quality reviews, and packaging as the finished drug or compounded drug preparation. (CCR 1735.2[i][4])

2.9.5 Shorter dating is used if it is deemed appropriate in the professional judgment of the responsible pharmacist. (CCR 1735.2[i][5])

☐☐☐ 2.10 The pharmacist performing, or supervising compounding is responsible for the proper preparation, labeling, storage, and delivery of the compounded drug preparation. (CCR 1735.2[j])

☐☐☐ 2.11 Self-assessment is completed, as required, prior to compounding a drug preparation. (CCR 1735.2[k])

☐☐☐ 2.12 Packages of ingredients, both active and inactive, which lack a supplier's expiration date are subject to the following limitations: (CCR 1735.2[l])

2.12.1 Ingredients are not used for any non-sterile compounded drug preparation more than three (3) years after the date of receipt by the pharmacy.

2.12.2 Ingredients are not used for any sterile compounded drug preparation more than one (1) year after the date of receipt by the pharmacy.

CORRECTIVE ACTION OR ACTION PLAN: _____

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3. Recordkeeping for Compounded Drug Preparation (CCR 1735.3)

Yes No N/A

☐☐☐ 3.1 The pharmacy makes and retains a record for each compounded drug preparation which includes, at least, the following: (CCR 1735.3[a][1-2])

3.1.1 The master formula document.

3.1.2 A compounding log consisting of a single document containing all of the following:

3.1.2.1 The name and strength of the compounded drug preparation.

3.1.2.2 The date the drug preparation was compounded.

3.1.2.3 The identity of the pharmacy personnel who compounded the drug preparation.

3.1.2.4 The identity of the pharmacist reviewing the final drug preparation.

3.1.2.5 The quantity of each component used in compounding the drug preparation.

3.1.2.6 The manufacturer or supplier, expiration date and lot number of each component.

3.1.2.7 The pharmacy assigned reference or lot number for the compounded drug preparation.

3.1.2.8 The beyond use date or beyond use date and time of the final compounded drug preparation.
3.1.2.9 The final quantity or amount of drug preparation compounded.
3.1.2.10 Documentation of quality reviews and required post-compounding process and procedures.

☐☐☐ 3.2 The pharmacy maintains records of the proper acquisition, storage, and destruction of chemicals, bulk drug substances, components and drug preparations used in compounding. (CCR 1735.3[b])

☐☐☐ 3.3 Active ingredients are obtained from a supplier registered with the Food and Drug Administration (FDA). All other chemicals, bulk drug substances, and drug components used to compound drug preparations are to be obtained, whenever possible, from FDA-registered suppliers. The pharmacy acquires and retains certificates of purity or analysis, either written in English or translated into English, for chemicals, bulk drug substances, and drug products used in compounding. (CCR 1735.3[c])

☐☐☐ 3.5 The pharmacy maintains and retains all records required in the pharmacy in a readily retrievable form for at least three years (CCR 1735.3[d]).

4. Labeling of Compounded Drug Preparation (CCR 1735.4)

Yes No N/A

☐☐☐ 4.1 Each compounded drug preparation has at least the following affixed to the container on a label prior to dispensing: (CCR 1735.4[a][1-6])
- 4.1.1 Name of the compounding pharmacy and dispensing pharmacy (if different);
- 4.1.2 Name (brand or generic) and strength, volume, or weight of each active ingredient. For admixed intravenous (IV) solutions, the IV solution utilized shall be included;
- 4.1.3 Instructions for storage, handling, and administration. For admixed IV solutions, the rate of infusion shall be included;
- 4.1.4 The beyond use date for the drug preparation;
- 4.1.5 The date compounded; and
- 4.1.6 The lot number or pharmacy reference number.

☐☐☐ 4.2 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient is labeled with the information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, section 1707.5. (CCR 1735.4[b])

☐☐☐ 4.3 Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient also includes, on the container label or on a receipt provided to the patient, a statement the drug preparation has been compounded by the pharmacy. (CCR 1735.4[c])

☐☐☐ 4.4 Drug preparations compounded into unit-dose containers that are too small or otherwise impractical for full compliance with the requirements of CCR 1735.4(a), (b), and (c) are labeled with at least the name(s) of the active ingredient(s), concentration of strength, volume or weight, pharmacy reference or lot number, and beyond use date. (CCR 1735.4[d])

☐☐☐ 4.5 All hazardous agents bear a special label which states “Chemotherapy - Dispose of Properly” or “Hazardous – Dispose of Properly. (CCR 1735.4[e])

CORRECTIVE ACTION OR ACTION PLAN: _____

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5. Compounding Policies and Procedures (CCR 1735.5)

Yes No N/A

☐☐☐ 5.1 The pharmacy maintains written policies and procedure for compounding which establish procurement procedures, methodologies for the formulation and compounding of drugs, facilities and equipment cleaning, maintenance, operation, and other standard operating procedures related to compounding. (CCR 1735.5[a])

☐☐☐ 5.2 The policy and procedures are reviewed on an annual basis by the pharmacist-in-charge and are updated whenever changes are implemented. (CCR 1735.5[b])

☐☐☐ 5.3 The policies and procedures include at least the following: (CCR 1735.5[c][1-11])

- 5.3.1 Procedures for notifying staff assigned to compounding duties of any changes in policies or procedures.
- 5.3.2 A written plan for recall of a dispensed compounded drug preparation where subsequent information demonstrates the potential for adverse effects with continued use. The plan ensures all affected doses can be accounted for during the recall and shall provide steps to identify which patients received the affected lot or compounded drug preparation(s).
- 5.3.3 Procedures for maintaining, storing, calibrating, cleaning, and disinfecting equipment used in compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- 5.3.4 Procedures for evaluating, maintaining, certifying, cleaning, and disinfecting the facility (physical plant) used for compounding, and for training on these procedures as part of the staff training and competency evaluation process.
- 5.3.5 Documentation of the methodology used to validate integrity, potency, quality, and labeled strength of compounded drug preparations. The methodology must be appropriate to compounded drug preparations.
- 5.3.6 Documentation of the methodology and rationale or reference source used to determine appropriate beyond use dates for compounded drug preparations.
- 5.3.7 Dates and signatures reflecting all annual reviews of the policies and procedures by the pharmacist-in-charge.
- 5.3.8 Dates and signatures accompanying any revisions to the policies and procedures approved by the pharmacist-in-charge.
- 5.3.9 Policies and procedures for storage of compounded drug preparations in the pharmacy and daily documentation of all room, refrigerator, and freezer temperatures within the pharmacy.
- 5.3.10 Policies and procedures for ensuring appropriate functioning of refrigeration devices, monitoring refrigeration device temperatures, and actions to take regarding any out of range temperature variations within the pharmacy.
- 5.3.11 Policies and procedures for proper garbing when compounding with hazardous products; including when to utilize double shoe covers.

