TITLE 16: BOARD OF PHARMACY

FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Automated Drug Delivery Systems (ADDS)

Sections Affected: Title 16, California Code of Regulations (CCR) sections 1711, 1713, & 1715.1

Updated Information

The Initial Statement of Reasons is included in this rulemaking file. The information contained therein accurately reflects the position of the Board of Pharmacy (board) regarding the amendment of the above section. The Initial Statement of Reasons (ISR) is updated as follows:

The 45-day public comment period began on July 3, 2020, and ended on August 17, 2020. The board's notice stated that the board did not intend to hold a hearing on the matter unless requested. The board did not receive a request for a hearing during the comment period and one was not held.

During the 45-day comment period, the board received several comments. At the September 17, 2020 board meeting, the board considered the comments and amended the regulation text to: (1) clarify which quality assurance reports must be reported within 30 days and which must be reported at the time of annual renewal; (2) add "patient or patient's agent" for clarity; and (3) allow for digital signature on the self-assessment form.

The board voted to initiate a 15-day public comment period, which commenced on September 25, 2020 and concluded on October 10, 2020. During the 15-day comment period, the board received several comments. At the October 27-28, 2020 board meeting, the board considered the comments submitted and determined that no additional modifications to the text were appropriate. The board voted to adopt the modified text as noticed for public comment on September 25, 2020.

Section 1711(f) was amended after adoption by the Board to add "of the facility license" to the end of the last sentence. This is a non-substantive change that does not change the regulatory effect of the language and the made to further define "annual renewal" by specifying that it is the annual renewal of the license issued to the facility.

The board notes that the proposed regulation clarifies the reporting requirements identified in Business and Professions Code section 4427.7. While the regulation does not establish the reporting requirement, the regulation does identify the specific information that must be reported via the self-assessment form. This information is

necessary for businesses to use as an aid in assessing their compliance with federal and state law and regulations. The annual review can increase compliance and accountability for licenses facilities.

Modified Text

Section 1711

The board amended subdivision (a) to changed the word “which” to “that” for grammatically clarity.

The board amended subdivision (f) to clarify that quality assurance (QA) records related to “licensed” ADDS must be submitted to the board within 30 days of completion of the QA review. Additionally, the board added language to clarify that facilities with unlicensed ADDS must report the quality assurance review to the board at the time of annual renewal of the facility license. Business and Professions Code (BPC) section 4427.8(b)(1) requires the board to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The board determined that QAs completed on unlicensed ADDS devices must be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the board will ensure the board has access to the data necessary to meet the statutorily mandated reporting.

Section 1713

The board amended subdivision (d)(2) to add “to the patient or patient’s agent.” This addition was made for consistency with BPC section 4427.6(c).

Section 1715.1

The board amended subdivisions (c)(4), (c)(5), and (c)(6) to add “or digitally signed in compliance with Civil Code Section 1633.2(h)” to allow for electronic signature on the self-assessment form instead of a handwritten signature in ink for those licensees who complete the form electronically.

The reference section was also updated to add section 16.5 of the Government Code to ensure accurate reference codes are identified.

Self-Assessment Form

Throughout the form, the Board renumbered sections to address additions or deletions in the document. Additionally, “Yes, No, N/A” was removed or added as needed above

the check boxes to ensure the boxes are identified at the top of each page and beginning of each section.

Page 2

The board added section 1.3, which reads “The pharmacy uses an AUDS – “Automated UNIT DOSE system,” an ADDS for the storage and retrieval of unit dose drugs for administration and dispensing to patients by a physician in a drug room or hospital emergency room when the pharmacy is closed. [BPC section 4427.2(i), BPC section 4056, BPC section 4068].” The Board added this section to ensure all appropriate AUDS machines are identified, specifically AUDS used by drug rooms and hospitals that do not have 24-hour pharmacies.

Page 6

The board amended section 5 to change the word “and” to “or located in” for clarity. The ADDS device could be adjacent to the pharmacy or in a Medical Office, two different locations, so the use of the word “and” was not appropriate.

