Board of Pharmacy
Initial Statement of Reasons

Subject Matter of Proposed Regulation: Self-Assessment of an ADDS

Section Affected: Amend Section 1715.1 of Article 2 of Division 17 of Title 16, California Code Regulations (CCR)

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 Profession Code (BPC) section 4000, et seq.). The board's mandate and mission are to protect the public (BPC section 4001.1).

Existing law at BPC section 4119.11 establishes the licensure requirement for an automated drug delivery system (ADDS) and establishes two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit Dose System (AUDS).

Additionally, existing law at BPC sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7 establish the ownership, placement, and operation requirements; the requirement for an exempt AUDS to comply with all other requirements of an ADDS; recordkeeping and quality assurance requirements; and the requirement for the completion of a self-assessment by the pharmacy.

Assembly Bill 1533 (Statutes of 2021, Chapter 629) amended BPC section 4427.7 to remove the requirement for the annual completion of the self-assessment form and mirrored the requirement for biennial completion consistent with CCR section 1715 and the requirement for the community pharmacy and hospital pharmacy self-assessment forms.

This proposal will amend 16 CCR section 1715.1 to change the requirement for the self-assessment form to be completed annually to biennially and update the self-assessment form that pharmacists-in-charge must complete (Automated Drug Delivery System Self-Assessment [17M-112]) to reflect current laws and regulations since the last revision in 2018. The proposal will also amend section 1715.1 to replace gendered terms with gender-neutral language in order to bring the regulatory text into compliance with Assembly Concurrent Resolution No. 260 of 2018 (ACR 260), in which the Legislature resolved that "state agencies should … use gender-neutral pronouns and avoid the use of gendered pronouns when drafting policies, regulations, and other guidance."

Benefits

Protection of the public is the board's highest priority in exercising its licensing, regulatory and disciplinary functions. This regulatory proposal benefits the health and welfare of California residents. By updating the form incorporated by reference to reflect

current laws and regulations, the pharmacists-in-charge (PIC) of pharmacies throughout California will be conducting self-assessments based on current and up-to-date laws, rather than inaccurate references to laws on outdated self-assessment forms. This will assist pharmacies in complying with current law, which will advance consumer protection. As PICs complete 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 improve facility 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 1715.1 of Article 2 of Division 17 of Title 16 of the CCR

Subdivision (a) is amended to strike "annually" and add "odd-numbered" to the second sentence. BPC section 4427.7(a) was amended effective January 1, 2022 and specifies that the self-assessment must be completed consistent with CCR section 1715, which requires assessments to be completed "before July 1 of every odd-numbered year." (16 CCR 1715(a).)

Subdivision (b)(2) is amended to strike "change in the pharmacist-in charge, and he or she becomes the new pharmacist in charge," and replaced with "new pharmacist-in-charge" in order to streamline the language and remove gendered language consistent with ACR 260.

Subdivision (c) is amended to update the revision date of Form 17M-112. The self-assessment form is being updated to reflect current laws and regulations since the last revision in 2018 and, as such, the revision date is being updated to reflect the amendment to (Rev 1/22).

Subdivision (c)(5) is amended to strike "he or she has" and replace it with "they have" in order to remove gendered language and use gender-neutral language, consistent with ACR 260.

Subdivision (c)(6) is amended to strike "he or she has" and to add "they have" in order to remove gendered language and use gender-neutral language, consistent with ACR 260.

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

Subdivision (f)(1) is added and reads: “The mechanical devices used as part of the automated drug delivery system to store, dispense or distribute dangerous drugs are of the same manufacturer and controlled by the same software system on a single server; and.” Subdivision (f)(2) is added and reads: “The same policies and procedures required by Section 4427.2 of BPC are used.”

It is common for a hospital to use such devices throughout a hospital and operated by the same staff and under the same procedures. Where the devices are from the same manufacturer, maintained on the same platform, and have the same policies and procedures required by BPC 4427.2, the board determined that it was appropriate to clarify that a single self-assessment form was sufficient to ensure compliance because the responses on the self-assessment form would be the same for each device. Thus, the public safety concerns, when addressed in one device’s instance, are covered for all devices. Requiring a different self-assessment form to be completed for each device would be unnecessary and unduly burdensome.

The reference statutes have been amended as appropriate. Sections 4117.3, 4119.1, 4427.6, and 4427.7 of the Business and Professions Code were added as references.

Form 17M-112 (Automated Drug Delivery System Self-Assessment) Incorporated by Reference

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

On every page of Form 17M-112, the footer at the bottom left corner is being amended to reflect the new revision date of “1/22”. Throughout the form “Yes, No, N/A” was added, deleted, or moved 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. Legal references have been updated as needed to ensure appropriate references. These references do not establish new requirements but merely provide information to the PIC to locate the requirements should they wish to research and validate the information.

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. These are added as needed at the end of each section.

The terms automated drug delivery system, automated patient delivery system, and automated unit dose system have been abbreviated within the self-assessment form to ADDS, APDS, and AUDS, as appropriate based on the type of device.

