Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Automated Drug Delivery Systems

Section Affected: Amend Section 1711 of Article 2 of Division 17 of Title 16, California Code Regulations
Amend Section 1713 of Article 2 of Division 17 of Title 16, California Code Regulations
Add Section 1715.1 of Article 2 of Division 17 of Title 16, California Code Regulations

Problems Addressed

The California State Board of Pharmacy (board) is a state agency vested with the authority to regulate the pharmacy industry, including pharmacies, pharmacists, and pharmacy technicians (Business and Professions Code (B&P) section 4000, *et seq*.). The board's mandate and its mission is to protect the public (B&P section 4001.1).

Existing law at B&P section 4105.5 establishes the requirement that a pharmacy that owns or provides dangerous drugs to an automated drug delivery system (ADDS) must register the ADDS with the board within 30 days of installation of the device.

Assembly Bill 2037 (Bonta, Statutes of 2018, Chapter 647) added, among other things, B&P Section 4119.11:

- **B&P section 4119.11** – Established two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit Dose System (AUDS). Additionally, it established the specific requirements for a pharmacy to apply for licensure to operate an ADDS.

Senate Bill (SB) 1447 (Hernandez, Chapter 666, Statutes of 2018) added, among other things, B&P Sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7:

- **B&P section 4427.2** – Established the board's authority to issue an ADDS license. Additionally, it established the requirements for and conditions of said licensure.

- **B&P section 4427.3** – Established the placement and operation requirements for an ADDS. Furthermore, it requires the development and implementation of policies and procedures for a pharmacy with an ADDS license.

- **B&P section 4427.4** – Established the ownership of ADDS and the drugs and devices stored within an ADDS. Additionally, it established the board's authority to inspect ADDS, identified access security, and the records requirement for each transaction.

- **B&P section 4427.6** – Established additional requirements for automated patient dispensing systems (APDS), which is an ADDS used by patients to receive patient specific medication. Additionally, it requires that incidents involving a complaint, error, or omission be reviewed as part of the pharmacy's quality assurance program.

- **B&P section 4427.7** – Established the requirement for a pharmacy to complete a self-assessment relating to the use of the ADDS. Additionally, it established the recordkeeping and quality assurance requirements.

Previously, pharmacy law did not allow for the licensure of an ADDS. This proposal will amend 16 CCR section 1711 to require that records related to the use of an ADDS developed as part of the quality assurance review, established by B&P section 4427.6(i), be submitted to the board. Additionally, this proposal will amend 16 CCR section 1713 to align the board's regulation with the newly established APDS license and clarify its use. Finally, this proposal will add 16 CCR section 1715.1 to identify the specific requirements for the completion of the self-assessment with respect to the use of ADDS as required by B&P section 4427.7.

In order to effectively administer this alternative program, the board is required to promulgate regulations because it is not exempt from the rulemaking process under to Administrative Procedures Act.

Benefits

This regulatory proposal benefits the health and welfare of California residents, as well as, benefiting employee safety and the state's environment. The proposed regulation will ensure that the board is aware of possible quality issues and/or complaints made with respect to the use of ADDS by requiring the quality assurance reports be submitted to the board. This will allow the board to inspect or investigate possible concerns with respect to the use of the systems. Additionally, the proposed regulation provides clarity to the regulated public with respect to APDS. This benefits the health and welfare of California residents by ensuring that they are properly counseled and their medications are appropriately labeled and accurately dispensed. Finally, the proposal identifies the specific requirements for the self-assessment form. The self-assessment form aids licensees in assessing their compliance with federal and state law and regulations. As the pharmacist-in-charge (PIC) completes the self-assessment form, they will identify any areas where the pharmacies use of an ADDS may be out of compliance. This awareness can increase self-correction and makes the ADDS inspection process more meaningful by providing useful information to the PIC about controlling statutes and regulations. This periodic review and accountability will result in increased consumer safety and will improve operations with respect to employee safety and the state's environment.

Specific Purpose of Proposed Changes and Rationale

The board's proposal makes the following amendments:

Amend Section 1711 of Article 2 of Division 17 of Title 16 of the CCR

Subdivision (e)(1) – (e)(4) is amended to remove the decimal after the number and place the number into parentheses. This change was completed for proper regulation text formatting and consistency within the board's regulations. This is a non-substantive change and will not have any regulatory effect.

Subdivision (f) is amended to add the requirement for any record developed during a quality assurance review of an ADDS be submitted to the board within 30 days of completion of the review. A quality assurance review is only completed when an error, complaint, or omission is identified. While existing law requires that the record of a quality assurance review be maintained within the pharmacy for at least one year, the board determined that the record of the review for an ADDS be submitted to the board to ensure that the board is aware of possible issues with the ADDS and allow the board the opportunity to inspect or investigate possible concerns with respect to the use of the ADDS. B&P section 4427.8 requires that the board report any possible safety concerns with respect to the use of ADDS to the state Legislature. In order to submit an accurate report to the Legislature, the board must review all quality assurance records to determine if a public safety concern exists.

The reference statutes were amended to add the appropriate section. Section "4427.7" of Business and Professions Code was added as reference.

Amend Section 1713 of Article 2 of Division 17 of Title 16 of the CCR

The board is proposing to amend section 1713 to remove duplication and inconsistency between the regulation section and statute. Legislation enacted effective July 1, 2019 (SB 1447) altered the condition under which a pharmacy can operate an ADDS and established two new types of ADDS devices (APDS and AUDS). This proposed change amends the board's regulation to address the new APDS type of ADDS device. Section 1713 is amended to apply specifically to APDS instead of the general ADDS term.

The title is amended to add "must be to or from a licensed pharmacy" for increased clarity to the regulated public. The licensed pharmacy is responsible for the operation and maintenance of the APDS. Additionally, they are solely responsible for the drugs within the system and for the stocking or restocking on the system, as such, adding the additional phase to the title provided greater clarity that the prescription must be to or from the licensed pharmacy.

Throughout the entire regulation section, the terms "automated delivery device" or "device" have been amended to "automated patient dispensing system" or "APDS" to provide clarity to the regulated public that this regulatory section only applies to an APDS.

Subsection (d) was further amended to remove "previously dispensed" and add "to patients" for clarity. The term "previously dispensed" was removed as BPC 4427.6 allows for pharmacist consultation to occur via two-way telecommunication. As such, pharmacists can provide consultation for new prescriptions and the restriction to

previously dispensed prescriptions no longer applies. Additionally, the term “to patients” was added as the prescription must be dispensed to the patient or the patient’s agent.

Subsection (d) has been renumbered as needed due to the elimination of requirements within the subsection as follows:

Subsection (d)(1) has been stricken from the regulation as it is duplicative, and it is specified within BPC 4427.6(b) and applied to all ADDS and not just APDS.

Subsection (d)(4) has been stricken from the regulation as it is inconsistent with statute. BPC 4427.6 allows for pharmacist consultation to occur via two-way telecommunication. As such, pharmacists can provide consultation for prescriptions via the APDS and the restriction no longer applies.

Subsection (d)(6) has been stricken from the regulation as it is inconsistent with statute. BPC 4427.6 allows for an APDS to be placed within a medical office or other location. The device is no longer restricted to adjacent to the pharmacy.

Subsection (d)(7) has been stricken from the regulation as it is duplicative, and it is specified within BPC 4427.2(d)(2) and applied to all ADDS and not just APDS.

Subsection (d)(8) has been stricken from the regulation as it is duplicative, and it is specified within BPC 4427.4(d) and applied to all ADDS and not just APDS.

Subsection (d)(10) has been stricken from the regulation as it is duplicative. The requirements for the policies and procedures are specified in subsection (e).

Subsection (g) has been stricken from the regulation as it defines “previously dispensed prescription medications” and the definition no longer applies as consultation can now be provided to new medications and the APDS is not restricted to previously dispended medications.

The reference statutes were amended to add the appropriate sections. Section “4017.3, 4417, 4427.1, 4427.2, 4427.3, 4427.4, 4427.5, 4427.7, and 4427.8” of Business and Professions Code was added as reference.

Add Section 1715.1 of Article 2 of Division 17 of Title 16 of the CCR

The board is proposing to add section 1715.1 to Article 2 of Division 17 of Title 16 within the CCR. The title of the section will read “Self-Assessment of an Automated Drug Delivery System by the Pharmacist-In-Charge.” This title will provide clarity to the regulated public with respect to the whom the section applies to. The title also identifies the individual that must complete the ADDS self-assessment. As the PIC is responsible for the operation and compliance with law for the ADDS, they are the appropriate party to complete the ADDS self-assessment. Additionally, the PIC is required by 16 CCR section 1715 to complete the self-assessment form specific to the operation of the pharmacy, so having them also complete the ADDS self-assessment is appropriate. B&P section 4427.7 specifies that a pharmacy holding the ADDS license must complete an annual self-assessment pursuant to section 1715 of the CCR. Section 1715 is

specific to the operation of a pharmacy and is not specific to a pharmacy operating an ADDS. As such, the board is adopting a new regulation at 1715.1 to establish a self-assessment form specific to ADDS to ensure that the pharmacy law references within the form is current and complete. This is necessary to ensure that the pharmacy completes a self-assessment consistent with the operation of an ADDS in addition to the completion of a self-assessment on the operation of the pharmacy.

Subdivision (a) is added to identify that the PIC of an ADDS as defined by B&P sections 4119.11, 4187.5, or 4427.3 must complete the self-assessment using form 17M-112. The PIC is responsible for overseeing the operation of the licensed facility and the ADDS. As such, they are responsible for ensuring that the facility is operating in compliance with state and federal law. Further, the subdivision specifies that the self-assessment must be completed annually, as required by B&P section 4427.7(a), and it specifies that the self-assessment must be completed by July 1 of every year. This date was selected for consistency with the other self-assessment forms that board licensees must complete (i.e. 16 CCR sections 1715 and 1784). Finally, the subdivision specifies the primary purpose of the self-assessment, which is to promote compliance through self-examination and education. This language is necessary to identify the main purpose of the self-assessment and for consistency with CCR sections 1715 and 1784.