The board amended section 6 to define what “LTC” (Long Term Care) according to the Health and Safety Code section. This change was made for clarity to the regulated public.

The board added section 9, which reads “AUDS used for dispensing pursuant to BPC section 4056 (Drug Room) or BPC section 4068 (when the hospital pharmacy is closed and no pharmacist is available).” The Board added this section to identify the new section that has been added specific to Drug Rooms and Hospital’s when the pharmacy is closed. This new section corresponds with the addition of section 1.3 on page 2. Hospital pharmacies using an AUDS for dispensing, in addition to administration to patients of the hospital, are not exempt from licensure and, therefore, will need to meet different requirements than what is listed in sections 1, 2, and 3.

Page 13

The board amended the section 5 heading to change the word “and” to “or located” for clarity. The ADDS device could be adjacent to the pharmacy or in a Medical Office, two different locations, so the use of the word “and” was not appropriate. This change corresponds to the change on page 6 identified above.

Pages 31 and 32

Based on addition of section 9 on page 6, the Board added requirements for section 9 board as follows:

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

This section title identifies that the requirements apply to AUDS used by Drug Rooms and Hospitals when a pharmacy is closed. Hospital pharmacies using an AUDS for dispensing, in addition to administration to patients of the hospital, are not exempt from licensure and, therefore, need to meet specific requirements.

The Board added subsection 9.1 to specify the requirements for AUDS use by drug rooms, specifically, for inpatients or a maximum 72-hour supply for outpatients in the best interest of the patient. The specific requirements for drug rooms are stated in BPC section 4056(a) and (f).

The Board added subsection 9.2 to provide the requirements for AUDS used by a hospital emergency room when the hospital pharmacy is closed. These specific requirements are stated in BPC section 4068(a)(1)-(6).

The Board added subsection 9.3 to require the prescriber ensure that the label contains the information required by BPC section 4076 and CCR section 1707.5.

The Board added subsection 9.4 to provide 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.

The Board added subsection 9.5 to provide 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).

The Board added subsection 9.6 to provide the requirement for the hospital pharmacy or drug room to report the dispensing information of controlled substances to the Department of Justice as required by BPC section 4068(a)(4) and HSC 11165(d).

The Board added subsection 9.7 to provide that patient package inserts must be dispensed with all estrogen medications as required by 21 CFR 310.515.

The Board added subsection 9.8 to ensure the hospital has policies and procedures to ensure each patient receives information regarding each drug given at the time of discharge or dispensed from a prescriber from a drug room, including the use and storage of each drug, the precautions and relevant warnings, and the importance of compliance with directions, as required by BPC section 4074(e).

The Board added subsection 9.9 to provide the requirement that the pharmacy must obtain a license to operate the AUDS license which must include the address of the AUDS location as required by BPC section 4427.2(i).

Following section 9.9, the Board added a location for the PIC to record corrective actions or an action plan and a completion date for any non-compliance issues identified. This area provides a tool for the PIC to document changes while completing the form and allow for future reference during an inspection.

Following adoption by the board, staff made non-substantive changes to the self-assessment form to the statutes and regulations identified on the form to ensure proper formatting and reference to the appropriate code sections.

Local Mandate

A mandate is not imposed on local agencies or school districts.

Small Business Impact

While the board does not have nor does it maintain data to define if any of its licensees are "small businesses" as defined in Government Code section 11342.610, the board determined that any adverse economic impact will not be significant. The board anticipates that most, if not all, of the pharmacies that will utilize an ADDS system will not be small businesses. While it is possible for a small business pharmacy to operate an ADDS, it is unlikely due to the size of the small business and the staffing requirements to maintain complete oversight and ensure proper operation of the device.

Fiscal Impact Statement

The board currently ensures compliance with Pharmacy Law and regulations through robust inspection and enforcement programs. The board indicates the proposed regulations are not anticipated to increase workload or costs to the state.