Finally, subsection numbering is updated as needed to account for the addition and removal of subsections. Grammar edits were also made throughout the form to correct typographical errors, as well as non-substantive word choice changes or additions.

Title Page – Page 1

An opening paragraph is amended to add "that" to the first sentence as a grammar edit and the phrase "an annual" has been changed to "a" as an annual self-assessment is no long required per BPC 4427.7. Additionally, the second sentence is amended to add "odd-numbered" in order to mirror the language change made to CCR section 1715.1 and to be consistent with amendments to BPC 4427.7. The second sentence was further amended to add "BPC" before section 4029, "section" was made plural, and the second use of "section" was stricken. The third sentence was amended to add "PIC" to reference the abbreviation of the term pharmacist-in-charge, the phrase "a new pharmacist" was added to the verb "becomes" for grammatical compliance, and the word "new" before "pharmacist-in-charge" was deleted as redundant.

Paragraph 2 is amended to relocate "Division 2" from after Chapter 9 to in front of Chapter 9, as this is the correct format order for the legal reference.

Paragraph 3 is amended to add "and the signed original must be readily available and" to mirror the requirement of CCR 1715.1(d), which requires that the signed original be readily available for review for three years.

Page 2

The board amended the second sentence to change "C2," which refers to Schedule II controlled substances, to "CS," which simply refers to controlled substances generally, to mirror the requirements of 21 United States Code section 827, which does not limit the inventory to Schedule II controlled substances only.

The board amended page two to include a check box for the PIC to identify the reason they are completing the self-assessment form. The additional language reads as follows:

"Reason for completing self-assessment:

- Performing self-assessment before July 1 of every odd-numbered year. [BPC 4427.7, CCR 1715.1(a)]
- Completing a self-assessment within 30 days when a new ADDS license was issued. [BPC 4427.7, CCR 1715.1(b)(1)]
- Completing a self-assessment within 30 days when there was a change in PIC. [BPC 4427.7, CCR 1715.1(b)(2)]
- Completing a self-assessment within 30 days when there was a change in the licensed location of an ADDS to a new address. [BPC 4427.7, CCR 1715.1(b)(3)]"

The addition of this information is to remind the PIC of the reasons for completing a self-assessment. Additionally, it will provide meaningful information for the PIC and Board Inspector during an inspection to ensure that the self-assessment forms will be completed in accordance with the requirements of law.

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

Section 2 – Location of Devices

Subsection 2.2 is amended to change "ADDS" to "APDS" as that is the type of ADDS that would be located outside of the secured pharmacy area.

Subsection 2.3 is amended to change "ADDS" to "AUDS" as that is the type of ADDS that would be utilized in a health facility. Additionally, "Long Term Care (LTC)" is stricken as unnecessary because the section applies to any health facility that is licensed pursuant to section 1250 of the HSC.

Subsection 2.4 is amended to add "an AUDS in" to identify that the ADDS utilized in the clinic is an AUDS.

Subsection 2.6 is amended to add "or other location where patients are regularly seen for purposes of diagnosis and treatment, and the APDS is only used to dispense dangerous drugs and dangerous devices to patients of the practice," which mirrors the requirement within BPC 4427.6(j) and is included for clarity of law and education for the PIC.

Subsection 2.7 is amended to add "of the Business and Professions Code" in two locations to appropriately identify the legal references within the subsection.

Subsection 2.8 is added and reads "**AUDS operated by a licensed hospital that contains 100 beds or fewer (Drug Room)**, as defined in section 4056 of the Business and Professions Code, and is used to provide doses administered to patients while in a licensed general acute care hospital and to dispense drugs to outpatients if the physician determines that it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued, and the physician reasonably believes that a pharmacy located outside the hospital is not available and accessible at the time of dispensation to the patient within 30 minutes of the hospital pharmaceutical services or within a 30-mile radius. The quantity dispensed is limited to an amount necessary to maintain uninterrupted therapy and does not exceed a 72-hour supply." This section is added to ensure that the PIC is aware of, and that the drug room facility is operating its AUDS in compliance with, the requirements of BPC 4056(f)-(h).

Subsection 2.9 is added and reads "**AUDS located in the emergency room operated by a licensed hospital pharmacy**, as defined in subdivisions (a) and (b) of section 4029 of the Business and Professions Code, and is used to provide **doses administered** to patients while in a licensed general acute care hospital facility or a

licensed acute psychiatric hospital facility, as defined in subdivisions (a) and (b) of section 1250 of the Health and Safety Code, **and to dispense** to an emergency room patient if:

2.9.1. The hospital pharmacy is closed and there is no pharmacist available in the hospital.
2.9.2. The drug is acquired by the hospital pharmacy.
2.9.3. The dispensing information is recorded and provided to the pharmacy when the pharmacy reopens.
2.9.4. The hospital pharmacy retains the dispensing information and controlled substances dispensing information is reported to the Department of Justice pursuant to section 11165 of the Health and Safety Code.
2.9.5. The prescriber determines it is in the best interest of the patient that a particular drug regimen be immediately commenced or continued and the prescriber reasonably believes a pharmacy located outside the hospital is not available and accessible at the time of dispensing to the patient.
2.9.6. The quantity is limited to an amount necessary to maintain uninterrupted therapy, but shall not exceed a 72-hour supply.