Subdivision (b) is added to clearly identify additional triggering events that would require a self-assessment to be completed for an ADDS. These additional self-assessments must be completed within 30 days of the triggering event. This language is necessary to ensure that the self-assessment is completed appropriately and ensures consistency with CCR sections 1715 and 1784.

Subdivision (b)(1) is added to require that a self-assessment be completed anytime a new automated drug delivery system license has been issued. A self-assessment must be completed when a new ADDS license is issued to ensure that the PIC has verified that the system is operating in compliance with state law at the time the system is put into use. This provision is necessary so that, if non-compliance issues are identified, the PIC can immediately take steps to correct the issues before system errors or drug errors happen. This addition also ensures consistency with CCR sections 1715 and 1784.

Subdivision (b)(2) is added to require that a self-assessment be completed anytime there is a change in the PIC of the ADDS. This requirement is necessary to ensure that the new PIC is aware of the requirements for the operation of the ADDS, as well as, the requirements of the PIC with respect to the ADDS. Additionally, the new PIC can identify any non-compliance issues and take steps to correct them. The new PIC will be responsible for the operation of the ADDS, so it is important that they be educated on the legal requirements of the system. This addition also ensures consistency with CCR sections 1715 and 1784.

Subdivision (b)(3) is added to require that a self-assessment be completed anytime there is a change in licensed location of the ADDS. For example, if an ADDS is relocated from one side of the building to another, a self-assessment will need to be

completed. This is to ensure that the ADDS is operating in compliance with legal requirements and that is was not inadvertently damaged or inappropriately accessed during the relocation. This provision is necessary because a damaged system could allow unauthorized individuals access to prescription medication within the system or it could dispense incorrect medication or quantities, which would jeopardize patient safety. This addition also ensures consistency with CCR sections 1715 and 1784.

Subdivision (c) is added to require the use of Form 17M-112 (Rev 12/18), which is the ADDS self-assessment document. In addition, this subdivision incorporates the form by reference. The form is necessary to ensure PIC self-assessments are consistent and complete. This form was specifically developed to provide the PIC with one document where all the current laws and regulations related to ADDS can be found. Additionally, as the PIC goes through the process of completing the self-assessment form, at least annually, the PIC is made aware of any areas where the pharmacy and/or ADDS may be out of compliance with laws and regulations. This awareness will increase self-correction and make the pharmacy site inspection process with board staff more meaningful by providing useful information to the PIC about controlling statutes and regulations. The self-assessment form serves as an easy reference guide for the PIC.

Subdivisions (c)(1) through (7) are added and articulate the required components of the self-assessment from. The components of the form consist of the elements that will make the assessment sufficient, mostly for the board to evaluate whether the PIC meaningfully and timely conducted the review. This addition also ensures consistency with CCR sections 1715 and 1784.

Subdivision (c)(1) is added to clearly state the requirement that the PIC is responsible for providing identifying information about the pharmacy, and that the identifying information shall include:

- Name and license number(s) of the pharmacy and their expiration dates;
- Address, phone number, and website address, if applicable, of the pharmacy;
- DEA registration number, expiration date and date of most recent DEA inventory;
- Hours of operation of the pharmacy; and
- ADDS license number, expiration date, address, and hours of operation.

A provision requiring this information is necessary because the identifying information makes it clear to board inspectors and the PIC which pharmacy and ADDS the form pertains to and keeps all the identifying information in one place. The board requires the PIC to be aware of such information. The PIC must record the name, license numbers, and expiration dates for the pharmacy and ADDS associated with the pharmacy to ensure all licenses are current. This process assists the PIC with compliance with state and federal law. The PIC is required to record the address, phone number, and website to specify the pharmacy's current information and that this information matches board records. The PIC must record the current DEA number, expiration date and most recent DEA inventory because the PIC is more likely to realize whether the pharmacy is out of compliance with DEA requirements due to an expired license or an out of date DEA inventory. Further, this information allows the board to confirm the DEA registration, expiration date and date of DEA inventory to ensure compliance with federal

requirements. The hours of operation are necessary for the board to properly monitor and enforce regulations. Further, as the board conducts random unannounced inspections, knowledge of the hours of operations facilitate inspections during business hours for both the pharmacy and ADDS. Additionally, if the ADDS hours of operation are different than the pharmacy, the board needs to be aware of this as the PIC is responsible for the operation of the ADDS at all time. If the ADDS is being used while the pharmacy is closed, different requirements apply, specifically, if the ADDS is an Automated PATIENT dispensing system (APDS). An APDS requires patient consultation with a pharmacist and there needs to be service available should the system malfunction.

Documentation of this information further requires deliberate review by the PIC and should highlight if the pharmacy is noncompliant with either reporting required changes to the board (for example a new address) or DEA inventory requirements. These components also mirror the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (c)(2) is added to require that the PIC report if the pharmacy/ADDS follows laws and regulations that apply to that setting. This is added to require the PIC to respond “yes”, “no” or “not applicable” (N/A) to whether the PIC, pharmacy, and ADDS is, at the time of the self-assessment, in compliance with each of the requirements that apply to that setting. This addition is necessary to require the PIC to acknowledge compliance and/or noncompliance with various provisions of pharmacy law. Each noted “yes”, “no” or “not applicable” identifies to both the PIC as well as board staff that this self-review and evaluation has been completed by the PIC on behalf of the pharmacy/ADDS and areas of noncompliance noted. This element is necessary to ensure deliberate assessment by the PIC by evoking a review that will result in better compliance with laws. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (c)(3) adds, “For each “no” response, the PIC shall develop a written corrective action or action plan to come into compliance with the law.” to require a written corrective action or action plan to address all areas of noncompliance identified and this must be completed by the PIC. This addition requires the PIC to create a plan to remedy areas of noncompliance and makes it more likely that the pharmacy/ADDS will become fully compliant. Board staff regularly inspect pharmacies for compliance with laws and regulations; the addition of (c)(3) is necessary for a streamlined, efficient, and effective inspection process as inspectors can monitor the development of a correction action or action plan. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (c)(4) adds a requirement that the PIC initial each original page of the self-assessment form, by hand, and in ink. This addition is necessary to ensure that the document is prepared by the PIC and not another member of pharmacy staff. The requirement of a handwritten initial in ink on the form may prevent other pharmacy personnel from completing the self-assessment form for the PIC. This requires

deliberate action by the PIC and helps to convey the significance of the PIC's role in ensuring compliance with state and federal law. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (c)(5) adds a specific requirement that the PIC certify, under penalty of perjury, that they completed the self-assessment form. This affirms the PIC has completed the self-assessment, and makes the PIC understand the significance of his or her role in ensuring compliance. The certification also requires the PIC to acknowledge that all responses are subject to verification by the board. The certification that the information provided in the self-assessment form is true and correct must be made under penalty of perjury of the laws of the State of California. By requiring attestation under penalty of perjury, the board is communicating to the PIC and all future pharmacists-in-charge the gravity of falsifying information to the board. Pursuant to B&P section 4301(g), the board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Certification under penalty of perjury is necessary to ensure that the statements regarding completion of the self-assessment form and the answers to the compliance questions are truthful, factual representations made in good faith. (See, e.g., *In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 [judicial explanation for the use of certifications].) Should a PIC falsely certify to the completion of the self-assessment, the PIC could be disciplined by the board. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (c)(6) adds the requirement for a certification and acknowledgement by the ADDS owner that he or she has read and reviewed the completed self-assessment and an acknowledgement 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 requires the ADDS owner to be aware of the contents of the assessment completed by the PIC, and to certify, under penalty of perjury, on the final page of the self-assessment and the consequences of failure to do so.

By requiring attestation under penalty of perjury, the board is communicating to the ADDS owner and all future owners, the gravity of falsifying information to the board. Pursuant to BPC section 4301 (g), the board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Like the PIC, the pharmacy's license may be disciplined if its ADDS owner provides a false certification to the board. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (d) is added to require that the entire form be completed, even if to indicate that it does not apply, and to require that the fully executed self-assessment form be kept in the pharmacy for three years. This provision is necessary because, when only portions of the self-assessment are completed, the PIC has not fully assessed the pharmacy/ADDS compliance, and a full and meaningful assessment is necessary to

make it more likely the pharmacy/ADDS is compliant. Additionally, the three-year time frame is established within several sections of pharmacy law related to record keeping, specifically B&P section 4081 and 4333. This requirement also mirrors the requirements of the self-assessment forms incorporated by reference within CCR sections 1715 and 1784.

Subdivision (d) also adds the ability for the pharmacy to scan the original, completed self-assessment and keep it on file at the pharmacy in that fashion. It is important to have the original signed by hand ("wet" signatures, as opposed to electronically or digitally signed) for the reasons described above, but as long as the board can see that the relevant parties prepared the assessment, the board believes a copy of the form may be saved electronically. If the board can, upon inspection, review the wet signatures for compliance, and to match with the respective parties' initials or signatures, it can still hold licensees accountable if they fail to comply.

Subdivision (e) is added to require any identified areas of noncompliance to be corrected. This addition is necessary to ensure that the PIC and owner of the ADDS not only identify areas of noncompliance but correct them as well. Failure to do so, without a valid justification, could result in administrative or disciplinary action against the license by the board.

The authority and reference statutes have been added as appropriate. Sections 4119.11 and 4427.7 of the Business and Professions Code were added as authority sections. Additionally, 4001.1, 4008, 4017.3, 4021, 4022, 4036, 4037, 4038, 4040, 4050, 4051, 4052, 4059, 4070, 4076, 4081, 4101, 4105, 4107, 4113, 4119.1, 4125, 4126, 4180, 4186, 4305, 4330, 4332, 4333, 4400, 4427, 4427.1, 4427.2, 4427.3, 4427.4, and 4427.5 of the Business and Professions Code were added as references.