Consideration of Alternatives

No reasonable alternative considered by the agency would be more effective in carrying out the purpose for which the regulation is proposed, would be as effective and less burdensome to affected private persons than the adopted regulation, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The board considered the following alternatives:

(1) The board considered not establishing the specific requirements of the self-assessment form in 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 BPC section 4427.8(b)(3).

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period from July 3, 2020, to August 17, 2020, the board received several comments. The comments were provided in the meeting materials for the September 17, 2020 board meeting, and the board reviewed and considered them. The board amended the regulation text to address some of the concerns raised and voted to initiate a 15-day comment period.

Summary and Response to 45-day Comments:

Written Comments from BJ Bartleson, California Hospital Association

Comment 1: Ms. Bartleson recommended that section 1711(f) be amended to read "Further, any record related to the use of a licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance (QA) review." Ms. Bartleson indicates that without the use of the term "licensed," the regulation could be interpreted to require the submission of quality assurance reports by General Acute Care Hospitals, which are exempt from licensure.

Response to Comment 1: The board considered this comment and amended the language with respect to the reporting of QA records to the board within 30 days for licensed ADDS devices. This change is reflected in the modified text to include the word "licensed." Further, as BPC section 4427.8(b)(1) requires the board to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, the board determined that QAs completed on unlicensed ADDS devices must be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track.

Comment 2: Ms. Bartleson recommended that section 1711(f) be amended to read "Further, any licensee with a record related to the use of an automated drug delivery system, must also notify the board during license renewal if any quality assurance records related to the use of the APDS were generated ~~be submitted to the board within 30 days of completion of the quality assurance review.~~" Ms. Bartleson indicated that notifying the board at the time of renewal of quality assurance records for automated patient dispensing system (APDS) could be easily done as opposed to submitting the records to the board within 30 days.

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. As mentioned in the response to comment one, the board is mandated to report to the Legislature on or before January 1, 2024 on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The reporting requirement established in BPC section 4427.8 applies to all ADDS devices used within the health care system and is not specific to only APDS devices. Further, timely receipt and review of QA reports will allow the board to appropriately monitor for patient safety concerns that could be identified through the timely review of the reports.

Comment 3: Ms. Bartleson recommended that section 1713(d)(2) be amended to add "to the patient or patient's agent" at the end of the subdivision for consistency with BPC section 4427.6(c).

Response to Comment 3: The board considered this comment and amended the language to add "to the patient or patient's agent" for clarity.

Written Comments from Mark Johnston, CVS Health

Comment 1: Mr. Johnston expressed concern that the changes proposed in Section 1711(f) are unclear and create an undue burden with respect to the term "any record" and Mr. Johnston requested clarification on the meaning. He recommended that the language be amended to read "any record related to a medication error associated with the use of an automated...." for clarity. Mr. Johnston indicated that numerous reports exist that are not relevant and have no bearing on the quality assurance review.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. The quality assurance review identified in this regulation is specific to medication errors, as such, the board determined that adding in medication error was not necessary; however, the board determined that the language should be amended to read "Any quality assurance record related...." for clarity and this change was included in the modified text.

Written Comments from Michael Tou, Providence St. Joseph Health

Comment 1: Mr. Tou recommended that section 1711(f) be amended to read "Further, any record related to the use of a~~n~~ licensed automated drug delivery system must also be submitted to the board within 30 days of completion of the quality assurance review." Mr. Tou indicated that the regulation is interpreted to apply to licensed ADDS and would exclude automated unit dose systems (AUDS) used in hospitals and adding "licensed" clarifies the language.

Response to Comment 1: The board considered this comment and amended the language with respect to the reporting of QA records to the board within 30 days for licensed ADDS devices. This change is reflected in the modified text to include the word "licensed." Further, as BPC section 4427.8(b)(1) requires the board to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, the board determined that QAs completed on unlicensed ADDS devices must be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track.