Note: Licensure of AUDS operated under these provisions is required. Please refer to FAQs for additional information."

Subsection 2.9 – 2.9.6 are added to educate and ensure that the PIC is aware of the requirements for a hospital pharmacy that utilizes an AUDS in an emergency room. These requirements are specified in BPC 4068(a)(1) – (a)(6). Additionally, a note is added to remind the PIC that the AUDS operated under the provisions of 4068(a)(1) – (a)(6) must be licensed.

Subsection 2.10 is added and reads "**A facility licensed in CA with the statutory authority to provide pharmaceutical services**." This subsection is added to educate and ensure that the PIC is aware that an ADDS could be placed in a facility licensed in California that can provide pharmaceutical services [pursuant to BPC 4427.65(a)(1)]. Additionally, space is provided for the PIC to list the type of facility where the ADDS is located and the code section that authorizes that facility to provide pharmaceutical services.

Subsection 2.11 is added and reads "**Jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director**." This subsection is added to educate and ensure that the PIC is aware that an ADDS could be placed in a jail, youth detention facility, or other correctional facility [pursuant to BPC 4427.65(a)(2)]. Additionally, space is provided for the PIC to list the type of facility where the ADDS is located and the code section that authorizes that facility to provide pharmaceutical services.

The term 'Please' is added after subsection 2.11 for consistency with other 'Note' statements throughout the form.

Section 3 – General Requirements for All Types of ADDS

Subsection 3.4 is amended to add check boxes and numbers (3.4.1 – 3.4.4) instead of the bullet points as a formatting change.

Subsection 3.5 is amended to make the date of the inspection singular and reduce the number of lines from three to one as a formatting change. There would only be one pre-license inspection, so there do not need to multiple lines and plural language.

Subsection 3.19 is amended to add "of the Business and Professions Code" in one location to appropriately identify the legal reference within the subsection. Additionally, the term "dangerous" was added in front of devices for consistency in the use of "dangerous drug and dangerous devices."

Subsection 3.22 is added and reads "The record of quality assurance review, as provided in California Code of Regulation section 1711(e), is immediately retrievable in the pharmacy for at least one year from the date the record was created." This subsection is added to provide education and ensure the PIC and pharmacy comply with the requirements of CCR 1711(f).

Subsection 3.23 is added and reads "The pharmacy will submit to the board any quality assurance record related to the use of a licensed ADDS within 30 days of completion of the quality assurance review. Any facility with an unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the pharmacy's license." This subsection is added to provide education and ensure the PIC and pharmacy comply with the requirements of CCR 1711(f).

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

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

The addition of this information is to remind the PIC of the reasons for completing a self-assessment pursuant to CCR 1715.1(a) and (b). This language is duplicated from page 2, because the purpose of the language on page 2 is to allow the person completing the form to identify the particular reason for which they are completing the assessment, whereas the language in section 3.24 is to remind the PIC of all the circumstances under which the PIC would be required to complete a new self-assessment.

Subsection 3.25 is added and reads: "The PIC of an ADDS assesses the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 1/22) entitled 'Automated Drug Delivery System Self-Assessment.'" The addition of this information is to remind the PIC of the reasons for completing the self-assessment form pursuant to CCR 1715.1(c).

Subsection 3.26 is added and reads: "The PIC responds 'yes', 'no', or 'not applicable' about whether the ADDS is, at the time of the self-assessment, in compliance with laws

and regulations that apply to that pharmacy setting." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(c)(2).

Subsection 3.27 is added and reads: "For each 'no' response, the PIC provides a written corrective action or action plan to come into compliance with the law." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(c)(3).

Subsection 3.28 is added and reads "The PIC initialed each page of the self-assessment with original handwritten initials in ink or digitally signed in compliance with Civil Code Section 1633.2(h) of the self-assessment form." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(c)(4).

Subsection 3.29 is added and reads "The PIC has certified on the last page of the self-assessment that they are the PIC, has certified a timeframe within which any deficiency identified within the self-assessment will be corrected, and has acknowledged all responses are subject to verification by the Board of Pharmacy. The certification is made under penalty of perjury of the laws of the State of California and the information provided in the self-assessment form is true and correct with an original handwritten signature in ink or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(c)(5).

Subsection 3.30 is added and reads "The ADDS owner has certified the final page of the self-assessment that they have read and reviewed the completed self-assessment and acknowledges that failure to correct any deficiency identified in the self-assessment could result in the revocation of the ADDS license issued by the Board. The certification is made under penalty of perjury of the laws of the State of California with an original handwritten signature or digitally signed in compliance with Civil Code Section 1633.2(h) on the self-assessment form." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(c)(6) and the requirement for the owner to also sign the certification, in addition to the PIC.