CORRECTIVE ACTION OR ACTION PLAN: _____

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6. Compounding Facilities and Equipment (CCR 1735.6)

Yes No N/A

☐☐☐ 6.1 The pharmacy maintains written documentation regarding the facilities and equipment necessary for safe and accurate compounding of compounded drug preparations which includes records of certification of facilities or equipment, if applicable. (CCR 1735.6[a])

☐☐☐ 6.2 All equipment used to compound a drug preparation is stored, used and maintained in accordance with manufacturers' specifications. (CCR 1735.6[b])

☐☐☐ 6.3 All equipment used to compound a drug preparation is calibrated prior to use to ensure accuracy. (CCR 1735.6[c])

6.3.1 Documentation of each calibration is recorded in a form which is not alterable and is maintained and retained in the pharmacy.

☐☐☐ 6.4 When engaged in hazardous drug compounding, the pharmacy maintains written documentation regarding appropriate cleaning of facilities and equipment to prevent cross-contamination with non-hazardous drugs. (CCR 1735.6[d])

☐☐☐ 6.5 Hazardous drug compounding is completed in an externally exhausted physically separate room with the following requirements: (CCR 1735.6[e])

6.5.1 Minimum of 30 air changes per hour except that 12 air changes per hour are acceptable for segregated compounding areas with a BSC or CACI when preparations are assigned a BUD of 12 hours or less or when nonsterile products are compounded; and

6.5.2 Maintained at a negative pressure of 0.01 to 0.03 inches of water column relative to all adjacent spaces (rooms, above ceiling, and corridors); and

6.5.3 For sterile compounding, each PEC BSC or CACI in the room shall also be externally exhausted.

6.5.3 For nonsterile compounding, a BSC, a CACI, or other containment ventilated enclosure shall be used and shall either use a redundant-HEPA filter in series or be externally exhausted,

6.5.4 All surfaces within the room are smooth, seamless, impervious, and non-shedding.

CORRECTIVE ACTION OR ACTION PLAN:

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7. Training of Compounding Staff (CCR 1735.7)

Yes No N/A

☐☐☐ 7.1 The pharmacy maintains documentation demonstrating personnel involved in compounding have the skills and training required to properly and accurately perform their assigned responsibilities and documentation demonstrating all personnel involved in compounding are trained in all aspects of policies and procedures. This training includes, but is not limited to, support personnel (e.g. institutional environmental services, housekeeping), maintenance staff, supervising pharmacists and all others whose jobs are related to the compounding process. (CCR 1735.7[a])

☐☐☐ 7.2 The pharmacy has developed and maintains an ongoing competency evaluation process for pharmacy personnel involved in compounding and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel. (CCR 1735.7[b])

☐☐☐ 7.3 Pharmacy personnel assigned to compounding duties demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug preparation. (CCR 1735.7[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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8. Compounding Quality Assurance (CCR 1735.8)

Yes No N/A

☐☐☐ 8.1 The pharmacy maintains, as part of its written policies and procedures, a written quality assurance plan to monitor and ensure the integrity, potency, quality and labeled strength of compounded drug preparation. (CCR 1735.8[a])

☐☐☐ 8.2 The pharmacy's quality assurance plan includes the written procedures and standards for at least the following:

- 8.2.1 Verification, monitoring and review of the adequacy of the compounding processes as well as documentation of review of those processes by qualified pharmacy personnel. (CCR 1735.8[b])
- 8.2.2 Qualitative and quantitative analysis of compounded drug preparations to ensure integrity, potency, quality and labeled strength, including the frequency of testing. Frequency of routine testing and analysis is done on an annual basis. (CCR 1735.8[c])
- 8.2.3 Such reports are retained by the pharmacy and collated with the compounding record and master formula document. (CCR 1735.8[c])
- 8.2.4 Scheduled action in the event any compounded drug preparation is ever discovered to be below minimum standards for integrity, potency, quality or labeled strength. (CCR 1735.8[d])
- 8.2.5 Response to out-of-range temperature variations within the pharmacy and within patient care areas of a hospital where furnished drug is returned for redispensing. (CCR 1735.8[e])

9. Compounding Consistent with United States Pharmacopeia – National Formulary (B&PC 4126.8)

☐☐☐ 9.1 The compounding of drug preparation is consistent with standards established in the pharmacy compounding chapters of the current version of the United States Pharmacopeia-National Formulary, including relevant testing and quality assurance.

10. Duties of a Pharmacy Issuing a Compounded Drug Recall (B&PC 4126.9)

Yes No N/A

☐☐☐ 10.1 When the pharmacy issues a recall notice regarding a nonsterile compounded drug product, in addition to any other duties all of the following take place, contact the recipient pharmacy, prescriber, or patient of the recalled drug and the board within 12 hours of the recall notice if both of the following apply: (B&PC 4126.9[a][1-2])

- 10.1.1 Use of or exposure to the recalled drug may cause serious adverse health consequences or death.
- 10.1.2 The recalled drug was dispensed, or is intended for use, in this state.