Written Comments from Rita Shane, Cedars-Sinai Medical Center

Comment 1: Dr. Shane recommended that section 1711(f) be amended to add "This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code." Dr. Shane indicated that this addition will exclude AUDS machines used in General Acute Care Hospitals from the quality assurance review process.

Response to Comment 1: The board considered this comment and amended the language with respect to the reporting of QA records to the board within 30 days for licensed ADDS devices. As mentioned in response to previous comments, the board determined that licensed ADDS should report to the board QA records within 30 days so that the board can track these medication errors more routinely, while balancing the need to also collect additional information for unlicensed ADDS. As reflected in the modified text, the board determined that QA completed on unlicensed ADDS devices be reported at the time of the annual renewal of the corresponding facility license. Such an approach will allow the board to review for patient safety issues and also ensure the board is positioned to prepare and report to the legislature on or before January 1, 2024 as required. BPC section 4427.8 establishes the requirement for the board to submit a report on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The legislative report requirement does not draw a distinction between licensed and unlicensed ADDS. This

annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track.

Comment 2: Dr. Shane recommended that section 1715.1 be amended to add a statement that "This section shall not apply to automated unit dose system located within a general acute care hospital as defined in subdivision (a) of Section 1250 of the Health and Safety Code." Dr. Shane states that the hospital self-assessment includes an ADDS section currently for hospitals to review.

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. The ADDS self-assessment applies to all ADDS devices. Hospitals would need to complete the appropriate sections of the ADDS self-assessment consistent with the provisions of this regulation and CCR section 1715. The board determined that the hospital self-assessment shall be updated in the future to remove the ADDS portion. As ADDS devices will now have their own self-assessment, duplicating the information in the hospital self-assessment will no longer be necessary.

Written Comments from John Gray, Kaiser Permanente

Comment 1: Dr. Gray recommended that section 1711(f) be amended to clarify whether a general acute care hospital would be required to submit quality assurance records.

Response to Comment 1: The board considered this comment and amended the language with respect to the reporting of QA records to the board within 30 days for licensed ADDS devices. This change is reflected in the modified text to include the word "licensed." Further, as BPC section 4427.8(b)(1) requires the board to provide a report to the legislature on or before January 1, 2024, on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS, the board determined that QAs completed on unlicensed ADDS devices must be reported at the time of the annual renewal of the corresponding facility license. This annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track.

Comment 2: Dr. Gray recommended that section 1711(f) be amended to allow for the disclosure of QA records at the time of renewal as opposed to the record keeping burden associated with submitting the records within 30 days of completing the review. Dr. Gray stated this would ensure that the board is notified of errors and eliminate the need to report for AUDS devices.

Response to Comment 2: The board considered this comment and determined that no changes were necessary to the text based thereon. As mentioned in the response to comment one, the board is mandated to report to the legislature on or before January 1, 2024 on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. This requirement is specific to all ADDS devices used within the health care system and does not exempt AUDS devices. The board noted that the reporting timeframes vary based primarily on the licensure status of the ADDS.

Comment 3: Dr. Gray recommended that section 1713(d)(2) be amended to add "to the patient or patient's agent" to the end of the subdivision for consistency with BPC section 4427.6(c).

Response to Comment 3: The board considered this comment and amended the language to add "to the patient or patient's agent" for clarity.

Comment 4: Dr. Gray recommends that a FAQ be developed with respect to section 1713(e)(5) on the content and manner in which patients be provided orientation on the use of a APDS.

Response to Comment 4: The board considered this comment and determined that no changes were necessary to the text based thereon. As not every pharmacy will have the same device or the same business model, the board determined that the pharmacy will need to develop the policies and procedures that are specific to their device and its practice.

Comment 5: Dr. Gray recommended that the self-assessment be amended on page 6 and page 13 to state "or located in a Medical office" instead of "and" for grammatical clarity. Additionally, Dr. Gray recommended that page 13 of the self-assessment be amended to allow electronic consent for the use of an APDS and that the term "signed" be changed to "executed" for electronic consent.