Subsection 3.31 is added and reads "Each self-assessment is completed in its entirety and kept on file in the underlying pharmacy for three (3) years after it is performed. The completed, initialed, and signed original is readily available for review during any inspection by the Board." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(d) and the requirement to maintain the self-assessment form for three years.

Subsection 3.32 is added and reads "Any identified area of noncompliance shall be corrected as specified in the self-assessment." The addition of this information is to remind the PIC of how they should complete the self-assessment form pursuant to CCR 1715.1(e).

Subsection 3.33 is added and reads “The PIC ensures the following: [CCR 1715.65(h)]

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

Subsections 3.33-3.33.4 are added to provide education to the PIC with respect to the inventory and security requirements of CCR 1715.65(h).

Subsection 3.34 is added and reads “The original board-issued ADDS permit and current renewal are posted at the ADDS premise, where they may be clearly read by the public.” The addition of this information is to remind the PIC that the board issued ADDS permit and current renewal must be posted on the ADDS and be clearly visible as required by BPC 4058.

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 that corresponding section of the self-assessment, meaning the PIC will not have to necessarily complete all sections of the self-assessment. They will complete sections 1, 2, 3, and one section between section 4 and 9. Additionally, the PIC and the pharmacy owner of the ADDS shall sign the certification on page 48 (page number may change once all stricken language is removed from the final version of the document) after completing the self-assessment. This is identified to ensure that this step is not inadvertently overlooked.

Section 5 was updated to apply to APDS to provide patient treatment outside of a covered entity (which is specified in Section 4). Two areas for the APDS were added to the list, specifically, an APDS located where patients are regularly seen for purposes of diagnosis and treatment to only be used for patients of the practice (or) an APDS located at a clinic pursuant to HSC 1204, HSC 1204.1, BPC 4180, or BPC 4190 to ensure a complete list of APDS devices. Section 7 previously included the requirements for APDS in a clinic. This previous section has been stricken from the self-assessment form as it has been added to Section 5.

Section 8 (which is now Section 7) was amended to add the legal references for an ADDS operated by a correctional clinic.

Section 9 (which is now Section 8) has been amended to specify the difference between a hospital pharmacy AUDS and a Drug Room AUDS (drug room is identified in subsection 2.8).

New Section 9 is added to specify the requirements for the other types of AUDS utilized outside for those identified in Section 8. Specifically, AUDS through a facility licensed in California with statutory authority to provide pharmaceutical services (see subsection 2.10) or AUDS through a jail, youth detention facility, or other correctional facility where

drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or BPC 4427.65(a)(2) (see subsection 2.11).

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

Subsection 4.3 is amended to spell out USC and reads United States Code in order to provide clarity as to what authority is being cited.

Subsection 4.15 is amended to change the term "annual" to "biennial" as a result of the change in frequency requirement of BPC 4427.7 and the changes being made to the proposed text at CCR section 1715.1. Additionally, check boxes are provided to identify the reason the self-assessment was being completed ("Reason: ☐ Biennial; ☐ New ADDS; ☐ Change in PIC; ☐ Change in location of ADDS").

Subsection 4.16 is stricken as it is duplicative with subsection 3.21.

Subsection 4.17 is stricken as it is duplicative with subsection 3.15.

Subsection 4.24 is stricken as it is duplicative with subsection 3.18.

Subsection 4.27.1 (now subsection 4.24.1) is amended to add "and maintained" for consistency with CCR 1713(e), which requires that policies and procedures be maintained. Subsection 4.24.1.2 was amended to add "including when consultation is needed," in order to mirror the language specified in CCR 1713(e).

Subsection 4.27.3 (now subsection 4.24.3) amends the term "device" to "APDS" for clarity by specifying the device being utilized.

Subsection 4.27.9 is stricken as it is duplicative with subsection 4.30.4.

Subsection 4.30 is added and reads: "The pharmacy uses the APDS to deliver prescription medications to patients as provided:".

Subsections 4.30.1 through 4.30.4 are added and read as follows:

"4.30.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.

4.30.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.

4.30.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

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

Subsections 4.30 through 4.30.4 are added to identify the specific requirements of CCR 1713(d)(1) – (4) for the education of the PIC and to ensure they are aware of the requirements for the use of an APDS to deliver medications as provided.

Subsection 4.33 is stricken as it is duplicative with subsection 3.21.

Subsection 4.34 is stricken as it is duplicative with subsection 5.26 (now subsection 5.19).

Subsection 4.36 (now subsection 4.32) is amended to change the bullet points to check boxes, to correct grammar, and to include the requirement for consultation, which is specified in BPC 4119.11(d) and CCR 1713(e). This requirement is added to mirror the regulation language to ensure that the PIC is aware that the policies and procedures must contain information about when consultation is needed.

Section 5

Check boxes have been added following Section 5 to include the updated requirements for Section 5 to apply to APDS. The PIC will check the box that applies to the APDS being utilized.

