TITLE 16: BOARD OF PHARMACY
FINAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Self-Assessment for Pharmacies

Sections Affected: Title 16, California Code of Regulations (CCR) section 1715

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 November 12, 2021, and ended on December 27, 2021. 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 one comment. At the January 27, 2022 board meeting, the board reviewed the comment received. Additionally, the board amended the regulation text and self-assessment forms due to pharmacy law changes that occurred between July 2018 and January 1, 2022. The board voted to initiate a 15-day public comment period, which commenced on February 15, 2022, and concluded on March 2, 2022. During the 15-day comment period, the board received one comment. At the March 16, 2022 board meeting, the board considered the comment submitted and determined that no additional modifications to the text or form were appropriate. The board voted to adopt the modified text as noticed for public comment on February 15, 2022.

Additionally, the board delegated to the Executive Officer the authority to make technical and non-substantive changes as necessary to complete the rulemaking file.

Following adoption by the board, staff made non-substantive changes to the self-assessment form to ensure all statutes and regulations identified on the form have consistent formatting and sections are appropriately referenced. Additionally, minor typographical and grammar edits were made to ensure the language on the self-assessment form appropriately mirrors the language in statute or regulation, and gendered terms were stricken and replaced with non-gendered language to conform with Assembly Concurrent Resolution (ACR) 260 of 2018, 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." Corresponding verbs were changed to the plural form for grammatical consistency.

The changes for the modified text comment period and the post-adoption non-substantive edits are as follows:

Section 1715

For the modified text period, the board amended subdivision (c) to change the revision date of the self-assessment forms incorporated by reference from 7/18 to 12/21. Following adoption, with non-substantive changes being made to the forms, this date was changed to 1/22 to reflect the last update. Following adoption by the board, staff made non-substantive changes to subdivisions (c)(6) and (c)(7) by removing gendered language and replacing it with gender-neutral terms, in accordance with ACR 260, discussed above. Because these changes are grammatical, they are without regulatory effect.

Self-Assessment Forms (17M-13 and 17M-14)

Throughout the forms, the board removed or added, "Yes, No, N/A" as needed above the check boxes to ensure the boxes are identified at the top of each page and beginning of each section. Items were renumbered as needed to adjust for added and/or removed text and a space to record a corrective action or action plan was added as needed to ensure this space was included at the end of each section. Additionally, spacing between words or letters was added or removed for consistency throughout the document. The statutes and regulations identified on the form were also amended or added to ensure appropriate references are identified throughout the self-assessment form. Further, grammatical changes were made to correct punctuation or spelling throughout the document and statutes and regulations identified on the form were updated to ensure reference to the appropriate code sections throughout the form. Finally, the revision date was amended at the bottom of each page from 07/18 to 12/21 in the modified text comment period, and then to 1/22 with the non-substantive changes after adoption to reflect the last update.

Community Pharmacy/Hospital Outpatient Pharmacy Self-Assessment (17M-13)

Page 1

In the introductory material on page 1, the reference to Form 17M-14's revision date was changed from 10/14 to 12/21. Post-adoption, non-substantive changes were made to refer to Form 17M-14 and Form 17M-39 by the corresponding regulation that incorporates each form. Thus, in referencing Form 17M-14, "Rev. 12/21" was stricken and replaced with "pursuant to 16 CCR 1715," and, in referencing Form 17M-39, "Rev. 02/12" was stricken and replaced with "pursuant to 16 CCR 1735.2(k)." The purpose of this change was to avoid the need to pursue regulations to update revision dates for forms merely being referenced, particularly given that, as commenter Joe Jolliff, Pharm.D. highlighted, Form 17M-39 is currently undergoing revisions.

On page 1, "Expiration" was changed to "Exp Date" for consistency with the other uses on page 1. Additionally, "Licensed Remote Dispensing Site Pharmacy License # and Exp Date" was added. BPC 4130 established the board's authority to issue a remote dispensing site pharmacy license. Adding the reference here provides a space for the

pharmacist-in-charge (PIC) to record the license number for this facility if this service is provided by the pharmacy.

At the bottom of page 1, “Accredited by (optional if any): __ From: __ To: _” was stricken. Accreditation does not apply to community pharmacies or outpatient hospital pharmacies, as such this information is not appropriate.