Form 17M-112 Incorporated by Reference

The board developed the self-assessment form to be utilized by the PIC and pharmacy yearly. The self-assessment form is an important educational tool to increase compliance with pharmacy law. By placing the statutory requirements within the form, the PIC and the regulated public have easy access to the legal requirements for ADDS.

On every page of Form 17M-112, the footer at the bottom left corner reads "17M-112 (Rev. 12/18)" to reflect the revision date. Section 1715.1 specifies that the self-assessment form must be completed by the PIC of the pharmacy. The PIC is to initial each page of the self-assessment as required in 1715.1(c)(4). The requirement of a handwritten initial in ink on the form requires acknowledgement of the PIC and may prevent other pharmacy personnel from completing the self-assessment form on the PIC's behalf. This also helps to convey the significance of the PIC's role in ensuring compliance with state and federal law.

Throughout the form "Yes, No, N/A" was added as needed above the check boxes to ensure the boxes are identified at the top of each page and the beginning of each section. For consistency of abbreviations, "BPC" is used throughout to reference Business and Professions Code sections, "HSC" is used throughout to reference Health and Safety Code sections, "CCR" is used throughout to reference sections of the

California Code of Regulations, “CFR” is used throughout to reference sections of the Code of Federal Regulations, and “USC” is used throughout to reference sections of the United States Code.

Throughout the form there are locations for the PIC to record corrective actions or an action plan and a completion date for any non-compliance issues identified. These areas provide tools for the PIC to document changes while completing the form and allow for future reference during an inspection.

Title Page – Page 1

The title of the self-assessment form is “Automated Drug Delivery System Self-Assessment” to accurately identify to whom the self-assessment form applies. The title will provide clarity to the regulated public.

An opening paragraph has been added to provide the legal references that require completion of the self-assessment and when additional self-assessments must be completed. Additionally, it provides the date when the self-assessments must be completed (annually by July 1st), what must be included (operation, maintenance, compliance, error, omissions, or complaints), and identifies the primary purpose of the self-assessment. Finally, it identifies the requirement that the self-assessment be completed and retained in the pharmacy for three years, as specified in 1715.1(d).

The PIC must complete the following fields on page 1 of the self-assessment:

- Pharmacy Name, Address, City, Phone and Fax number;
- Website (if any);
- Pharmacy license number and expiration date;
- DEA Registration number and expiration date;
- Date of last C2 Inventory Reconciliation and DEA Inventory; and
- Weekly Pharmacy Hours.

This information is required to accurately identify the pharmacy and ensure that the license/registration and required inventories are current. While completing this information the PIC will be able to identify possible compliance issues and take immediately steps to address the issues.

Page 2

The PIC must complete the following fields on page 2 of the self-assessment:

- PIC name and Pharmacist license number;
- ADDS license number, expiration date, Address, and City; and
- Weekly ADDS Hours and explanation if they are different than the pharmacy.

This information is required to accurately identify the appropriate ADDS that the self-assessment applies to because the pharmacy can have multiple ADDS licenses and the PIC must complete a separate self-assessment for each system. Additionally, this ensures that the ADDS license is current and that the PIC is cognizant that the ADDS is available for use outside of the pharmacy hours. The PIC must ensure that a pharmacist is available to address system issues or provide necessary patient consultation at any time the ADDS is in use.

The following changes are identified by the section number within the self-assessment form and not by the page number.

Section 1 – Definitions/Type of ADDS Device Used

The definition of ADDS is provided at the beginning of this section. Additionally, the law sections of BPC 4119.1(b)(1) and 4017.3(a) are provided as reference. As the purpose of the self-assessment is self-examination and education, the definitions and law sections are provided so that the PIC can locate the reference with the lawbook should they wish to further research the law specific to ADDS.

Subsection 1.1 is added to provide the definition of an automated patient delivery system (APDS) and the corresponding law sections [BPC 4119.11(b)(2), 4017.3(c)].

Subsection 1.2 is added to provide the definition of an automated unit dose system (AUDS) and the corresponding law sections [BPC 4119.11(b)(3), 4017.3(b)].

Subsections 1.1 and 1.2 are necessary to include for the PIC to identify the type of ADDS device. An APDS and an AUDS have different licensing and operation requirements so it is necessary for the PIC to clearly identify which type of machine is being utilized.

Section 2 – Location of Devices

Subsection 2.1 is added to identify if the ADDS is an APDS that provides services to patients of covered entities, as defined in section 256b of Title 42 of the USC. This information is necessary to ensure that the pharmacy is meeting all the requirements of BPC 4119.11(a) – (a)(11).

Subsection 2.2 is added to identify if the ADDS is located outside of the secured pharmacy area.

Subsection 2.3 is added to identify if the ADDS is located within a licensed health care facility as defined by HSC 1250.

Subsection 2.4 is added to identify if the ADDS is located within a licensed clinic as defined by HSC 1204 or 1204.1.

Subsection 2.5 is added to identify if the ADDS is located within a correctional clinic.

Subsection 2.6 is added to identify if the ADDS is located within a medical office.

Subsection 2.7 is added to identify if the ADDS is an AUDS that is operated by a licensed hospital pharmacy, which does not require a license if the specific requirements of BPC 4427.2(i) are met.

Subsections 2.1 through 2.7 are added to ensure that the ADDS is located at a location approved by the board and allowed by statute (BPC 4427.3(b)(1) – (b)(5) and 4427.2(i)). This information provides important detail to both the PIC and board inspectors. If the PIC determines that the ADDS is not located in one of the areas identified, the PIC can take steps to correct the issue and contact the board for assistance. Additionally, the information will be valuable during routine board

inspections as the PIC and the Inspector will be able to quickly identify the type of ADDS and ensure that it is properly licensed and appropriately inspected.

Finally, a note is added are the end of section 2 to provide clarity to licensees that an ADDS license is not needed for technology installed within the secured premises of a licensed pharmacy, as specified in BPC 4427.2(j).

Section 3 – General Requirements for All Types of ADDS

This section title accurately identifies that the requirements identified apply to all ADDS. The following subsections are necessary to ensure that the pharmacy and PIC are aware of the general requirements that apply to all ADDS and to ensure that the ADDS, pharmacy, and PIC are operating in compliance with pharmacy law. Each subsection identifies a specific requirement within statute. A reference to the statute is included to allow the PIC or regulated public to further review the law section should they wish to do so. Additionally, there are specific requirements based on the location of the ADDS that will be identified in other sections within the self-assessment form.

Subsection 3.1 is added to specify the requirement that an ADDS installed, leased, owned, or operated and located within California be licensed by the board [BPC 4427.2(a) and 4427.4(a)]. ADDS located outside California are not subject to these requirements.

Subsection 3.2 is added to specify the requirement that the ADDS license must be issued to a California pharmacy that holds a current, valid, and active pharmacy license [BPC 4427.2(b)].

Subsection 3.3 is added to specify the requirement that each ADDS has its own separate license [BPC 4427.2(c)].

Subsection 3.4 is added to specify the conditions for which an ADDS operates. The conditions are identified within BPC 4427.2(d)(1) – (d)(4) and are as follows:

- 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.

Subsection 3.5 is added to specify the requirement that a prelicensure inspection be completed and to allow space for the PIC to record the date of the inspection. BPC 4427.2(e) requires that the inspection be completed within 30 days of completion of the application for licensure. The recording of the date ensures that an inspection was completed prior to the licensure and prior to the use of the device.

Subsection 3.6 is added to specify the requirement that a new application for licensure be submitted should the ADDS be relocated from its approved/licensed location [BPC 4427.2(e)].

Subsection 3.7 is added to specify the requirement that the board be notified within 30 days should the ADDS be replaced with a new device [BPC 4427.2(e)].

Subsection 3.8 is added to specify the requirement that the ADDS license be cancelled by operation of law if the underlying pharmacy license is not current, valid, and active. Additionally, it specifies that the pharmacy must apply for a new ADDS license once the underlying license is reissued or reinstated as required by BPC 4427.2(f).

Subsection 3.9 is added to specify the requirement for the underlying pharmacy to notify the board within 30 days should the use of the ADDS be discontinued per BPC 4427.2(g).

Subsection 3.10 is added to specify the requirement for the ADDS license to be renewed annually at the time of the underlying pharmacy license renewal per BPC 4427.2(h).

Subsection 3.11 is added to specify the requirement for the ADDS to be located within an enclosed building with a premises address at a location approved by the board per BPC 4427.3(a).

Subsection 3.12 is added to specify the requirement for the underlying pharmacy and the location of the ADDS jointly establish written policies and procedures per BPC 4427.3(c).

Subsection 3.13 is added to specify the requirement that the ADDS is operated under the supervision of the pharmacy that was issued the ADDS license per BPC 4427.4(b).

Subsection 3.14 is added to specify that the ADDS is an extension of the pharmacy and, as such, it is also subject to board inspection per BPC 4008 [BPC 4427.4(c)].

Subsection 3.15 is added to specify that the drugs and devices (which is defined within BPC sections 4022, 4023, and 4025) are the responsibility of the pharmacy and are considered part of its inventory per BPC 4427.4(d). Additionally, all items dispensed from the ADDS are considered dispensed from the pharmacy. The pharmacy and PIC are responsible for the inventory within the pharmacy and are required to conduct quarterly inventories of all Schedule II controlled substances (16 CCR 1715.65). This section ensures that they are aware that the ADDS inventory is included and must be counted.