☐☐☐ 10.2 A recall notice issued pursuant to subdivision (a) is made as follows: (B&PC 4126.9[b][1-3])

- 10.2.1 If the recalled drug was dispensed directly to the patient, the notice is be made to the patient.
- 10.2.2 If the recalled drug was dispensed directly to the prescriber, the notice is be made to the prescriber, who shall ensure the patient is notified.
- 10.2.3 If the recalled drug was dispensed directly to a pharmacy, the notice is be made to the pharmacy, which shall notify the prescriber or patient, as appropriate. If the pharmacy notifies the prescriber, the prescriber ensures the patient is notified.

☐☐☐ 10.3 If the pharmacy has been advised that a patient has been harmed by using a nonsterile compounded product potentially attributable to the pharmacy reports the event to MedWatch within 72 hours of the pharmacy being advised. (B&PC 4126.9[c])

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COMPOUNDING STERILE DRUGS

Does the pharmacy compound sterile drug preparation? (B&PC 4127)

☐ **Yes** ☐ **No**

If yes, complete Sections 11 through 27.

FOR PHARMACIES THAT COMPOUND STERILE DRUG preparation:

11. Compounding Drug for Other Pharmacy for Parenteral Therapy

Yes No N/A

☐☐☐ 11.1 Any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report that contractual arrangement to the board. (B&PC 4123)

11.1.1 The contractual arrangement is reported to the board within 30 days of commencing that compounding.

12. Sterile Compounding; Compounding Area (CCR 1751)

Yes No N/A

☐☐☐ 12.1 The pharmacy conforms to the parameters and requirements stated by Article 4.5 (Section 1735 et seq.), applicable to all compounding, and shall also conform to the parameters and requirements stated by this Article 7 (Section 1751 et seq.), applicable solely to sterile compounding. (CCR 1751[a])

Yes No N/A

☐☐☐ 12.2 The pharmacy has a compounding area designated for the preparation of sterile drug preparations in a restricted location where traffic has no impact on the performance of the Primary Engineering Control(s) (PEC). (CCR 1751[b])

12.2.1 The cleanroom, including the walls, ceilings, and floors, are constructed in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations.

12.2.2 The pharmacy is ventilated in a manner in accordance with Section 505.5 of Title 24, Part 4, Chapter 5 of the California Code of Regulations.

12.2.3 The environments within the pharmacy meet at least the following standards: (CCR 1751[b])

12.2.3.1 Each ISO environment is certified at least every six months by a qualified technician in accordance with Section 1751.4.

12.2.3.1.1Certification records must be retained in the pharmacy.

12.2.3.2 Items related to the compounding of sterile drug preparations within the compounding area are stored in such a way as to maintain the integrity of an aseptic environment.

12.2.3.3 A sink is included in accordance with Section 1250.4 of Title 24, Part 2, Chapter 12, of the California Code of Regulations. Sinks and drains are not present in any ISO Class 7 or better cleanroom, nor in a segregated sterile compounding area within three feet of an ISO Class 5 or better PEC, with the exception of emergency eye-rinsing stations. A sink may be located in an ante-area.

12.3.3.4 There is a refrigerator and where appropriate, a freezer, of sufficient capacity to meet the storage requirements for all material requiring refrigeration or freezing, and a backup plan is in place to ensure continuity of available compounded drug preparations in the event of a power outage.

13. Sterile Compounding; Compounding Area (CCR 1250.4, 505.5 and 505.5.1)

TITLE 24, PART 2, CHAPTER 12, REGULATIONS

Yes No N/A

☐☐☐ 13.1 The pharmacy has designated area for the preparation of sterile products for dispensing which meets at least the following: (24 CCR 1250.4)

- 13.1.1 In accordance with Federal Standard 209(b), Clean Room and Work Station Requirements, Controlled Environment, as approved by the Commission, Federal Supply Service, General Services Administration meet standards for class 100 HEPA (high efficiency particulate air) filtered air such as laminar air flow hood or clean room. (24 CCR 1250.4[1])
- 13.1.2 Has non-porous and cleanable surfaces, walls, floors, ceilings and floor coverings. (24 CCR 1250.4[2])
- 13.1.3 The pharmacy is arranged in such a manner that the laminar-flow hood (PEC) is located in an area which is exposed to minimal traffic flow, and is separate from any area used for bulk storage of items not related to the compounding of parenteral preparations. There is sufficient space, well separated from the laminar-flow hood area, for the storage of bulk materials, equipment and waste materials. (24 CCR 1250.4[3])
- 13.1.4 A sink with hot and cold running water is within the parenteral preparation compounding area or adjacent to it. (24 CCR 1250.4[4])
- 13.1.5 The pharmacy compounding sterile injectable preparations from one or more nonsterile ingredients, compounds the preparations in one of the following environments: (24 CCR 1250.4[5])
  - 13.1.5.1 An ISO Class 5 laminar airflow hood within an ISO Class 7 cleanroom. The cleanroom must have a positive air pressure differential relative to adjacent areas.
  - 13.1.5.2 An ISO Class 5 cleanroom.
  - 13.1.5.3 A barrier isolator that provides an ISO Class 5 environment for compounding.

Yes No N/A

☐☐☐ 13.2 The pharmacy has a designated area for the compounding of sterile preparations for dispensing which shall: (24 CCR 505.5)

- 13.2.1 Be ventilated in a manner not interfering with laminar air flow.

Yes No N/A

☐☐☐ 13.3 Pharmacies preparing parenteral cytotoxic agents, all compounding is conducted within a certified Class II Type A or Class II Type B vertical laminar air flow hood with bag in-bag out design. The pharmacy ensures that contaminated air plenums under positive air pressure are leak tight. (24 CCR 505.5.1)

CORRECTIVE ACTION OR ACTION PLAN: _____

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14. Sterile Compounding Recordkeeping Requirements. (CCR 1751.1)

Yes No N/A

☐☐☐ 14.1 In addition to the records required by section 1735.3 the pharmacy maintains at least the following records, which are in a readily retrievable, within the pharmacy: (CCR 1751.1[a][1-11])

- 14.1.1 Documents evidencing training and competency evaluations of employees in sterile drug preparation policies and procedures.