Page 4

Section 1.11 was amended to remove reference to “Section 27” and added “self-assessment as required by CCR 1735.2(k).” The change ensures that the self-assessment form referenced within CCR 1735.2 is completed in the event that form 17M-39 is updated outside future updates to form 17M-14.

Sections 1.12 and 1.14 were amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Section 1.17 was added and reads: “The pharmacy informs the customer at the point of sale for a covered prescription drug whether the retail price is lower than the applicable cost-sharing amount for the prescription drug unless the pharmacy automatically charges the customer the lower price. Additionally, the pharmacy submits the claim to the health care service plan or insurer.” Adding this information provides educational notice to the PIC that the pharmacy must disclose the retail price if it is lower than the cost-sharing cost and bill the health care plan or insurer appropriately.

Page 5

Section 1.18 was added and reads: “A pharmacy that dispenses controlled substances shall display safe storage products (a device made with the purpose of storing prescription medications with a locking or secure mechanism for access by the patient i.e. medicine lock box, locking medicine cabinet, locking medication bags, prescription locking vials, etc.) in a place on the premise that is located close to the pharmacy unless the pharmacy is owned and managed by pharmacists and owns 4 or less pharmacy.” Adding this information provides educational notice to the PIC that the pharmacy must display safe storage products under specific conditions per BPC 4106.5, which was established effective January 1, 2019.

Section 1.19 was added and reads: “A community pharmacy does not require a pharmacist employee to engage in practice of pharmacy at any time the pharmacy is open to the public unless either another employee at the establishment is made available to assist the pharmacist at all times unless the pharmacy is exempted.” Adding this information provides educational notice to the PIC that the pharmacy must have someone available to assist the pharmacist at all times, unless the pharmacy is exempted per BPC 4113.5, which was established effective January 1, 2019.

Sections 1.19.1 through 1.19.5 identify the requirements of CCR 1714.3, which was effective September 20, 2020. Consistent with BPC 4113.5, CCR 1714.3 identifies the requirements that the pharmacy must meet to comply with the statute, including identifying the name of the assigned person/people who shall be available to assist the pharmacist, ensuring that the assigned person/people is/are able to perform the duties identified in CCR 1793.3, ensuring that the assigned person/people qualifies/qualify to have access to controlled substances (i.e. a background check has been completed), and ensuring that the person/people assigned is/are available to assist within five minutes. Finally, sections 1714.3(b) and (c) identify the requirements for the pharmacy to develop and maintain policies and procedures and ensure that all impacted staff have read and signed a copy of the policies and procedures. Adding this information provides educational notice to the PIC about the requirements for community pharmacy staffing.

Section 1.19.2 was non-substantively amended post adoption to add a comma between "1714.3[a][2]" and "[3]" in order to grammatically clarify that these are two distinct regulatory subdivisions.

Section 1.20 was added and reads: "The pharmacy has the capability to receive an electronic data transmission prescription on behalf of a patient." Adding this information provides educational notice to the PIC about the requirements for electronic data transmission established by BPC 688(b), effective January 1, 2022.

Section 1.20.1 was added and reads: "For prescriptions for controlled substances, as defined by Section 4021, generation and transmission of the electronic data transmission prescription complies with Parts 1300, 1304, and 1311 or Title 21 of the Code of Federal Regulations." Adding this information provides educational notice to the PIC about the requirements for electronic data transmission established by BPC 688(c), effective January 1, 2022.

Section 1.20.2 was added and reads: "At the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester (BPC 688 (g). Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law." Adding this information provides educational notice to the PIC about the requirements for electronic data transmission established by BPC 688(g), effective January 1, 2022.

Section 1.20.3 was added and reads: "If the pharmacy, or its staff, is aware that an attempted transmission of an electronic data transmission prescription failed, is incomplete, or is otherwise not appropriately received, pharmacy staff immediately notifies the prescribing health care practitioner." Adding this information provides educational notice to the PIC about the requirements for electronic data transmission established by BPC 688(h), effective January 1, 2022.

Section 1.21 was added and reads: “The pharmacy performs FDA approved or authorized tests that are classified as CLIA waived.” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10, effective January 1, 2022.

Page 6

Section 1.21.1 was added and reads: “The pharmacy is appropriately licensed as a laboratory under Section 1265. CDPH (CLIA) Registration #: _____ Expiration: _____.” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10(a), effective January 1, 2022.