Subsection 3.16 is added to specify that only a pharmacist or a pharmacy technician or intern under the supervision of a pharmacist may restock an ADDS. Additionally, ADDS located within a health facility may be restocked in compliance with HSC 1261.6, per BPC 4427.4(e)(1). Unauthorized individuals are not permitted to access the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 3.17 is added to ensure that access to the ADDS is restricted to authorized individuals and that access is tracked using an ID and password or a biosensor for accountability of the drugs and devices within the system per BPC 4427.4(e)(2). Unauthorized individuals are not permitted to access the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 3.18 is added to ensure that complete and accurate records of all transactions completed on the system, this includes who accesses it and drugs added to or removed from the system per BPC 4427.4(e)(3). These records ensure accountability of the individuals accessing the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 3.19 is added to specify that drugs and devices must be stored in a secured room authorized by the board for no more than 48 hours if they are not immediately added to the ADDS. Additionally, to ensure that an inventory is taken on any drugs and devices stored in the secured storage prior to removal to identify any losses or overages per BPC 4427.4(f). These requirements ensure the safety and security of the drugs and devices stored and identify possible diversion.

Subsection 3.20 is added to specify the training requirement for the ADDS. Pharmacy personnel and the personnel using the ADDS must receive training on the use of the ADDS prior to installation and annually ongoing per BPC 4427.5. This is to ensure that everyone is aware of how to operate and use the system.

Subsection 3.21 is added to specify the recordkeeping and quality assurance requirements for the ADDS. Additionally, it ensures that these records are maintained separate from the other pharmacy records per BPC 4427.7(b).

Additional instructions follow section 3. The PIC must check the box next to the section that applies to the ADDS the pharmacy is using. The selection within this area should match the answers within Section 2 – Location of Device. Based on the type of ADDS in use, the PIC would complete the corresponding section of the self-assessment, meaning the PIC will not complete all sections of the self-assessment. They will complete sections 1, 2, 3, and one section between section 4 and 8. Additionally, the PIC and the owner of the ADDS shall sign the certification on page 33 after completing the self-assessment. This is identified to ensure that this step is not inadvertently overlooked.

Section 4 – APDS used to provide pharmacy service to covered entities and medical professionals contracted with a covered entity

Subsection A identifies the general requirements for this type of ADDS.

Subsection 4.1 is added to specify that the pharmacy and the covered entity must have a contract for the pharmacy to provide services through the use of the ADDS as required by BPC 4119.11(a)(2).

Subsection 4.2 is added to specify that the contract between the covered entity and the pharmacy for service must comply with the guidelines published by the Health

Resources and Services Administration and that the contract must be available for inspection by board staff during normal business hours per BPC 4126(a).

Subsection 4.3 is added to ensure that the drug purchased and received pursuant to Section 256b of Title 42 USC are segregated and not commingled with that pharmacy's other drug inventory by physical or electronic means per BPC 4126(b). Drugs purchased pursuant to Section 256b of Title 42 USC are purchased at a reduced price for patients of the covered entity. These drugs cannot be commingled with the pharmacy inventory because they can only be dispensed to patients of the covered entity.

Subsection 4.4 is added to ensure that all records of acquisition and disposition are maintained in the readily retrievable form separate from the pharmacy's other records per BPC 4126(b). The records must be readily retrievable so that board staff can review them during an inspection. Additionally, it is necessary to keep the records separate to ensure that the drugs are going to patients of the covered entity. The records can be maintained electronically as long as they are readily retrievable at the time of the inspection.

Subsection 4.5 is added to ensure that drugs for a patient of a covered entity are returned to the distributor is there is a change in circumstance of the covered entity. As identified in BPC 4126(c), a change if circumstance includes, but is not limited to, the termination or expiration of the contract between the pharmacy and the covered entity, the closure of a pharmacy, disciplinary action against the pharmacy, or closure of the covered entity. This ensures that the drugs are not inadvertently commingled with the pharmacy's inventory and given to a patient other than those of the covered entity.

Subsection 4.6 is added to ensure that the PIC is aware that the licensee cannot have a pharmacy license and a wholesaler license while participating in a contract to dispense preferentially priced drugs, per BPC 4126(d).

Subsection B identifies the requirements for the underlying pharmacy with this type of ADDS (an APDS for patients of a covered entity).

Subsection 4.7 is added to ensure that the pharmacy has obtained a license to operate to the APDS at the covered entity site, per BPC 4119.11(a)(1).

Subsection 4.8 is added to ensure that the pharmacy has obtained a separate license for each APDS location and that each license has been renewed annually with the pharmacy license. Additionally, a note is provided to ensure that the PIC is aware that that board can issue an APDS at a location where another site license has been issued per BPC 4119.11(a)(8). Previously, the board could only issue one site license per address, so this note is added to specify the new statute specific to APDS.

Subsection 4.9 is added to ensure that the APDS was inspected prior to use of the APDS per BPC 4119.11(a)(9). Additionally, a space is provided for the PIC to record the date of the inspection. This serves as a check for the PIC to confirm that the inspection was completed and requires a deliberate action by the PIC. The PIC could face

disciplinary action should they confirm that an inspection was completed, and board inspectors determine that this was not the case.

Subsection 4.10 is added to specify that a new APDS application must be submitted for approval if the APDS is relocated.

Subsection 4.11 is added to specify that the pharmacy must notify the board within 30 days of discontinuing use of the APDS or replacement of the APDS.

Subsection 4.12 is added to specify that a new APDS application is required if the license is cancelled due to the underlying pharmacy's license being inactive, expired, not valid, or cancelled. Additionally, should the APDS license be cancelled, a new license can only be issued if the underlying pharmacy license has been reissued or reinstated.

Subsection 4.13 is added to ensure that the underlying pharmacy does not have more than 15 APDS licensees. Additionally, space is provided for the PIC to list the APDS licenses per BPC 4119.11(d)(10). During this process, the PIC will determine if the underlying pharmacy obtained more than 15 licenses and the PIC can take corrective action to address the non-compliance issue.

Subsection 4.14 is added to ensure that the pharmacy maintains written policies and procedures for the APDS for 3 years from the date of last use of the APDS as required by BPC 4119(d)(11).

Subsection 4.15 is added to ensure that the pharmacy has completed the annual self-assessment pursuant to CCR 1715 and BPC 4427.7(a). Additionally, space is provided for the PIC to provide the date of the last self-assessment.

Subsection 4.16 is added for the PIC to ensure that the pharmacy is compliant with all recordkeeping and quality assurance requirements of BPC 4119.11 and that those record are maintained separately from the other pharmacy records per BPC 4119.11(j).

Subsection 4.17 is added specify that the drugs stored within the APDS are part of the pharmacy's inventory and that the drugs dispensed are considered to have been dispended by the pharmacy per BPC 4119.11(a)(3). This requirement is important as should drug shortages or overages occur with the use of the APDS, the PIC and pharmacy are responsible for those losses or overages and must attempt to identify the cause of the loss or overage and report the information to the board as required by CCR 1715.6.

Subsection 4.18 is added to specify that the pharmacy is responsible for the operation, maintenance, and security of the APDS and for the training of staff on the use of the APDS.

Subsection C identifies the requirements the pharmacist with this type of ADDS (an APDS for patients of a covered entity).

Subsection 4.19 is added to ensure that the APDS is operated under the supervision of a licensed pharmacist acting on behalf of the pharmacy. Additionally, it is noted that the pharmacist need not be present at the site of the APDS and that the system may be supervised electronically per BPC 4119.11(a)(7).

Subsection 4.20 is added to ensure that only the pharmacist is stocking the APDS. Additionally, the APDS may be stocked outside the facility if it is stocked with removable pockets, cards, drawers, or single dose containers if specific conditions are met per BPC 4119.11(g).

Subsection 4.20.1 specifies that only a pharmacist, intern, or pharmacy technician working under the supervision of the pharmacist may place drugs into the removable pockets, cards, drawers, or single dose containers.

Subsection 4.20.2 specifies that transportation of the removable pockets, cards, drawers, or single dose containers must be done in a tamper-evident container.

Subsection 4.20.3 specifies that there are policies and procedures in place to ensure that the removable pockets, cards, drawers, or single dose containers are properly placed into the APDS.

If any of the three conditions above are not met, the drugs cannot be stocked into the removable pockets, cards, drawers, or single dose containers outside of the facility.

Subsection 4.21 specifies that the pharmacist must conduct a monthly review and physical inspection of the APDS and the drugs within the system. This review shall include the operation, maintenance, and cleanliness of the APDS, as well as, a review of all transaction records to ensure the security and accountability of the system per BPC 4119.11(h). Additionally, space is provided for the PIC to provide the date of the last monthly review.

Subsection 4.22 specifies that the PIC has ensured that all controlled substances are accounted for, access to the system is limited to authorized personnel, ongoing evaluations are completed for discrepancies or unusual access, and confirmed drug losses are reported to the board per CCR 1715.65(h).

Subsection D identifies the device requirements of this type of ADDS (an APDS for patients of a covered entity).

Subsection 4.23 specifies the requirement that access to the APDS be controlled and tracked using an identification/password system or biosensor. Additionally, it specifies that systems that use password tracking must also include a camera to record an image on the person accessing the system and that the image must be maintained for at least 180 days per BPC 4119.11(e).

Subsection 4.24 specifies that the APDS must make complete and accurate records of all transactions, including the user that accessed the system and the drugs added or removed from the system per BPC 4119.11(f).

Subsection 4.25 specifies that the APDS must collect, control, and maintain all transaction information to track the movement of drugs into and out of the system per BPC 4119.11(c)(1).

Subsection 4.26 specifies that the APDS maintain the transaction information in a readily downloadable format for a minimum of 3 years per BPC 4119.11(c)(2).

Subsection 4.27 specifies that the APDS may dispense medication directly to patients if specific conditions are met per BPC 4119.11(d).

Subsection 4.27.1 specifies that the pharmacy must develop and implement written policies and procedures that are reviewed annually and include numerous items, including: maintaining security, determining and applying inclusion criteria to establish which drugs and devices may be placed into the system, ensuring patients are aware of consultation services, describe responsibilities and training of pharmacy personnel and others who use the system, orientating patients on the use of the systems, ensuring that the use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of the drugs and devices in the event the systems is disabled or malfunctions per BPC 4119.11(d)(1) – (d)(1)(F). Additionally, space is provided for the PIC to provide the date of the last policy review.