14.1.2 Results of hand hygiene and garbing assessments with integrated gloved fingertip testing.
14.1.3 Results of assessments of personnel for aseptic techniques including results of media-fill tests and gloved fingertip testing performed in association with media-fill tests.
14.1.4 Results of viable air and surface sampling.
14.1.5 Biannual video of smoke studies in all ISO Class 5 certified spaces.
14.1.6 Documents indicating daily documentation of room, refrigerator, and freezer temperatures appropriate for sterile compounded drug preparations consistent with the temperatures listed in section 1735.1 for:
14.1.6.1 Controlled room temperature.
14.1.6.2 Controlled cold temperature.
14.1.6.3 Controlled freezer temperature.
14.1.7 Certification(s) of the sterile compounding environment(s).
14.1.8 Documents indicating daily documentation of air pressure differentials or air velocity measurements between all adjoining ISO rooms or areas, including those associated with compounding aseptic (containment) isolators, and air pressure differentials or air velocity measurements between all rooms or spaces with an immediate entry or opening to ISO rooms or areas.
14.1.9 Other facility quality control records specific to the pharmacy's policies and procedures (e.g., cleaning logs for facilities and equipment, incubator temperatures).
14.1.10 Logs or other documentation of inspections for expired or recalled chemicals, bulk drug substances, drug products, or other ingredients.
14.1.11 Preparation records including the master formula document, the preparation compounding log, and records of end-product evaluation testing and results.

☐☐☐ 14.2 The pharmacy compounds for future use pursuant to section 1735.2, and in addition to those records required by section 1735.3, the pharmacy makes and keeps records indicating the name, lot number, and amount of any drug preparation compounded for future use, the date on which any preparation was provided to a prescriber, and the name, address, license type and number of the prescriber. (CCR 1751.1[b])

☐☐☐ 14.3 The pharmacy maintains and retains all records required by this article in the pharmacy in a readily retrievable form for at least three years from the date the record was created. If only recorded and stored electronically, on magnetic media, or in any other computerized form, the records are maintained as specified by Business and Professions Code section 4070 subsection (c). (CCR 1751.1[c])

CORRECTIVE ACTION OR ACTION PLAN: _____

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15. Sterile Labeling Requirements (CCR 1751.2)

Yes No N/A

☐☐☐ 15.1 In addition to the labeling information required under Business and Professions Code section 4076 and California Code of Regulations, title 16, sections 1707.5 and 1735.4, the pharmacy label each compounded sterile drug preparation with at least the following information: (CCR 1751.2[a-c])
15.1.1 The telephone number of the pharmacy.
15.1.2 Instructions for storage, handling, and administration.
15.1.3 All hazardous agents shall bear a special label which states "Chemotherapy - Dispose of Properly" or "Hazardous – Dispose of Properly.":

CORRECTIVE ACTION OR ACTION PLAN: _____

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PIC Initials

16. Sterile Policies and Procedures (CCR 1751.3)

Yes No N/A

☐☐☐ 16.1 The pharmacy maintains written policies and procedures for compounding and understands any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. CCR 1751.3[a])

16.2 In addition to the elements required by section 1735.5, there are written policies and procedures regarding at least the following: (CCR 1751.3[a][1-24])

- 16.2.1 Action levels for colony-forming units (CFUs) detected during viable surface sampling, glove fingertip, and viable air sampling and actions to be taken when the levels are exceeded.
- 16.2.2 Airflow considerations and pressure differential monitoring.
- 16.2.3 An environmental sampling plan and procedures specific to viable air, surface and gloved fingertip sampling as well as nonviable particle sampling.
- 16.2.4 Cleaning and maintenance of ISO environments and segregated compounding areas.
- 16.2.5 Compounded sterile drug preparation stability and beyond use dating.
- 16.2.6 Compounding, filling, and labeling of sterile drug preparations.
- 16.2.7 Daily and monthly cleaning and disinfection schedule for the controlled areas and any equipment in the controlled area as specified in section 1751.4.
- 16.2.8 Depyrogenation of glassware (if applicable)
- 16.2.9 Facility management including certification and maintenance of controlled environments and related equipment.
- 16.2.10 For compounding aseptic isolators and compounding aseptic containment isolators, documentation of the manufacturer's recommended purge time.
- 16.2.11 Hand hygiene and garbing.
- 16.2.12 Labeling of the sterile compounded drug preparations based on the intended route of administration and recommended rate of administration.
- 16.2.13 Methods by which the supervising pharmacist will fulfill his or her responsibility to ensure the quality of compounded drug preparations.
- 16.2.14 Orientation, training, and competency evaluation of staff in all aspects of the preparation of sterile drug preparations including didactic training and knowledge/competency assessments which include at minimum: hand hygiene and garbing; decontamination (where applicable); cleaning and disinfection of controlled compounding areas; and proper aseptic technique demonstrated through the use of a media-fill test performed by applicable personnel; and aseptic area practices.
- 16.2.15 Preparing sterile compounded drug preparations from non-sterile components (if applicable). This shall include sterilization method suitability testing for each master formula document.
- 16.2.16 Procedures for handling, compounding and disposal of hazardous agents. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.17 Procedures for handling, compounding and disposal of infectious materials. The written policies and procedures shall describe the pharmacy protocols for cleanups and spills in conformity with local health jurisdiction standards.
- 16.2.18 Proper use of equipment and supplies.
- 16.2.19 Quality assurance program compliant with sections 1711, 1735.8, and 1751.7.
- 16.2.20 Record keeping requirements.
- 16.2.21 Temperature monitoring in compounding and controlled storage areas.
- 16.2.22 The determination and approval by a pharmacist of ingredients and the compounding process for each preparation before compounding begins.
- 16.2.23 Use of automated compounding devices (if applicable).

16.2.24 Visual inspection and other final quality checks of sterile drug preparations.

☐☐☐ 16.3 For lot compounding, the pharmacy maintains ~~a~~ written policies and procedures which include~~s~~ at least the following: (CCR 1751.3[b][1-3])
- 16.3.1 Use of master formula documents and compounding logs.
- 16.3.2 Appropriate documentation.
- 16.3.3 Appropriate sterility and potency testing.