Subsection 5.2 is stricken, and new information is added to include the requirements of CCR 1713(d). The new subsection 5.2 reads "The pharmacy uses the APDS to deliver prescription medications to patients as provided:" CCR 1713(d) was revised in 2021 and the addition of this information ensures that the PIC is aware of and in compliance with the changes in law.

Subsections 5.2.1 through 5.2.4 are also added and read as follows:

"5.2.1 The pharmacist has determined that each patient using the APDS met the inclusion criteria for use of the APDS established by the pharmacy prior to the delivery of the prescription medication to the patient.

5.2.2 The APDS has a means to identify each patient and only release the patient's prescription medications to the patient or patient's agent.

5.2.3 The pharmacy provides an immediate consultation with a pharmacist, either in-person or via telephone, upon the request of a patient.

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

Subsections 5.2 through 5.2.4 are added to identify the specific requirements of CCR 1713(d) for the education of the PIC and to ensure they are aware of the requirements for the use of an APDS to deliver medications as provided.

Subsection 5.6 has been amended to update the language to mirror the specific statutory language for clarity that consultation must be provided for all prescription drugs and devices dispensed from an APDS and be provided by a board licensed

pharmacist via telecommunication link that has two-way audio and video capabilities per BPC 4427.6(f).

Subsection 5.8 is stricken as it is duplicative with subsection 4.15.

Subsection 5.9 is stricken as it is duplicative with subsection 3.16.

Subsection 5.10 is stricken as it is duplicative with subsection 3.17.

Subsection 5.11 is stricken as it is duplicative with subsection 3.18.

Subsection 5.12 is stricken as it is duplicative with subsection 3.19.

Subsection 5.13 is stricken as it is duplicative with subsection 3.15.

Subsection 5.25 is stricken as it is duplicative with subsection 3.21.

Subsection 5.28 (now subsection 5.21) is amended to add “maintained and” for consistency of CCR 1713(e), which requires that policies and procedures be maintained. The bullet points beneath this subsection were amended to add subdivision numbers, check boxes, and correct grammar.

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

The title of the subsection has been amended to strike “long term care facilities” and add “that complies with HSC 1261.6” for clarity and education of the PIC regarding ADDS in a health facility.

Subsection 6.1 is stricken as it is duplicative with subsection 3.12.

Subsection 6.3 is stricken as it is duplicative with subsection 3.24.

Subsection 6.5 (now subsection 6.3) is amended to strike “are used” as a grammar change as the terms were duplicative within the subsection.

Subsection 6.6 is added and reads: “A Schedule II controlled substance for a patient in a licensed skilled nursing facility or licensed intermediate care facility is dispensed only after the pharmacist has received:”. This information is added for education of the PIC with respect to the requirements for dispensing a Schedule II controlled substance to a patient in a licensed skill nursing facility or intermediate care facility as specified within HSC 11167.5.

Subsections 6.6.1 through 6.6.1.6 are added for the education of the PIC to identify the requirements for an orally transmitted prescription for a Schedule II controlled substance for a patient in a licensed skill nursing facility or intermediate care facility. These requirements are identified within HSC 11167.5(a) and are as follows:

“6.6.1 An **orally transmitted** prescription for a Schedule II controlled substance from the prescriber and only after the pharmacist reduced the prescription to writing

in ink in the handwriting of the pharmacist on a form developed by the pharmacy. The prescription must contain: [HSC 11167.5(a)]

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

Subsections 6.6.2 through 6.6.2.2 are added for the education of the PIC to identify the requirements for an electronically transmitted prescription for a Schedule II controlled substance for a patient in a licensed skill nursing facility or intermediate care facility. These requirements are identified within HSC 11167.5(a) and are as follows:

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

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

Subsection 6.6.3 is added for the education of the PIC to identify the requirements for an original prescription presented for a Schedule II controlled substance for a patient in a licensed skill nursing facility or intermediate care facility. An original Schedule II prescription must be written on a form that complies with HSC section 11162.1 pursuant to HSC 11164(a).

Subsection 6.6.4 is added for the education of the PIC and reads: "An original Schedule II prescription is written with the '11159.2 exemption' for the terminally ill." This provides a reminder to the PIC that controlled substance prescriptions for terminally ill patients must include the statement "11159.2 exemption" pursuant to HSC 11159.2(a)(2).

Subsection 6.6.5 is added for the education of the PIC with respect to the ability to dispense a prescription that does not comply with the prescription requirements for oral or electronic transmission or one that is not written on an HSC 11162.1 compliant prescription form. Pursuant to HSC 11167(a)-(c), the dispensing is allowed subject to the following:

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

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

6.6.5.3 If the prescription is orally or electronically transmitted, it must be reduced to hard copy.

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

Subsection 6.6.6 is added for education of the PIC with respect to the ability to accept federally compliant electronic prescriptions, also known as e-scripts, pursuant to 21 Code of Federal Regulations sections 1306.08 and 1311. The section reads "An electronic prescription (e-script) for controlled substances that is received from the prescriber and meets federal requirements."