Subsection 4.27.2 specifies that the APDS may only be used for patients who have signed a consent waiver demonstrating their informed consent to receive prescribed drugs and devices via the APDS per BPC 4119.11(d)(2). Additionally, the PIC is instructed to attach a copy of the consent form utilized to the back of the self-assessment form. This is done in order for the consent form will be readily available for review during an inspection so that board staff can confirm that the consent form demonstrates informed consent by a patient.

Subsection 4.27.3 specifies that the APDS shall have the ability to identify each patient and only release that specific patient’s drug and devices to the patient or the patient’s agent per BPC 4119.11(d)(3).

Subsection 4.27.4 specifies that the pharmacist must perform all clinical services as part of the dispensing process. This includes, but is not limited to, a drug utilization review and patient consultation per BPC 4119.11(d)(4).

Subsection 4.27.5 specifies that drugs are only dispensed from the APDS upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient’s profile for potential contraindications and adverse drug reactions per BPC 4119.11(d)(5).

Subsection 4.27.6 specifies that the pharmacist shall consult with patients for the first time on all prescribed drugs and devices dispensed from the APDS. Additionally, it specifies that the consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities per BPC 4119.11(d)(6).

Subsection 4.27.7 specifies that the APDS shall have the name, address, and telephone number of the pharmacy displayed prominently on the system per BPC 4119.11(d)(7).

Subsection 4.27.8 specifies that the prescription labels on the drugs dispensed from the APDS must comply with BPC 4076 and CCR 1707.5 per BPC 4119.11(d)(8).

Subsection 4.27.9 specifies that complaints, errors, or omissions involving the APDS must be reviewed as part of the pharmacy's quality assurance pursuant to BPC 4125 as required by BPC 4119.11(d)(9).

Subsection 4.28 specifies that a federal warning label prohibiting the transfer of controlled substances must be included on the prescription container, as required by 21 CFR 290.5.

Subsection 4.29 specifies that prescriptions must be dispensed in a new, child-resistant container or a senior-adult ease-of-opening container per 16 CFR 1700.15. Additionally, a non-complying package may be used when requested by the prescriber or the purchaser per 15 USC 1473(b).

Subsection 4.30 specifies that patient package inserts must be dispensed with all estrogen medications as required by 21 CFR 310.515.

Subsection 4.31 specifies that the pharmacy is required to provide patients with Black Box Warning information as required by 21 CFR 201.57(c).

Subsection 4.32 specifies that the pharmacy is required to provide patients with medication guides as required by 21 CFR 208.1.

Subsection E identifies the record keeping requirements.

Subsection 4.33 is added for the PIC to ensure that the pharmacy and APDS is compliant with all recordkeeping and quality assurance requirements of BPC 4119.11 and that those record are maintained separately from the other pharmacy records per BPC 4119.11(j).

Subsection 4.34 is added for the PIC to ensure that the pharmacy is keeping the acquisition and disposition records for dangerous drugs stored in the APDS separate from other pharmacy records as required by BPC 4119.11(a)(4).

Subsection 4.35 specifies that records maintained electronically must be done in a way so that the PIC or pharmacist on duty can produce a hardcopy and electronic copy of all records of acquisition and disposition at all times when the licensed premises is open for business as required by BPC 4105(d)(1).

Subsection F identifies the requirements for the Policies and Procedures.

Subsection 4.36 is added for the PIC to ensure that the pharmacy has developed and implemented written policies and procedures that are reviewed annually and include

numerous items, including: maintaining security, determining and applying inclusion criteria to establish which drugs and devices may be placed into the system, ensuring patients are aware of consultation services, describe responsibilities and training of pharmacy personnel and others who use the system, orientating patients on the use of the systems, ensuring that the use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of the drugs and devices in the event the systems is disabled or malfunctions per BPC 4119.11(d)(1) – (d)(1)(F). Additionally, space is provided for the PIC to provide the date of the last policy review.

Subsection 4.37 is added for the PIC to ensure that the pharmacy has policies and procedures that include appropriate security measures and monitoring on the inventory within the APDS to prevent theft and diversion as required by BPC 4105.5(c)(2).

Subsection 4.38 specifies that the pharmacy must report drug losses as required by BPC 4104, 4105.5(c), CCR 1715.6, and 21 CFR 1301.76. Additionally, space is provided for the PIC to provide the date of the last report of a drug loss.

Section 5 – ADDS adjacent to the secured pharmacy area or in Medical Offices

Subsection A identifies the general requirements for this type of ADDS.

Subsection 5.1 is added to ensure that the pharmacy maintains written policies and procedures for the APDS for 3 years from the date of last use of the APDS as required by BPC 4427.6(l).

Subsection 5.2 is added for the PIC to ensure that the pharmacy has developed and implemented written policies and procedures that are reviewed annually and include numerous items, including: maintaining security, determining and applying inclusion criteria to establish which drugs and devices may be placed into the system, ensuring patients are aware of consultation services, describe responsibilities and training of pharmacy personnel and others who use the system, orientating patients on the use of the systems, ensuring that the use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of the drugs and devices in the event the systems is disabled or malfunctions per BPC 4427.6(a) – (a)(6).

Subsection 5.3 is added to ensure that the underlying pharmacy does not have more than 15 APDS licensees. Additionally, space is provided for the PIC to list the APDS licenses per BPC 4427.6(k). During this process, the PIC will determine if the underlying pharmacy obtained more than 15 licenses and the PIC can take corrective action to address the non-compliance issue.

Subsection B identifies the requirements the pharmacist with this type of ADDS (adjacent to the secured pharmacy area or in Medical Offices)

Subsection 5.4 specifies that the pharmacist must perform all clinical services as part of the dispensing process. This includes, but is not limited to, a drug utilization review and patient consultation per BPC 4427.6(d).

Subsection 5.5 specifies that drugs are only dispensed from the APDS upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions per BPC 4427.6(e).

Subsection 5.6 specifies that the pharmacist shall consult with patients for the first time on all prescribed drugs and devices dispensed from the APDS. Additionally, it specifies that the consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities per BPC 4427.6(f).

Subsection 5.7 specifies that the PIC has ensured that all controlled substances are accounted for, access to the system is limited to authorized personnel, ongoing evaluations are completed for discrepancies or unusual access, and confirmed drug losses are reported to the board per CCR 1715.65(h).

Subsection 5.8 is added to ensure that the pharmacy has completed the annual self-assessment pursuant to CCR 1715 and BPC 4427.7(a). Additionally, space is provided for the PIC to provide the date of the last self-assessment.

Subsection C identifies the device requirements of this type of ADDS (adjacent to the secured pharmacy area or in Medical Offices)

Subsection 5.9 specifies that only a pharmacist or a pharmacy technician or intern under the supervision of a pharmacist may restock an APDS. Additionally, an APDS located within a health facility may be restocked in compliance with HSC 1261.6, per BPC 4427.4(e)(1). Unauthorized individuals are not permitted to access the APDS for the safety and security of the drugs and devices stored within the system.

Subsection 5.10 specifies that access to the APDS is restricted to authorized individuals and that access is tracked using an ID and password or a biosensor for accountability of the drugs and devices within the system per BPC 4427.4(e)(2). Unauthorized individuals are not permitted to access the APDS for the safety and security of the drugs and devices stored within the system.

Subsection 5.11 specifies that complete and accurate records of all transactions completed on the system, this includes who accesses it and drugs added to or removed from the system per BPC 4427.4(e)(3). These records ensure accountability of the individuals accessing the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 5.12 specifies that drugs and devices must be stored in a secured room authorized by the board for no more than 48 hours if they are not immediately added to the ADDS. Additionally, to ensure that an inventory is taken on any drugs and devices stored in the secured storage prior to removal to identify any losses or overages per BPC 4427.4(f). These requirements ensure the safety and security of the drugs and devices stored and identify possible diversion.

Subsection 5.13 specifies that the drugs stored within the APDS are part of the pharmacy's inventory and that the drugs dispensed are considered to have been dispended by the pharmacy per BPC 4427.4(d). This requirement is important as should drug shortages or overages occur with the use of the APDS, the PIC and pharmacy are responsible for those losses or overages and must attempt to identify the cause of the loss or overage and report the information to the board as required by CCR 1715.6.

Subsection 5.14 specifies that the APDS may only be used for patients who have signed a consent waiver demonstrating their informed consent to receive prescribed drugs and devices via the APDS per BPC 4427.6(b). Additionally, the PIC is instructed to attach a copy of the consent form utilized to the back of the self-assessment form. This is done in order for the consent form will be readily available for review during an inspection so that board staff can confirm that the consent form demonstrates informed consent by a patient.

Subsection 5.15 specifies that the APDS shall have the ability to identify each patient and only release that specific patient's drug and devices to the patient or the patient's agent per BPC 4427.6(c).

Subsection 5.16 specifies that the APDS shall have the name, address, and telephone number of the pharmacy displayed prominently on the system per BPC 4427.6(g).

Subsection 5.17 specifies that complaints, errors, or omissions involving the APDS must be reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125 as required by BPC 4427.6(i).

Subsection 5.18 specifies that an APDS located and operated within a medical office or other location where patients are regularly seen for diagnosis and treatment, can only be used to dispense dangerous drugs and devices to the patients of the practice per BPC 4427.6(j).

Subsection 5.19 specifies that the prescription labels on the drugs dispensed from the APDS must comply with BPC 4076 and CCR 1707.5 per BPC 4427.6(h).

Subsection 5.20 specifies that a federal warning label prohibiting the transfer of controlled substances must be included on the prescription container, as required by 21 CFR 290.5.

Subsection 5.21 specifies that prescriptions must be dispensed in a new, child-resistant container or a senior-adult ease-of-opening container per 16 CFR 1700.15. Additionally, a non-complying package may be used when requested by the prescriber or the purchaser per 15 USC 1473(b).

Subsection 5.22 specifies that patient package inserts must be dispensed with all estrogen medications as required by 21 CFR 310.515.