☐☐☐ 16.4 For non-sterile-to-sterile batch compounding, the pharmacy maintains a written policies and procedures for compounding which included at least the following. (CCR 1751.2[c][1-2])
- 16.4.1 Process validation for chosen sterilization methods.
- 16.4.2 End-product evaluation, quantitative, and qualitative testing.

☐☐☐ 16.5 All personnel involved have read the policies and procedures before compounding sterile drug preparations. All personnel involved have read all additions, revisions, and deletions to the written policies and procedures. Each review is documented by a signature and date. (CCR 1751.3[e])

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17. Facility & Equipment Standards for Sterile Compounding (CCR 1751.4)

Yes No N/A

☐☐☐ 17.1 No sterile drug preparation is compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations (CCR 1751.4[a])

☐☐☐ 17.2 During the compounding of sterile drug preparations, access to the areas designated for compounding is limited to those individuals who are properly attired (CCR 1751.4[b])

☐☐☐ 17.3 All equipment used in the areas designated for compounding is made of a material that can be easily cleaned and disinfected. (CCR 1751.4[c])

☐☐☐ 17.4 Cleaning is done using a germicidal detergent and sterile water. A sporicidal agent is used at least monthly (CCR 1751.4[d][1-4])
- 17.4.1 All ISO Class 5 surfaces, work table surfaces, carts, counters, and the cleanroom floor are cleaned at least daily. After each cleaning, disinfection using a suitable sterile agent occurs on all ISO Class 5 surfaces, work table surfaces, carts, and counters.
- 17.4.2 Walls, ceilings, storage shelving, tables, stools, and all other items in the ISO Class 7 or ISO Class 8 environment are cleaned at least monthly.
- 17.4.3 Cleaning shall also occur after any unanticipated event that could increase the risk of contamination.
- 17.4.4 All cleaning materials, such as wipers, sponges, and mops, shall be non-shedding and dedicated to use in the cleanroom, or ante-area, and segregated sterile compounding areas and shall not be removed from these areas except for disposal.

☐☐☐ 17.5 Disinfection, using a suitable sterile agent, occurs on all surfaces in the ISO Class 5 PEC frequently, including: (CCR 1751.4[e])
- 17.5.1 At the beginning of each shift;
- 17.5.2 At least every 30 minutes when compounding involving human staff is occurring or before each lot;
- 17.5.3 After each spill; and
- 17.5.4 When surface contamination is known or suspected.

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☐☐☐ 17.6 Pharmacies preparing sterile compounded preparations are using a PEC that provides ISO Class 5 air or better air quality (CCR 1751.4[f])

17.6.1 Certification and testing of primary and secondary engineering controls are performed no less than every six months and whenever the device or area designated for compounding is relocated, altered or a service to the facility is performed which would impact the device or area.

17.6.2 Certification is completed by a qualified technician who is familiar with certification methods and procedures in accordance with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.6.2.1 Certification records are retained for at least 3 years.

17.6.3 Unidirectional compounding aseptic isolators or compounding aseptic containment isolators used outside of an ISO Class 7 cleanroom if the isolators are certified to meet the following criteria: (CCR 1751.4[f][1-3])

17.6.3.1 Particle counts sampled approximately 6-12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.

17.6.3.2 Not more than 3520 particles (0.5 um and larger) per cubic meter shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing transfer.

17.6.3.3 Recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

17.6.4 Compounding aseptic isolators that do not meet the requirements as outlined in this subdivision or are not located within an ISO Class 7 cleanroom are only be used to compound preparations that meet the criteria specified in accordance with subdivision (d) of Section 1751.8 of Title 16, Division 17, of the California Code of Regulations.

☐☐☐ 17.7 Pharmacies preparing sterile hazardous agents shall do so in accordance with Section 505.5.1 of Title 24, Chapter 5, of the California Code of Regulations, requiring a negative pressure PEC.

17.7.1 Additionally, each PEC used to compound hazardous agents shall be externally vented.

17.7.2 The negative pressure PEC is certified every six months by a qualified technician who is familiar with CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006-13, Revised May 20, 2015).

17.7.3 Any drug preparation compounded in a PEC where hazardous drugs are prepared are labeled as hazardous, regardless of whether the drug ingredients are considered hazardous. (CCR 1751.4[g])

17.7.4 During hazardous drug compounding performed in a compounding aseptic containment isolator, full hand hygiene and garbing occurs. Garbing shall include hair cover, facemask, beard cover (if applicable), polypropylene or low shedding gown that closes in the back, shoe covers, and two pairs of sterile ASTM D6978-05 standard gloves. (CCR 1751.4[g][1])

☐☐☐ 17.8 If a compounding aseptic isolator is certified by the manufacturer to maintain ISO Class 5 air quality during dynamic operation conditions during compounding as well as during the transfer of ingredients into and out of the compounding aseptic isolator, then it may be placed into a non-ISO classified room. Individuals who use compounding aseptic isolators in this manner must ensure appropriate garbing, which consists of donning sterile gloves over the isolator gloves immediately before non-hazardous compounding. These sterile gloves must be changed by each individual whenever continuous compounding is ceased and before compounding starts again. (CCR 1751.4[h])

☐☐☐ 17.9 Compounding aseptic isolators and compounding aseptic containment isolators used in the compounding of sterile drug preparations shall use non-turbulent unidirectional air flow patterns. A smoke patterned test shall be used to determine air flow patterns. (CCR 1751.4[i])

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☐☐☐ 17.10 Viable surface sampling is done at least every six months for all sterile-to-sterile compounding and quarterly for all non-sterile-to-sterile compounding. (CCR 1751.4[j])

17.10.1 Viable air sampling is be done by volumetric air sampling procedures which test a sufficient volume of air (400 to 1,000 liters) at each location and is done at least once every six months.

17.10.2 Viable surface and viable air sampling are performed by a qualified individual who is familiar with the methods and procedures for surface testing and air sampling.