Subsection 6.10 (now subsection 6.9) is amended to add "biennial" as a result of the change in frequency requirement of BPC 4427.7 and the changes being made to the proposed text.

Subsection 6.12 is stricken as it is duplicative with subsection 3.19.

Subsection 6.21 is stricken as it is duplicative with subsection 3.17.

Subsection 6.22 is stricken as it is duplicative with subsection 3.18.

Following subsection 6.25 (now subsection 6.21), a "Note" is added for education of the PIC that, if they use an ADDS that allows licensed personnel to have access to multiple drugs, they must notify the Department of Public Health prior to using the device, as required by HSC 1261.6(f)(7)(A). The board specified "Department of Public Health" and identified the specific unit at the Department of Public Health as "Licensing and Certification" to provide additional clarity to the PIC about what the "department" is as referenced in the statute.

Subsection 6.26 is stricken as it is duplicative with subsection 3.21.

New subsection 6.23 is added to remind the PIC that pharmacist inspection records must be maintained for three years pursuant to 22 CCR 70263(f)(3) and HSC 1261.6(b).

Subsection 6.32 is stricken as it is duplicative with subsection 3.4.

Section 7 and subsections 7.1 – 7.36 are stricken as the requirements have been relocated to section 5 as they relate to the use of an APDS.

Previous section 8 has been renumbered to section 7. Throughout this section, "statewide Inmate Medical Services Policies and Procedures" has been changed to "California Correctional Health Care Services Health Care Department Operations Manual" due to a statutory change to BPC 4187.2 in 2020 that amended the name of the manual (SB 118, Chapter 29, Statutes of 2020). This affects subsections 8.3 and 8.4 (now subsections 7.3 and 7.4), 8.15, 8.17, and 8.18 (now subsections 7.14, 7.16, and 7.17), and 8.21 (now subsection 7.20)

Subsection 8.11 is stricken as it is duplicative with subsection 3.4.

Subsection 8.21 (now subsection 7.20) is being amended to strike "If the correctional pharmacy is closed" and replace it with "Where administration of the drug is necessary before a pharmacist has reviewed the prescription" to mirror the statutory language within BPC 4187.5(b) for clarity and education of the PIC.

Subsection 8.26 (now subsection 7.25) is being amended to add "authorized to stock the ADDS, or by a person" to mirror the language with statute (BPC 4187.5(g)) to make clear who may remove drugs from the ADDS and for education of the PIC.

Section 9 (which is now Section 8) is amended to specify the difference between a hospital pharmacy AUDS and a Drug Room AUDS (drug room is identified in subsection 2.8). Additionally, a note is added to ensure that the PIC is aware that section 6 of the self-assessment must also be completed for any ADDS used for administration.

Subsection 9.2 (now subsection 8.2) is amended to mirror the language of BPC 4068(a) with respect to dispensing a dangerous drug from an AUDS to an emergency room patient to provide additional clarity and education for the PIC. The paragraph was amended to separate the requirements into numbered subsections 8.2.1 – 8.2.7 to ensure that all the requirements listed are met.

Subsections 8.2.1 to 8.2.3 are maintained as existing language, with the exception of a grammar correction in subsection 8.2.2.

Subsection 8.2.4 is amended to add "and, if the drug is a schedule II, schedule III, or schedule IV controlled substance, reports the dispensing information to the Department of Justice pursuant to Section 11165 of the Health and Safety Code" to mirror the language within BPC 4068(a)(4) for clarity and for education of the PIC.

Subsections 8.2.5 and 8.2.6 are maintained as existing language, with the exception that a code citation was stricken in subsection 8.2.6 as duplicative.

Subsection 8.2.7 is added and reads "The prescriber ensures that the label on the drug contains all the information required by BPC section 4076" to include the requirement of BPC 4068(a)(7), which was previously omitted. This subsection is added to ensure that

the PIC is aware of this requirement as the PIC is responsible for the security and stock of controlled substances.

New subsection 8.3 is added and reads: “The operating pharmacy has obtained a license from the Board to operate the AUDS that is used for administration and dispensing which includes the address of the AUDS location.” This requirement is a relocation of the requirement formerly in subsection 9.9, which is now stricken. The subsection was moved up within the section due to the content and flow of the form. The information before subsection 8.3 is specific to the pharmacy and the information after subsection 8.3 is specific to labels and policies.

Subsection 8.10 is added and reads: “Medication guides are provided on required medications.” Medication guides are required by 21 Code of Federal Regulations section 208.1 and adding this subsection to the form provides education and a reminder to the PIC of the requirement.

Subsection 8.11 is added and reads: “Black box warning information is in conformance with 21 CFR 201.57(c).” Black box warnings are required by 21 Code of Federal Regulations section 201.57(c) and adding this subsection to the form provides education and a reminder to the PIC of the requirement.