Subsection 5.23 specifies that the pharmacy is required to provide patients with Black Box Warning information as required by 21 CFR 201.57(c).

Subsection 5.24 specifies that the pharmacy is required to provide patients with medication guides as required by 21 CFR 208.1.

Subsection E identifies the record keeping requirements.

Subsection 5.25 is added for the PIC to ensure that the pharmacy and APDS is compliant with all recordkeeping and quality assurance requirements of BPC 4427.6 and that those record are maintained separately from the other pharmacy records per BPC 4427.6(b).

Subsection 5.26 is added for the PIC to ensure that the pharmacy is keeping the acquisition and disposition records for dangerous drugs stored in the APDS separate from other pharmacy records as required by BPC 4119.11(a)(4).

Subsection 5.27 specifies that records maintained electronically must be done in a way so that the PIC or pharmacist on duty can produce a hardcopy and electronic copy of all records of acquisition and disposition at all times when the licensed premises is open for business as required by BPC 4105(d)(1).

Subsection F identifies the requirements for the Policies and Procedures.

Subsection 5.28 is added for the PIC to ensure that the pharmacy has developed and implemented written policies and procedures that are reviewed annually and include numerous items, including: maintaining security, determining and applying inclusion criteria to establish which drugs and devices may be placed into the system, ensuring patients are aware of consultation services, describe responsibilities and training of pharmacy personnel and others who use the system, orientating patients on the use of the systems, ensuring that the use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of the drugs and devices in the event the systems is disabled or malfunctions per BPC 4427.6(a)(1) – (a)(6). Additionally, space is provided for the PIC to provide the date of the last policy review.

Subsection 5.29 specifies that the pharmacy must report drug losses as required by BPC 4104, 4105.5(c), CCR 1715.6, and 21 CFR 1301.76. Additionally, space is provided for the PIC to provide the date of the last report of a drug loss.

Section 6 – ADDS in a health facility pursuant to HSC 1250

Subsection A identifies the general requirements for this type of ADDS

To ensure clarity to the regulated public within this section, the terms “facility” and “pharmacy services” are defined.

“Facility” means a health facility licensed pursuant to subdivisions (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)]

“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)]

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

Subsection 6.2 is added to ensure that the policies and procedures define access to the ADDS and limits to access to equipment and drugs per HSC 1261.6(d)(1).

Subsection 6.3 specifies that the ADDS policies and procedures must be maintained at the pharmacy and the location where the ADDS is in used per HSC 1261.6(d)(2) and BPC 4427.3(c).
Subsection 6.4 specifies that the pharmacy is responsible for reviewing the drugs contained within the ADDS and the operation and maintenance of the ADDS per HSC 1261.6(h).

Subsection B identifies the requirements the pharmacist with this type of ADDS (ADDS in a health facility pursuant to HSC 1250)

Subsection 6.5 is added to ensure that only the pharmacist is stocking the ADDS. Additionally, the ADDS may be stocked outside the facility if it is stocked with removable pockets, cards, drawers, or single dose containers if specific conditions are met per HSC 1261.6(g).

Subsection 6.5.1 specifies that only a pharmacist, intern, or pharmacy technician working under the supervision of the pharmacist may place drugs into the removable pockets, cards, drawers, or single dose containers per HSC 1261.6(g)(1).

Subsection 6.5.2 specifies that transportation of the removable pockets, cards, drawers, or single dose containers must be done in a tamper-evident container per HSC 1261.6(g)(2).

Subsection 6.5.3 specifies that the facility and pharmacy have policies and procedures in place to ensure that the removable pockets, cards, drawers, or single dose containers are properly placed into the APDS.

If any of the three conditions above are not met, the drugs cannot be stocked into the removable pockets, cards, drawers, or single dose containers outside of the facility.

Subsection 6.6 specifies that access to the ADDS must be individualized, specific, and limited to facility and contract personnel who are authorized by law to administer drugs per HSC 1261.6(c).

Subsection 6.7 specifies that the pharmacist must review and approve all orders prior to a drug being removed from the ADDS for administration to a patient per HSC 1261.6(f)(2). The pharmacist must review the prescriber’s orders and the patient’s

profile for potential contraindications and adverse drug reactions as is necessary for patient safety.

Subsection 6.8 specifies that the pharmacist must conduct a monthly review and physical inspection of the ADDS and the drugs within the system. This review shall include the operation, maintenance, and cleanliness of the ADDS, as well as, a review of all transaction records to ensure the security and accountability of the system per HSC 1261.6(h). Additionally, space is provided for the PIC to provide the date of the last monthly review.

Subsection 6.9 specifies that the PIC has ensured that all controlled substances are accounted for, access to the system is limited to authorized personnel, ongoing evaluations are completed for discrepancies or unusual access, and confirmed drug losses are reported to the board per CCR 1715.65(h).

Subsection 6.10 is added to ensure that the pharmacy has completed the annual self-assessment pursuant to CCR 1715 and BPC 4427.7(a). Additionally, space is provided for the PIC to provide the date of the last self-assessment.

Subsection C identifies the requirements the pharmacist with this type of ADDS (ADDS in a health facility pursuant to HSC 1250).

Subsection 6.11 specifies that the stocking and restocking of the ADDS must be performed in compliance with HSC 1261.6 per BPC 4427.4(e)(1).

Subsection 6.12 is added to ensure the PIC is aware that drugs and devices must be stored in a secured room authorized by the board for no more than 48 hours if they are not immediately added to the ADDS. Additionally, to ensure that an inventory is taken on any drugs and devices stored in the secured storage prior to removal to identify any losses or overages per BPC 4427.4(f). These requirements ensure the safety and security of the drugs and devices stored and identify possible diversion.

Subsection 6.13 specifies that the transaction information from the ADDS must be in a readily available format for review and inspection and maintained in the facility a minimum of 3 years per HSC 1261.6(b).

Subsection 6.14 specifies that the information required by BPC Section 4076 and HSC 111480 must be readily available at the time of drug administration if unit dose packaging or unit of use packaging is used per HSC 1261.6(i). Unit dose packaging, for purposes of this section, includes blister pack cards.

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

Subsection 6.15 specifies that 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. Additionally, the drug must only be retrieved 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 per HSC 1261.6(e)(1).

Subsection 6.16 specifies that the 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 per HSC 1261.6(e)(2).

Subsection 6.17 specifies that the 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 per HSC 1261.6(e)(3).

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

Subsection 6.18 specifies that the drugs removed from the ADDS for administration to a patient must be in properly labeled units of administration containers or packages per HSC 1261.6(f)(1).

Subsection 6.19 specifies that a pharmacist must review and approve all orders prior to a drug being removed from the ADDS for administration to a patient per HSC 1261.6(f)(2). The pharmacist must review the prescriber's orders and the patient's profile for potential contraindications and adverse drug reactions as is necessary for patient safety.

Subsection 6.20 specifies that the pharmacy controls access to the drugs stored within the ADDS per HSC 1261.6(f)(3).

Subsection 6.21 specifies that access to the ADDS is controlled and tracked using an ID and password or a biosensor for accountability of the drugs and devices within the system per BPC 4427.4(e)(2) and HSC 1261.6(f)(4). Unauthorized individuals are not permitted to access the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 6.22 specifies that complete and accurate records of all transactions completed on the system, this includes who accesses the system and all drugs added to or removed from the system per BPC 4427.4(e)(3) and HSC 1261.6(f)(5). These records ensure accountability of the individuals accessing the ADDS for the safety and security of the drugs and devices stored within the system.

Subsection 6.23 specifies that after review of the prescriber's order, access to the ADDS is limited to licensed personnel and only to the drugs ordered by the prescriber and reviewed by the pharmacist and only for the specific patient per HSC 1261.6(f)(6).

Subsection 6.24 specifies that licensed personnel should only have access to the drug ordered for the specific schedule administration time when the prescriber's order requires dosage variation of the same drug per HSC 1261.6(f)(6).

Subsection 6.25 specifies that the ADDS must have electronic and mechanical safeguards in place to ensure that the drugs delivered to the patient are specific to that patient if the ADDS allows for licensed personnel to access multiple drugs and are not patient specific in their design per HSC 1261.6(f)(7).

Subsection D identifies the record keeping requirements.

Subsection 6.26 is added for the PIC to ensure that the pharmacy and ADDS is compliant with all recordkeeping and quality assurance requirements established within pharmacy law and regulation, and that those record are maintained separately from the other pharmacy records per BPC 4427.7(b).

Subsection 6.27 specifies that the transaction information from the ADDS must be in a readily available format for review and inspection and maintained in the facility a minimum of 3 years per HSC 1261.6(b).

Subsection E identifies the requirements for the Policies and Procedures.

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

Subsection 6.29 is added to ensure that the policies and procedures define access to the ADDS and limits to access to equipment and drugs per HSC 1261.6(d)(1).

Subsection 6.30 specifies that the ADDS policies and procedures must be maintained at the pharmacy and the location where the ADDS is in used per HSC 1261.6(d)(2) and BPC 4427.3(c).

Subsection 6.31 specifies that there are policies and procedures in place to ensure that the removable pockets, cards, drawers, or single dose containers are properly placed into the ADDS per HSC 1261.6(g)(3).

Subsection 6.32 is added for the PIC to ensure that the pharmacy has policies and procedures that include appropriate security measures and monitoring on the inventory within the ADDS to prevent theft and diversion as required by BPC 4105.5(c)(2).

Subsection 6.33 specifies that the pharmacy's policies and procedures include a provision for reporting drug losses as required by BPC 4104, 4427.2(d)(4), CCR 1715.6, and 21 CFR 1301.76. Additionally, space is provided for the PIC to provide the date of the last report of a drug loss.

<u>Section 7 – APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190</u>

Subsection A identifies the general requirements for this type of ADDS.

Subsection 7.1 specifies that the ADDS must be located inside an enclosed building with a premises address, at a location approved by the board per BPC 4427.3(a). Additionally, the clinic must have a current clinic license issued by the Board of Pharmacy per BPC 4180 or 4190 or be licensed per HSC 1204 or 1204.1. A space is provided for the PIC to provide the license number and expiration date.