17.10.3 Viable air sampling is performed under dynamic conditions which simulate actual production.

17.10.3 Viable surface sampling is performed under dynamic conditions of actual compounding.

17.10.5 When the environmental monitoring action levels are exceeded, the pharmacy identifies the CFUs at least to the genus level in addition to conducting an investigation pursuant to its policies and procedures. Remediation includes, at minimum, an immediate investigation of cleaning and compounding operations and facility management.

☐☐☐ 17.11 The sterile compounding area in the pharmacy has a comfortable and well-lighted working environment, which typically includes a room temperature of 20 degrees Celsius (68 degrees Fahrenheit) or cooler to maintain comfortable conditions for compounding personnel when attired in the required compounding garb. (CCR 1751.4[k])

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18. Sterile Compounding Attire (CCR 1751.5)

Yes No N/A

☐☐☐ 18.1. When compounding sterile drug preparations, the following standards are met: (CCR 1751.5[a][1-6])

- 18.1.1 Personal protective equipment consisting of a low non-shedding coverall gown, head cover, face mask, facial hair covers (if applicable), and shoe covers are worn inside the designated area at all times. For hazardous compounding, double shoe covers are worn.
- 18.1.2 Personal protective equipment is donned and removed in an ante-area or immediately outside the segregated compounding area.
- 18.1.3 Personnel dons personal protective equipment in an order that proceeds from those activities considered the dirtiest to those considered the cleanest.
- 18.1.4 Compounding personnel does not wear any wrist, hand, finger, or other visible jewelry, piercing, headphones, earbuds, or personal electronic devices.
- 18.1.5 Sterile gloves that have been tested for compatibility with disinfection by isopropyl alcohol are worn.
- 18.1.6 Hand cleansing with a persistently active alcohol-based product followed by the donning of sterile gloves may occur within the ante or cleanroom.
- 18.1.7 Gloves are routinely disinfected with sterile 70 percent isopropyl alcohol before entering or re-entering the PEC and after contact with non-sterile objects.
- 10.1.8 Gloves are routinely inspected for holes, punctures, or tears and replaced immediately if such are detected.
- 18.1.9 Individuals experiencing exposed rashes, sunburn, weeping sores, conjunctivitis, active respiratory infections or other communicable disease, or those wearing cosmetics, nail polish, or artificial nails are excluded from the ISO Class 5 and ISO Class 7 compounding areas until their conditions are remedied.

☐☐☐ 18.2. When preparing hazardous agents, appropriate gowns and personal protective equipment are worn regardless of the PECs used (e.g., biological safety cabinet and compounding aseptic containment isolator). (CCR 1751.5[b])

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19. Sterile Compounding Consultation; Training of Sterile Compounding Staff. (CCR 1751.6)

Yes No N/A

☐☐☐ 19.1 Consultation is available to the patient and/or primary caregiver concerning proper use, storage, handling, and disposal of sterile drug preparations and related supplies furnished by the pharmacy. (CCR 1751.6[a])

☐☐☐ 19.2 The pharmacist-in-charge ensures all pharmacy personnel engaging in compounding sterile drug preparations have training and demonstrated competence in the safe handling and compounding of sterile drug preparations, including hazardous agents if the pharmacy compounds products with hazardous agents. (CCR 1751.6[b])

☐☐☐ 19.3 Records of training and demonstrated competence are available for each individual and shall be retained for three years beyond the period of employment (CCR 1751.6[c])

☐☐☐ 19.4 The pharmacist-in-charge is responsible to ensure the continuing competence of pharmacy personnel engaged in compounding sterile drug preparations (CCR 1751.6[d])

☐☐☐ 19.5 The pharmacy complies with at least the following training requirements: (CCR 1751.6[e])

19.5.1 The pharmacy establishes and follows a written program of training and performance evaluation designed to ensure each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. This program of training and performance evaluation must address at least the following: (CCR 1751.6[e][1][A-J])

19.5.1.1 Aseptic technique.
19.5.1.2 Pharmaceutical calculations and terminology.
19.5.1.3 Sterile preparation compounding documentation.
19.5.1.4 Quality assurance procedures.
19.5.1.5 Aseptic preparation procedures.
19.5.1.6 Proper hand hygiene, gowning and gloving technique.
19.5.1.7 General conduct in the controlled area (aseptic area practices).
19.5.1.8 Cleaning, sanitizing, and maintaining of the equipment and the controlled area.
19.5.1.9 Sterilization techniques for compounding sterile drug preparations from one or more non-sterile ingredients.
19.5.1.10 Container, equipment, and closure system selection.

19.5.2 Each person engaged in sterile compounding has successfully completed practical skills training in aseptic technique and aseptic area practices using models that are comparable to the most complex manipulations to be performed by the individual. (CCR 1751.6[e][2])

19.5.2.1 Each pharmacist responsible for, or directly supervising and controlling, aseptic techniques or practices, must demonstrate the skills needed to ensure the sterility of compounded drug preparations.
19.5.2.2 Evaluation must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.
19.5.2.3 Each person's proficiency and continuing training needs must be reassessed at least every 12 months.
19.5.2.3 Results of these assessments must be documented and retained in the pharmacy for three years.