Subsection 8.12 is added and reads: “Whenever an opioid prescription drug is dispensed to a patient for outpatient use, the pharmacy or practitioner dispensing the drug prominently displays on the label or container, by means of a flag or other notification mechanism attached to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” Adding this subsection to the form provides education and a reminder to the PIC of the requirement of BPC 4076.7 to include the caution on the label or container.

Section 9 is added to specify the requirements for the other types of AUDS utilized outside of those identified in Section 8, specifically AUDS operated through a facility licensed in California with statutory authority to provide pharmaceutical services (subsection 2.10) or AUDS through a jail, youth detention facility, or other correctional facility where drugs are administered within the facility under the authority of the medical director pursuant to BPC 4187.1, 4427.3(b)(6), or BPC 4427.65(a)(2). As the requirements for these types of ADDS may be a little different, adding a separate section was determined to be appropriate.

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

Subsection 9.1 is added and reads: “Review of the drugs contained within, and the operation and maintenance of, the ADDS is done in accordance with law and is the responsibility of the pharmacy. A pharmacist conducts the review on a monthly basis, which includes a physical inspection of the drugs in the ADDS, an inspection of the ADDS for cleanliness, and a review of all transaction records in order to verify the security and accountability of the ADDS.” Adding this subsection to the form provides education and reminder to the PIC of the requirement of BPC 4427.65(c)(7) to conduct a monthly review of the ADDS. Additionally, a space is provided for the PIC to record

the date of the last review. Recording this date is evidence of compliance with the monthly requirement or provides evidence that corrective action is needed.

Subsection B identifies the requirements the pharmacist with this type of ADDS.

Subsection 9.2 is added and reads: “The stocking of an ADDS is performed by a pharmacist. If the ADDS utilizes removable pockets, cards, drawers, similar technology, or unit of use or single dose containers, as defined by the United States Pharmacopoeia, the stocking system may be done outside of the facility and be delivered to the facility, if all the following conditions are met:

- 9.2.1 The task of placing drugs into the removable pockets, cards, drawers, or unit of use or single dose containers is performed by a pharmacist, or by an intern pharmacist or a pharmacy technician working under the direct supervision of a pharmacist.
- 9.2.2 The removable pockets, cards, drawers, or unit of use or single dose containers are transported between the pharmacy and the facility in a secure tamper-evident container.
- 9.2.3 The facility, in conjunction with the pharmacy, has developed policies and procedures to ensure that the removable pockets, cards, drawers, or unit of use or single dose containers are properly placed into the ADDS.”

Subsections 9.2.1-9.2.3 are added to include the conditions that permit the routine stocking of an ADDS for delivery to the facility. These conditions are provided as a reminder and for education of the PIC and are required by BPC 4427.65(c)

Subsection 9.3 is added and reads: “The pharmacist-in-charge of a pharmacy servicing an onsite or offsite ADDS ensures the following: [CCR 1715.65(h)]

- 9.3.1 All controlled substances added to an ADDS are accounted for.
- 9.3.2 Access to the ADDS is limited to authorized facility personnel.
- 9.3.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed.
- 9.3.4 Confirmed losses of controlled substances are reported to the board.”

Subsections 9.3-9.3.4 are added to provide education to the PIC with respect to the inventory and security requirements of CCR 1715.65(h).

Subsection C identifies the device requirements of this type of ADDS.

Subsection 9.4 is added and reads: “Individualized and specific access to the ADDS is limited to facility and contract personnel authorized by law to administer drugs” to provide education and a reminder to the PIC with respect to restricted access requirements of an ADDS pursuant to BPC 4427.65(c)(2).

A note is added following subsection 9.4 to address the limitations for the use of an ADDS as an emergency pharmaceutical supplies container. Specifically, BPC 4427.65(c)(4) limits the removal of drugs the ADDS. Subsections 9.5 – 9.7 define these limitations to ensure that the PIC is aware of the limitations and the pharmacy is complying. Subsections 9.5 – 9.7 read as follows:

Subsection 9.5: “A new drug order given by a prescriber for a patient of the facility for administration prior to the next scheduled delivery from the pharmacy, or 72 hours, whichever is less. The drugs are retrieved only upon authorization by a pharmacist and after the pharmacist has reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions.”

Subsection 9.6: “Drugs that a prescriber has ordered for the patient on an as-needed basis, if the utilization and retrieval of the drugs are subject to ongoing review by the pharmacist.”

Subsection 9.7: “Drugs designed by the patient care policy committee or pharmaceutical service committee of the facility as emergency drugs or acute onset drugs. These drugs may be retrieved from the ADDS pursuant to the order of the prescriber for emergency or immediate administration to the patient of the facility. Within 48 hours after retrieval, the case is reviewed by the pharmacist.”

A note is added following subsection 9.7 to address the requirements for the use of an ADDS to provide pharmacy services as defined by BPC 4017.3. Specifically, BPC 4427.65(c)(5) establishes the requirements for utilizing this type of ADDS. Subsections 9.8 – 9.12 define the requirements to ensure that the PIC is aware of the requirements and that the pharmacy is complying. Subsections 9.8 – 9.12 read as follows:

Subsection 9.8: “The drugs removed from the ADDS for administration to a patient are in properly labeled units of administration containers or packages.”