Subsection 7.2 specifies that the clinic 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 per BPC 4186(a). Additionally, the policies and procedures must be maintained at the location where the ADDS is being used.

Subsection 7.3 specifies that the drugs removed from the ADDS must be provided to the patient by a licensed health professional per BPC 4186(b).

Subsection 7.4 specifies that the clinic is responsible for the review of the drugs within the ADDS, as well as, the operation and maintenance of the system.

Subsection 7.5 specifies that the prescription labels on the drugs dispensed from the ADDS must comply with BPC 4076 and CCR 1707.5 per BPC 4186(g) and 4427.6(h).

Subsection 7.6 specifies that the clinic must keep records of the kind and amount of drugs purchased, administered, and dispensed. Additionally, the records must be maintained for a minimum of three years and must be available for inspection per BPC 4180(a)(2).

Subsection 7.7 specifies that the ADDS location must meet the requirements of BPC 4427.3 and be secure from access and removal by unauthorized individuals per BPC 4427.2(d)(2).

Subsection 7.8 specifies that clinics licensed under BPC 4180 and 4190 shall perform periodic inventory and inventory reconciliation functions as required by CCR 1715.65 to detect and prevent the loss of controlled substances.

Subsection 7.9 specifies that the clinic must compile an inventory reconciliation report of all federal Schedule II controlled substances at least every three months as required by CCR 1715.65(c). Additionally, a space is provided for the PIC to record the date that the last inventory was completed.

Subsection 7.10 specifies that the clinic shall report identified drug losses and known causes to the board within 30 days of discovery as required by CCR 1715.65(d). Additionally, if the loss is due to theft, diversion, or for self-use, the loss shall be reported to the board within 14 days of discovery as required by BPC 4104. Finally, if the clinic is unable to identify the cause of the loss, additional investigation shall be undertaken to identify the cause and actions necessary to prevent additional losses.

Subsection 7.11 specifies that the individual(s) who completed the inventory reconciliation report and the professional director of the clinic shall date and sign the

report. Additionally, the reports shall be readily retrievable within the clinic for three years as required by CCR 1715.65(e).

Subsection 7.12 specifies that complaints, errors, or omissions involving the ADDS must be reviewed as part of the pharmacy's quality assurance program pursuant to BPC 4125 as required by BPC 4427.6(i).

Subsection 7.13 specifies that a federal warning label prohibiting the transfer of controlled substances must be included on the prescription container, as required by 21 CFR 290.5.

Subsection 7.14 specifies that prescriptions must be dispensed in a new, child-resistant container or a senior-adult ease-of-opening container per 16 CFR 1700.15. Additionally, a non-complying package may be used when requested by the prescriber or the purchaser per 15 USC 1473(b).

Subsection 7.15 specifies that patient package inserts must be dispensed with all estrogen medications as required by 21 CFR 310.515.

Subsection 7.16 specifies that the pharmacy is required to provide patients with Black Box Warning information as required by 21 CFR 201.57(c).

Subsection 7.17 specifies that the pharmacy is required to provide patients with medication guides as required by 21 CFR 208.1.

Subsection 7.18 specifies that an ADDS located and operated within a medical office or other location where patients are regularly seen for diagnosis and treatment, can only be used to dispense dangerous drugs and devices to the patients of the practice per BPC 4427.6(j).

Subsection 7.19 is added to ensure that the underlying pharmacy does not have more than 15 APDS licensees. Additionally, space is provided for the PIC to list the APDS licenses per BPC 4119.11(d)(10). During this process, the PIC will determine if the underlying pharmacy obtained more than 15 licenses and the PIC can take corrective action to address the non-compliance issue.

Subsection B identifies the requirements the pharmacist with this type of ADDS (an APDS through a clinic pursuant to HSC 1204 or 1204.1 or BPC 4180 or 4190).

Subsection 7.20 is added to ensure that only the pharmacist is stocking the ADDS per BPC 4186(c).

Subsection 7.21 specifies that drugs are only to be removed from the ADDS upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions per BPC 4186(b).

Subsection 7.22 specifies that the pharmacist must conduct a monthly review and physical inspection of the ADDS and the drugs within the system. This review shall

include the operation, maintenance, and cleanliness of the ADDS, as well as, a review of all transaction records to ensure the security and accountability of the system per BPC 4186(d). Additionally, space is provided for the PIC to provide the date of the last monthly review.

Subsection 7.23 specifies that the pharmacist must perform all clinical services as part of the dispensing process. This includes, but is not limited to, a drug utilization review and patient consultation per BPC 4427.6(d).

Subsection 7.24 specifies that drugs are only dispensed from the APDS upon authorization from the pharmacist after the pharmacist has reviewed the prescription and the patient's profile for potential contraindications and adverse drug reactions per BPC 4427.6(e).

Subsection 7.25 specifies that the pharmacist shall consult with patients for the first time on all prescribed drugs and devices dispensed from the APDS. Additionally, it specifies that the consultation shall be provided by a Board licensed pharmacist via telecommunication link that has two-way audio and video capabilities per BPC 4427.6(f).

Subsection 7.26 specifies that the APDS shall have the name, address, and telephone number of the pharmacy displayed prominently on the system per BPC 4427.6(g).

Subsection 7.27 specifies that the pharmacist must provide patient consultation via a two-way audio and video telecommunication link for drugs dispensed by the clinic ADDS per BPC 4186(e).

Subsection 7.28 specifies that the pharmacist operating the ADDS must be located within California per BPC 4186(f).

Subsection 7.29 specifies that the consultant pharmacist for the clinic shall review all inventory and inventory reconciliation reports taken and establish and maintain secure methods to prevent losses of controlled substances. Additionally, the clinic shall develop written policies and procedures for performing the inventory reconciliation reports per CCR 1715.65(b).

Subsection C identifies the requirements for the Policies and Procedures.

Subsection 7.32 specifies that the pharmacy must develop and implement written policies and procedures that are reviewed annually and include numerous items, including: maintaining security, determining and applying inclusion criteria to establish which drugs and devices may be placed into the system, ensuring patients are aware of consultation services, describe responsibilities and training of pharmacy personnel and others who use the system, orientating patients on the use of the systems, ensuring that the use of the APDS does not interfere with delivery of drugs and devices, and ensuring delivery of the drugs and devices in the event the systems is disabled or malfunctions per BPC 4427.6(a) – (a)(6). Additionally, space is provided for the PIC to provide the date of the last policy review.

Subsection 7.33 specifies that the APDS may only be used for patients who have signed a consent waiver demonstrating their informed consent to receive prescribed drugs and devices via the APDS and whose use of the APDS meets the inclusion criteria established in the policies and procedures per BPC 4427.6(b).

Subsection 7.34 specifies that the APDS shall have the ability to identify each patient and only release that specific patient's drug and devices to the patient or the patient's agent per BPC 4427.6(c).

Subsection 7.35 is added to ensure that the pharmacy maintains written policies and procedures for the APDS for 3 years from the date of last use of the APDS as required by BPC 4427.6(l).

Subsection 7.36 is added for the PIC to ensure that the pharmacy and ADDS is compliant with all recordkeeping and quality assurance requirements established within pharmacy law and regulation, and that those record are maintained separately from the other pharmacy records per BPC 4427.7(b).

Section 8 – ADDS operated by a correctional clinic

Subsection A identifies the general requirements for this type of ADDS.

Subsection 8.1 defines "automated drug delivery system" as it applies to correctional clinics as 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. Additionally, the ADDS must 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 per BPC 4187.5(h).

Subsection 8.2 defines "correctional clinic" as 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 per BPC 4187.

Subsection 8.3 specifies that a correctional clinic may obtain drugs for patients under the care of the correctional facility based on the directions of a physician and surgeon, dentist, or other person lawfully authorized to prescribe, or an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures. Additionally, the drugs may be obtained 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 per BPC 4187.1(a).

Subsection 8.4 specifies that the dispensing or administering of drugs in a correctional clinic can only be done pursuant to a chart order (BPC 4019), a valid prescription, or pursuant to an approved protocol as identified within the statewide Inmate Medical Services Policies and Procedures per BPC 4187.1(b).

Subsection 8.5 specifies that medications dispensed to patients that are to be kept on the patient's person must meet the labeling requirements of BPC 4076 and all record keeping requirements within pharmacy law per BPC 4187.1(b)

Subsection 8.6 specifies that the correctional clinic must keep records of the kind and amounts of drugs purchased, administered, and dispensed. Additionally, the records must be maintained for a minimum of three years and must be available for inspection per BPC 4180(a)(2).

Subsection 8.7 specifies that the correctional clinic must obtain a license from the board per BPC 4187.1(d)(1).

Subsection 8.8 specifies that the correctional clinic must obtain a separate license for each location where an APDS is located and the license is not transferrable per BPC 4187.1(d)(2).

Subsection 8.9 specifies that the correctional clinic's location and address must be identified by the correctional institution and the building within the correctional institution per BPC 4187.1(d)(3).

Subsection 8.10 specifies that the correctional clinic must notify the board in advance of any change in the clinic's address on a form furnished by the board per BPC 4187.1(d)(4).

Subsection 8.11 specifies that the ADDS must be secured from access and removal by unauthorized individuals per BPC 4427.2(d)(2).

Subsection B identifies the requirements for the Policies and Procedures.

Subsection 8.12 specifies that the policies and procedures to implement the law and regulations with respect to correctional clinics must be developed and approved by the statewide Correctional Pharmacy and Therapeutics Committee referenced in Section 5024.2 of the Penal Code per BPC 4187.2(a).

Subsection 8.13 specifies that an acknowledgement of the policies and procedures must be signed by the correctional facility PIC servicing the institution, the PIC 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 per BPC 4187.2(a).