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20. Sterile Compounding Quality Assurance and Process Validation (CCR 1751.7)

Yes No N/A

☐☐☐ 20.1 There is a written, documented, ongoing quality assurance program maintained by the pharmacy that monitors personnel performance, equipment, and facilities, and the pharmacist-in-charge assures the end-product meets the required specifications by periodic sampling. (CCR 1751.7[a])

20.1.1 The quality assurance program shall include at least the following: (CCR 1751.7[a][1-3])

20.1.1.1 Procedures for cleaning and sanitization of the sterile preparation area.

20.1.1.2 Actions to be taken in the event of a drug recall.

20.1.1.3 Documentation justifying the chosen beyond use dates for compounded sterile drug preparations.

☐☐☐ 20.2.1 The pharmacy and each individual involved in the compounding of sterile drug preparations successfully demonstrate competency on aseptic technique and aseptic area practices before being allowed to prepare sterile drug preparations. (CCR 1751.7[b][1])

20.2.2 Each individual's competency is revalidated at least every twelve months for sterile to sterile compounding and at least every six months for individuals compounding sterile preparations from non-sterile ingredients. (CCR 1751.7[b][2])

20.2.3 The pharmacy's validation process on aseptic technique and aseptic area practices is to be revalidated whenever: (CCR 1751.7[b][3][A-B])

20.2.3.1 The quality assurance program yields an unacceptable result.

20.2.3.2 There is any change in the compounding process, the Primary Engineering Control (PEC), or the compounding environment. For purposes of this subsection, a change includes, but is not limited to, when the PEC is moved, repaired or replaced, when the facility is modified in a manner affecting airflow or traffic patterns, or when improper aseptic techniques are observed.

20.2.4 The pharmacy must document the validation and revalidation process (CCR 1751.7[b][4]).

☐☐☐ 20.3 All sterile compounding personnel have successfully completed an initial competency evaluation. In addition, immediately following the initial hand hygiene and garbing procedure, each individual who may be required to do so in practice has successfully completed a gloved fingertip (all fingers on both hands) sampling procedure (zero colony forming units for both hands) at least three times before initially being allowed to compound sterile drug preparations. (CCR 1751.7[c])

☐☐☐ 20.4 Re-evaluation of garbing and gloving competency occurs at least every 12 months for personnel compounding products made from sterile ingredients and at least every six months for personnel compounding products from non-sterile ingredients. (CCR 1751.7[d])

☐☐☐ 20.5 Batch-produced sterile drug preparations compounded from one or more non-sterile ingredients, except as provided in paragraph (2), are subject to documented end product testing for sterility and pyrogens and are quarantined until the end product testing confirms sterility and acceptable levels of pyrogens. Sterility testing is performed per USP chapter 71 and pyrogen testing confirms acceptable levels of pyrogen per USP chapter 85 limits before dispensing. This requirement of end product testing confirming sterility and acceptable levels of pyrogens prior to dispensing applies regardless of any sterility or pyrogen testing that may have been conducted on any ingredient or combination of ingredients which were previously non-sterile. Exempt from pyrogen testing are topical ophthalmic and inhalation preparation. (CCR 1751.7[e][1])

20.5.1 The following non-sterile-to-sterile batch drug preparations do not require end product testing for sterility and pyrogens: (CCR 1751.7[e][2][A-B)

20.5.1.1 Preparations for self-administered ophthalmic drops in a quantity sufficient for administration to a single patient for 30 days or less pursuant to a prescription.

20.5.1.2 Preparations for self-administered inhalation in a quantity sufficient for administration to a single patient for 5 days or less pursuant to a prescription.

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21. Beyond Use Dating for Sterile Compounded Drug Preparations (CCR 1751.8)

Yes No N/A

☐☐☐ 21.1 Every sterile compounded drug preparation is given and labeled with a beyond use date incompliance with 1735.2 and does not exceed the shortest expiration date or beyond use date of any ingredient in sterile the compounded drug preparation, nor the chemical stability of any one ingredient in the sterile compounded drug preparation, nor the chemical stability of the combination of all ingredients in the sterile compounded drug preparation, and , in the absence of passing a sterility test in accordance with standards for sterility testing found in Chapter 797 of the United States Pharmacopeia would justify an extended beyond use date, conforms to the following limitations:

☐☐☐ 21.2 The beyond use date states storage and exposure periods cannot exceed 48 hours at controlled room temperature, 14 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[a])

- 21.2.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using only sterile ingredients, products, components, and devices; **and**
- 21.2.2 The compounding process involves transferring, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile preparations and not more than two entries into any one sterile container or package of sterile preparations or administration containers/devices to prepare the drug preparation; **and**
- 21.2.3 Compounding manipulations are limited to aseptically opening ampules, penetrating disinfected stoppers on vials with sterile needles and syringes or spiked transfer devices, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile preparations, and containers for storage dispensing.

☐☐☐ 21.3 The beyond use date states storage and exposure periods cannot exceed 30 hours at controlled room temperature, 9 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[b])

- 21.3.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3), using multiple individual or small doses of sterile preparations combined or pooled to prepare a compounded sterile preparation that will be administered either to multiple patients or to one patient on multiple occasions; and
- 21.3.2 The compounding process involves complex aseptic manipulations other than the single-volume transfer; and
- 21.3.3 The compounding process requires unusually long duration such as that required to complete dissolution or homogenous mixing.

☐☐☐ 21.4 The beyond use date states storage and exposure periods cannot exceed 24 hours at controlled room temperature, 3 days at controlled cold temperature, and 45 days in solid frozen state, where the sterile compounded drug preparation is compounded solely with aseptic manipulations using non-sterile

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ingredients, regardless of intervening sterilization of that ingredient and the following applies: (CCR 1751.8[c])

21.4.1 The preparation is compounded entirely within an ISO Class 5 PEC located in an ISO Class 7 cleanroom with an ante-area or compounded entirely within a CAI which meets the requirements in 1751.4(f)(1)-(3).

☐☐☐ 21.5 The beyond use date states storage and exposure periods cannot exceed 12 hours where the sterile compounded drug preparation is compounded solely with aseptic manipulations and all of the following apply: (CCR 1751.8[d])

21.5.1 The preparation was compounded entirely within an ISO Class 5 PEC that is located in a segregated sterile compounding area and restricted to sterile compounding activities, using only sterile ingredients, components, and devices, by personnel properly cleansed and garbed; and

21.5.2 The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous preparations or diagnostic radiopharmaceutical preparations from the manufacturer's original containers; and

21.5.3 The compounding process involves not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device.

☐☐☐ 21.6 Any sterile compounded drug preparation which was compounded either outside of an ISO class 5 PEC or under conditions that do not meet all of the requirements for any of subdivisions (a) through (e), the sterile compounded drug preparation is be labeled "for immediate use only" and administration shall begin no later than one hour following the start of the compounding process.