Subsection 9.9: “The pharmacist reviewed and approved all orders prior to a drug being removed from the ADDS for administration to the patient. The pharmacist reviewed the prescriber’s order and the patient’s profile for potential contraindications and adverse drug reactions.”

Subsection 9.10: “The pharmacy providing services to the facility controls the access to the drugs stored in the ADDS.”

Subsection 9.11: “After the pharmacist reviews the prescriber’s order, access by licensed personnel to the ADDS is limited only to drugs ordered by the prescriber and reviewed by the pharmacist and that are specific to the patient. When the prescriber’s order requires a dosage variation of the same drug, licensed personnel has access to the drug ordered for that scheduled time of administration.”

Subsection 9.12: “ADDS that allow licensed personnel to have access to multiple drugs and are not patient specific in their design, shall be allowed if the ADDS has electronic and mechanical safeguards in place to ensure the drugs delivered to the patient are specific to the patient.”

Subsection D identifies the record keeping requirements.

Subsection 9.13 is added and reads: “Transaction information shall be made readily available in a written format for review and inspection by individuals authorized by law and are maintained in the facility for a minimum of three years.” This addition is for the education of the PIC and to ensure that the records are maintained and available pursuant to BPC 4427.65(c)(1).

Subsection E identifies the requirements for the Policies and Procedures.

Subsection 9.14 is added and reads: “The pharmacy operating the AUDS shall develop and implement, and review annually, the written policies and procedures pertaining to the ADDS.” This addition is for the education of the PIC and to ensure that the pharmacy has developed, and is implementing and performing an annual review of its written policies and procedures pursuant to BPC 4427.65(b).

Subsection 9.15 is added and reads: “The facility and the pharmacy has developed and implemented written policies and procedures to ensure safety, accuracy, accountability, security, patient confidentiality, and maintenance of the quality, potency, and purity of stored drugs. The policies and procedures define access to the ADDS and limits to access to equipment and drugs.” This addition is for the education of the PIC and to ensure that the pharmacy has developed and implemented written policies and procedures that include specific standards pursuant to BPC 4427.5(c)(3)(A).

Subsection 9.16 is added and reads: “All policies and procedures are maintained at the pharmacy operating the ADDS and the location where the ADDS is being used.” This addition is for the education of the PIC and to ensure that the policies and procedures are maintained and available pursuant to BPC 4427.5(c)(3)(B). As described above, a corrective action plan area is added for convenience and to ensure compliance.

The Acknowledgment by Owner of ADDS on page 44 has been amended to change “pharmacy’s” to “automated drug delivery system” to reference the appropriate license that may be revoked for non-compliance.

The Pharmacist-in-Charge Certification on page 45 has been amended to change completed” to “corrected the” for clarity that the PIC must correct any deficiencies identified during the completion of the self-assessment.

The Acknowledgment by Owner of ADDS on page 45 has been amended to change “pharmacy’s” to “automated drug delivery system” to reference the appropriate license that may be revoked for non-compliance.

Underlying Data

1. Assembly Bill 1533 (Omnibus, Statutes of 2021, Chapter 629).
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held January 27-28, 2022 (Meeting Materials Agenda Item XI, Meeting Minutes).
3. Relevant Meeting Materials and Minutes from Enforcement and Compounding Committee Meeting held January 18, 2022 (Meeting Materials Agenda Item VII, Meeting Minutes).

4. Relevant Meeting Materials and Minutes from Board Meeting held July 27-28, 2022 (Meeting Materials Agenda Item XI(a), Draft Meeting Minutes

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 also required by statute and regulation. This proposal is updating the self-assessment form, incorporated by reference, specific to ADDS to ensure that the pharmacy law references within the form are current and complete and is not establishing new requirements.

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 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 eliminate or expand businesses. The proposed regulation updates the statutes and regulations identified on the self-assessment form. 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 and completion of the self-assessment form is required by BPC section 4427.7. As such, completing the updated form itself will not create or eliminate jobs or businesses.

The regulatory proposal will benefit the health and welfare of California residents because pharmacies who provide drugs to California consumers will be conducting the self-assessment based on current and up-to-date laws, rather than outdated laws, which will make it more likely that pharmacies will follow current laws and regulations. When PICs are actively engaged in reviewing the current laws and regulations, they are more likely to identify and remedy any violations of pharmacy law and regulations, which exist primarily for consumer safety. This regulatory proposal benefits worker safety because it will help educate PICs, which helps ensure that a pharmacy is operating the ADDS in compliance with state and federal laws and regulations. The proposal does not impact the state's environment.

Specific Technologies or Equipment

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

Consideration of Alternatives

The board has initially determined that 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 not updating the self-assessment form specified within the regulation. The board determined that this alternative was unacceptable because the board would be requiring that an outdated form be completed. This would cause confusion to the regulated public with respect to repealed and existing state and federal law.
The board invites comments from the public regarding alternatives.