Subsection 8.14 specifies that the chief executive officer is responsible for the safe, orderly and lawful provision of pharmacy services per BPC 4187.2(b)(1).

Subsection 8.15 specifies that the PIC of the correctional facility must 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 per BPC 4187.2(b)(1).

Subsection 8.16 specifies that the licensed correctional clinic must notify the board within 30 days of any change in the chief executive officer on a form furnished by the board per BPC 4187.2(b)(2).

Subsection 8.17 specifies that 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 per BPC 4187.3.

Subsection 8.18 specifies that the ADDS location must implement 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 per BPC 4187.5(a).

Subsection 8.19 specifies that the policies and procedures must be maintained in electronic form or paper form at the location where the ADDS is used per BPC 4187.5(a).

Subsection C identifies the requirements the pharmacist with this type of ADDS (ADDS operated by a correctional clinic)

Subsection 8.20 specifies that a correctional facility pharmacist must inspect the clinic at least quarterly per BPC 4187.2(c).

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

Subsection 8.22 specifies that the pharmacist must conduct a monthly review and physical inspection of the ADDS and the drugs within the system. This review shall include the operation, maintenance, and cleanliness of the ADDS, as well as, a review of all transaction records to ensure the security and accountability of the system per BPC 4187.5(e). Additionally, space is provided for the PIC to provide the date of the last monthly review.

Subsection D identifies the device requirements of this type of ADDS (ADDS operated by a correctional clinic).

Subsection 8.23 specifies that the drugs removed from the ADDS must be provided to the patient by a licensed health professional per BPC 4187.5(c).

Subsection 8.24 specifies that the correctional clinic is responsible for the review of the drugs within the ADDS, as well as, the operation and maintenance of the system.

Subsection 8.25 specifies that the ADDS must be operated by a licensed correctional pharmacy. Additionally, any drugs within the ADDS are considered owned by the licensed correctional pharmacy until they are dispensed from the ADDS per BPC 4187.5(f).

Subsection 8.26 specifies that the drugs can only be removed from the ADDS by a person lawfully authorized to administer or dispense the drugs per BPC 4187.5(g).

Subsection E identifies the record keeping requirements.

Subsection 8.27 is added to ensure that all records of manufacture and sale, acquisition, receipt, shipment, and disposition are maintained in the readily retrievable form during business hours and are preserved for at least three years from the date of making. The records must be readily retrievable so that board staff can review them during an inspection. Additionally, a currently inventory must be kept by the licensed correctional clinic per BPC 4081(a).

Pharmacist-in-Charge Certification

A certification has added identify the appropriate individual responsible for completing and certifying completion of the self-assessment. The PIC certification specifies that the PIC is certifying that they completed the self-assessment and that any identified deficiency will be corrected. Additionally, it specifies that the Board of Pharmacy can verify the responses and the PIC is certifying under penalty of perjury that the self-assessment form is true and correct.

Additionally, there is a second acknowledgment that the PIC will sign once they have completed the deficiencies identified within the self-assessment. Additionally, it specifies that the Board of Pharmacy can verify the responses and the PIC is certifying under penalty of perjury that the self-assessment form is true and correct.

By requiring attestation under penalty of perjury, the board is communicating to the PIC and all future pharmacists-in-charge, the gravity of falsifying information to the board. Pursuant to B&P section 4301(g), the board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Should a PIC falsely certify to the completion of the self-assessment, the PIC could be disciplined by the board. Certification under penalty of perjury helps ensure that the statements regarding compliance with the requirements are truthful, factual representations made in good faith. (See, e.g., *In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 [judicial explanation for the use of certifications].)

Acknowledgement by Owner of ADDS

A certification has added identify the appropriate individuals responsible for completing and certifying completion of the self-assessment. The owner certification specifies that the owner is certifying that they have read and reviewed the self-assessment and that they understand that failure to correct identified deficiencies could result in the revocation of the license. Additionally, it specifies that the Board of Pharmacy can verify the responses and that the owner is certifying under penalty of perjury.

Additionally, there is a second acknowledgment that the owner will sign once the PIC has corrected any deficiencies identified within the self-assessment. Additionally, it specifies that the Board of Pharmacy can verify the responses and the owner is certifying under penalty of perjury that they have read and reviewed the self-assessment and that they understand that failure to correct identified deficiencies could result in the revocation of the license.

By requiring attestation under penalty of perjury, the board is communicating to the owner, the gravity of falsifying information to the board. Pursuant to B&P section 4301(g), the board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Certification under penalty of perjury helps ensure that the statements regarding compliance with the requirements are truthful, factual representations made in good faith. (See, e.g., *In re Marriage of Reese & Guy* (1999) 73 Cal.App.4th 1214, 1223 [judicial explanation for the use of certifications].)

Underlying Data

1. Assembly Bill 1812 (Omnibus, Statutes of 2018, Chapter 36).
2. Assembly Bill 2037 (Bonta, Statutes of 2018, Chapter 647)
3. Senate Bill 1447 (Hernandez, Statutes of 2018, Chapter 666)
4. 15 USC Chapter 39A, Special Packaging for Household Substances http://uscode.house.gov/browse/prelim@title15/chapter39&edition=prelim
5. 42 USC Chapter 6A, Subchapter II, Part D, subpart vii: Primary Health Care, Drug Pricing Agreements http://uscode.house.gov/browse/prelim@title42/chapter6A/subchapter2/partD&edition=prelim
6. 16 Code of Federal Regulations, Chapter 2, Subchapter E – Consumer Product Safety Commission (https://www.govinfo.gov/app/collection/cfr/2018/)
7. 21 Code of Federal Regulations, Chapter 1, Subchapters C (Parts 201, 208, and 290) and D (Part 310) – Food and Drug Administration, Department of Health and Human Services (https://www.govinfo.gov/app/collection/cfr/2018/)
8. 21 Code of Federal Regulations, Chapter 2, Part 1301 – Drug Enforcement Administration, Department of Justice (https://www.govinfo.gov/app/collection/cfr/2018/)
9. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 30-31, 2018 (Meeting Materials (Licensing Committee Pages 1, 6-7 and Attachment 2), (Enforcement Committee Pages 1, 3-4, 11 and Attachments 4 and 13), Minutes Pages (Pending)).

Business Impact

The board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses and/or employees including the ability of California businesses to compete with businesses in other states. This determination is based on the fact that completion of the self-assessment is required by statute and this proposal is establishing a self-assessment form specific to ADDS to ensure that the pharmacy law references within the form are current and complete. Additionally, the proposal is establishing the regulation to clearly specify the requirements for ADDS which currently only exist for pharmacies and hospitals within CCR 1715. The board estimates that completion of the self-assessment form should only take an hour or two, if the pharmacy is operating in compliance with federal and state law and regulation. As such, the board determined that completing the form will not have an adverse economic impact on businesses and it would improve business practices by educating and ensuring that board licensees are operating in compliance with federal and state law and regulation.

Economic Impact Assessment

The Board has determined that:

(1) this proposal will not create jobs within California;
(2) this proposal will not eliminate jobs within California;
(3) this proposal will not create new businesses within California;
(4) this proposal will not eliminate of existing businesses within California;
(5) this proposal will not expand businesses currently doing business in the State of California.

The board determined that this proposal will not create or eliminate jobs or businesses. The proposed regulation provides clarity to the regulated public with respect to the use of APDS. Additionally, the proposal identifies the specific requirements for the self-assessment form. Completion of the self-assessment form is required by B&P section 4427.7. The self-assessment form aids licensees in assessing their compliance with federal and state law and regulations. A pharmacy operating an ADDS should already follow the laws and regulations identified within the self-assessment form, so simply completing the form itself will not create or eliminate jobs or businesses. There may be a minor additional cost for the pharmacy to complete the ADDS self-assessment. The estimated cost to the pharmacy would be the staff time spent to complete the self-assessment form (an hour to two) and the paper. In addition, the completed self-assessment form must be maintained within the facility, so there would be minor storage requirement of the document for three years. The board believes these costs to be minor. Finally, the proposal does require that a pharmacy submit quality assurance records to the board within 30 days of completion of a quality assurance review. The cost associated would be the cost of the paper and the staff time submit the documents to the board. The board believes these costs to be minor.

This regulatory proposal benefits the health and welfare of California residents. Existing pharmacy law requires a pharmacy holding an ADDS license to complete a self-assessment. This proposal establishes the specific requirements for the self-assessment form and frequency of completion. The use of the self-assessment form

helps educate the PICs, which helps ensure that pharmacy is operating the ADDS in compliance with state and federal laws and regulations. Additionally, requiring the submission of quality assurance reports to the board will alert the board to possible issues with ADDS and allow the board to investigate these issues. This will benefit the health and welfare of California residents by ensuring that the ADDS machines are operating and being utilized consistent with state and federal laws and regulations.

This regulatory proposal benefits worker safety because it will help educate PICs, which helps ensure that pharmacy is operating the ADDS in compliance with state and federal laws and regulations. Operating in compliance with state and federal law will make the pharmacy operating the ADDS a safer work place.

The regulatory proposal benefits the state's environment because it will help educate PICs, which helps ensure that pharmacy is operating the ADDS in compliance with state and federal laws and regulations.

Specific Technologies or Equipment

This regulation does not mandate the use of specific technologies or equipment.

Consideration of Alternatives

No reasonable alternative to the regulatory proposal would be either more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific. The board considered the following alternatives:

(1) The board considered not establishing the specific requirements of the self-assessment form within the regulation. The board determined that this alternative was unacceptable because a form specific to ADDS would not be available for pharmacy's operating ADDS. This would cause confusion to the regulated public with respect to which self-assessment form they should be completing.

(2) The board considered establishing the specific requirements of the self-assessment form within the regulation and not requiring the submission of quality assurance reports to the board. The board determined that this alternative was unacceptable as the board would not be aware of possible issues with the systems and would be unable to investigate possible causes of concern. Additionally, the board would be unable to report to the legislature public safety concerns as required by B&P section 4427.8(b)(3).