21.6.1 Unless the "immediate use" preparation is immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the preparation shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the compounded sterile preparation, and the exact one-hour beyond use date and time.

21.6.2 If administration has not begun within one hour following the start of the compounding process, the compounded sterile preparation shall be promptly, properly, entirely, and safely discarded.

21.6.3 "Immediate use" preparations are only compounded in those limited situations where there is a need for immediate administration of a sterile preparation compounded outside of an ISO Class 5 environment and where failure to administer could result in loss of life or intense suffering.

21.6.4 Any such compounding shall be only in such quantity as is necessary to meet the immediate need and the circumstance causing the immediate need shall be documented in accordance with policies and procedures. (CCR 1751.8[e])

☐☐☐ 21.7 The beyond use date for any compounded allergen extracts is the earliest manufacturer expiration date of the individual allergen extracts. (CCR 1751.8[f])

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22. Single-Dose and Multi-Dose Containers; Limitations on Use (CCR 1751.9)

Yes No N/A

☐☐☐ 22.1 Single-dose ampules are for immediate use only, and once opened are not stored for any time period. (CCR 1751.9[a])

☐☐☐ 22.2 Unless otherwise specified by the manufacturer, any single-dose container of a compounded sterile drug preparation other than an ampule, such as a bag, bottle, syringe or vial, is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within the following time limit, depending on the environment: (CCR 1751.9[b])

22.2.1 When needle-punctured in an environment with air quality worse than ISO Class 5, within one (1) hour.

22.2.2 When needle-punctured in an environment with ISO Class 5 or better air quality, within six (6) hours. A container remains within the ISO Class 5 or better air quality to be used for the full six hours, unless otherwise specified by the manufacturer.

22.2.3 If the puncture time is not noted on the container, the container is immediately discarded.

☐☐☐ 22.3 Unless otherwise specified by the manufacturer, a multi-dose container stored according to the manufacturer's specifications is used in its entirety or its remaining contents are be labeled with a beyond use date and discarded within twenty-eight (28) days from initial opening or puncture. (CCR 1751.9[c])

22.3.1 Any multi-dose container not stored according to the manufacturer's specifications is discarded immediately upon identification of such storage circumstance.

22.3.2 If any open container is not labeled with a beyond use date or the beyond use date is not correct, the container is immediately be discarded.

23. Sterile Compounding Reference Materials (CCR 1751.10)

☐☐☐ 23.1 The pharmacy has current and appropriate reference materials regarding the compounding of sterile drug preparations located in or immediately available to the pharmacy. (CCR 1751.10)

24. Sterile Compounding License Renewal (B&PC 4127.1, 4127.15, 4127.2)

A license to compound sterile drug preparation will not be renewed until the following is met: (B&PC 4127.1, 4127.15 4127.2)

Yes No N/A

☐☐☐ 24.1 The pharmacy has been inspected by the board and is in compliance with applicable laws and regulations.

☐☐☐ 24.2 The board reviews a current copy of the pharmacy's policies and procedures for sterile compounding.

☐☐☐ 24.3 The board is provided with copies of all inspection reports conducted of the pharmacy's premises in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.4 The board is provided with copies of any reports from a private accrediting agency conducted in the prior 12 months documenting the pharmacy's operation.

☐☐☐ 24.5 The board receives a list of all sterile medications compounded by the pharmacy since the last license renewal.

☐☐☐ 24.6 A nonresident pharmacy has reimbursed the board for all actual and necessary costs incurred by the board in conducting an inspection of the pharmacy at least once annually. (B&PC 4127.2[c])

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25. Hospital Satellite Compounding Pharmacy (B&PC 4127.15)

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☐☐☐ 25.1 A hospital satellite compounding pharmacy compounds sterile drug products for administration only to registered hospital patients who are on the premises of the same physical plant in which the hospital satellite compounding pharmacy is located.

25.2 The services provided shall be directly related to the services or treatment plan administered in the physical plant.

26. Nonresident Pharmacy (B&PC 4127.2)

☐☐☐ 26.1 Pharmacy notifying the board within 10 days of the suspension of any accreditation held by the pharmacy.

26.2 Pharmacy provides to the board, within 12 hours, any recall notice issued by the pharmacy for sterile drug products it has compounded that have been shipped into, or dispensed in, California.

26.3 Advise the board of any complaint it receives from a provider, pharmacy, or patient in California.

27. Duties of a Pharmacy Issuing a Sterile Compounded Drug Recall (B&PC 4127.9)

Yes No N/A

☐☐☐ 27.1 The pharmacy contacts the recipient pharmacy, prescriber or patient of the recalled drug and the board as soon as possible within 12 hours of the recall notice if both (1) the use of or exposure to the recalled drug preparations may cause serious adverse health consequences or death; and (2) the recalled drug was dispensed or is intended for use in California. (B&PC 4127.9[a] B&PC 4127.1 and 4127.2)

☐☐☐ 27.2 A recall notice is made to the patient if the recalled drug was dispensed directly to the patient. (B&PC 4127.9[b][1])

Yes No N/A

☐☐☐ 27.3 A recall notice is made to the prescriber if the recalled drug was dispensed directly to the prescriber. (B&PC 4127.9[b][2])

☐☐☐ 27.4 A recall notice is made to the recipient pharmacy who shall notify the prescriber or patient if the recalled drug was dispensed thereafter. (B&PC 4127.9[b][3])

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PHARMACIST-IN-CHARGE CERTIFICATION:

I, (Please print) _____, RPH # _____ hereby certify that I have completed the self-assessment of this pharmacy of which I am the pharmacist-in-charge. Any deficiency identified herein will be corrected. I understand that all responses are subject to verification by the Board of Pharmacy. I further state under penalty of perjury of the laws of the State of California that the information I have provided in this self-assessment form is true and correct.

Signature _____ Date _____
(Pharmacist-in-Charge)

ACKNOWLEDGEMENT BY OWNER OR HOSPITAL ADMINISTRATOR:

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

Signature _____ Date _____

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