Response to Comment 5: The board considered this comment and amended that language in part to accept a digital signature and to change the language to "or located in a medical office." The board determined that the recommended change on page 13 of the self-assessment form was not necessary. Patients who have provided informed consent are eligible for inclusion in receiving prescription drugs via APDS. The signed written consent required under BPC section 4427.6(b) can be satisfied by a digital signature that is retained as part of the patient's record.

15-Day Public Comment Period

During the public comment period from September 25, 2020, to October 10, 2020, the board received several comments. The comments were provided in the meeting

materials for the October 27-28, 2020 board meeting, and the board reviewed and considered them.

Summary and Response to 15-day Comments:

Written Comments from John Gray, Kaiser Permanente

Comment 1: Dr. Gray stated he does not believe it is necessary for the board to report to the Legislature on the public safety concerns related to all ADDS throughout the health care system. Dr. Gray stated that the proposed modified text of section 1711(f) on quality assurance (QA) programs is broader than the Legislature intended when it enacted BPC section 4427.8 and he believes the board can only require quality assurance reports for licensed ADDS devices.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. As reflected in the modified text, the board determined that QAs completed on unlicensed ADDS devices should be reported at the time of the annual renewal of the corresponding facility license. Such an approach will allow the board to review for patient safety issues and also ensure the board is positioned to prepare and report to the legislature on or before January 1, 2024 as required. BPC section 4427.8 establishes the requirement for the board to submit a report on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The legislative report requirement does not draw a distinction between licensed and unlicensed ADDS. This annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track. The previous review and consideration for this topic is available with the September 2020 board's meeting materials (Agenda item VII(b) and 45-day comment responses), and webcast, which can be found on the board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Written Comments from Michael Tou, Providence St. Joseph Health

Comment 1: Mr. Tou requested clarification on the QA required for unlicensed automated drug delivery systems. Mr. Tou recommended amending section 1711(f) to require that the QA only be submitted for medication errors from actions by a Board licensee.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. As identified in previous comment responses, BPC section 4427.8 establishes the requirement for the board to submit a report on the use and dispersion of ADDS throughout the health care system, as well as any public safety concerns relating to the use of ADDS. The legislative report requirement does not draw a distinction between licensed and unlicensed ADDS. This

annual reporting to the board will ensure that the board has access to the data necessary to meet the statutorily mandated reporting. Additionally, following the reporting in 2024, the board can revisit and determine if this data is still necessary for the board to monitor and track. The previous review and consideration for this topic is available with the September 2020 board's meeting materials (Agenda item VII(b) and 45-day comment responses), and webcast, which can be found on the board's website, available at https://www.pharmacy.ca.gov/about/meetings_full.shtml.

Written Comments from Seema Siddiqui, SpotRx Pharmacy

Comment 1: The commenter expressed concern about the complexity of the ADDS Self-Assessment form and recommended that the board adopt a different form for each device. The commenter also recommended that the language in section 1715.1 be amended to read as follows:

> (c) A pharmacist-in-charge of an automated drug delivery system shall assess the system's compliance with current laws and regulations by using the components of Form 17M-112 (Rev 12/18) entitled "Automated Drug Delivery System Self Assessment". Form 17M-112 shall be used for all automated drug delivery systems ~~and is hereby incorporated by reference~~ and may be revised from time to time by pharmacy board staff provided, however, that such revisions do not conflict with then existing statute or regulations.

Response to Comment 1: The board considered this comment and determined that no changes were necessary to the text based thereon. Under the Administrative Procedure Act, if the board requires the completion of a specific form, the form must be incorporated by reference in the regulation. The board cannot require the completion of a revised form without incorporating it by reference. The board determined that multiple forms were not necessary as everything can be completed using one document.

At its October 27-28, 2020 meeting, after reviewing and considering all comments in the record, the board voted to adopt the regulation text as noticed for public comment on September 25, 2020. Additionally, the board delegated to the Executive Officer the authority to make technical and non-substantive changes as necessary to complete the rulemaking file.