Section 1.21.2 was added and reads: “The pharmacy maintains policies and procedures as specified in BPC 4119.10(b).” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10(b), effective January 1, 2022.

Section 1.21.3 was added and reads: “The tests are authorized to be administered by a pharmacist pursuant to BPC 4052.4(b)(1).” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10(c), effective January 1, 2022.

Section 1.21.4 was added and reads: “The pharmacist-in-charge reviews the policies and procedures annually, accesses compliance with its policies, and documents corrective actions to be taken when noncompliance is found and maintains documentation of the annual review and assessment in a readily retrievable format for a period of three years.” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10(d), effective January 1, 2022.

Section 1.21.5 was added and reads: “The pharmacy maintains documentation related to performing tests, including the name of the pharmacist performing the test, the results of the test, and communication of results to the patient’s primary medical provider, and is maintained in a readily retrievable format for a period of three years.” Adding this information provides educational notice to the PIC about the requirements for CLIA waived testing established by BPC 4119.10(e), effective January 1, 2022.

Page 7

Section 2.2.5 was non-substantively amended post-adoption to strike the word “being” for grammatical consistency.

Section 3.2 has been amended to add “warehoused, distributed” and “third-party logistics provider” for consistency with BPC 4169. This requirement mirrors the language of BPC 4169(a)(1), which prohibits the purchase, trade, sale, wholesale,

distribution or transfer of dangerous drugs and dangerous devices to a person or entity that is not licensed by the board.

Page 8

Section 3.3 was added and reads: “If the pharmacy reasonably has cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge.” This requirement mirrors the language of BPC 4107.5 and is added to ensure that the PIC is aware of the 72-hour reporting requirement when counterfeit dangerous drugs or dangerous devices or fraudulent transactions are identified.

Section 3.4 was added and reads: “The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person.” This requirement mirrors the language of BPC 4163 which prohibits an unauthorized person from acquiring dangerous drugs or dangerous devices.

Section 3.5 was added and reads: “The pharmacy is aware that pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023, unit-level traceability.” This addition was added to include the reference to the DQSA, which was passed in 2017 with three year and six-year implementation milestones. The DQSA established Federal medication tracing requirements within 21 USC 360eee-I(g). Post-adoption, this section was amended non-substantively to replace the reference to a section of the DQSA legislation with the codified citation.

Page 9

Section 6.1 was amended to add “HIV preexposure prophylaxis, HIV postexposure prophylaxis,” to the sixth check box. BPC sections 4052.02 and 4052.03 authorize a pharmacist to furnish preexposure prophylaxis (PrEP) and postexposure prophylaxis (PEP), respectively, if certain conditions are met. Adding this information includes PEP and PrEP within the list of medications that may be furnished by pharmacists.

Two additional check boxes were added to the bottom of the list. These check boxes read as follows:

- ☐ Initiate, adjust, or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority.
- ☐ Provide medication-assisted treatment pursuant to a state protocol, to the extent authorized by federal law.

These requirements mirror the language of BPC 4052(a)(13) and 4052(a)(14), which became effective January 1, 2022, via Assembly Bill 1533 (Stats. 2021, Ch. 629, Sec. 11). Non-substantively, post-adoption, this section was amended by striking the word “only” to mirror the permissive language in the statute (BPC 4052), as this is the only

legally tenable interpretation of the statutory language, and the word “a” was capitalized for grammatical compliance.

Page 10

Section 6.2 was amended to add “In addition” as the information within this section is to be included with the information in section 6.1, so the addition of the term “In addition” provides clarity to this. Non-substantively, post-adoption, the word “only” was deleted to mirror the permissive language in the regulation (CCR 1793.1), as this is the only legally tenable interpretation of the regulation.

Page 11

Section 6.6 was amended to strike “No CDPH registration required” from the form. This information was removed to mirror the language within BPC 1206.6, which does not indicate CDPH registration is required.

Section 6.7 was amended to strike “where the pharmacy is registered with the CDPH to perform such services” from the form. This information was removed to mirror the language within BPC 1206.6, which does not indicate CDPH registration is required. Additionally, “FDA-approved or authorized” and “specified in BPC 4052.4” was added to mirror the language within BPC 1206.6(a) and (c).

Section 6.9 was added to read: “Effective July 1, 2022, a pharmacist who is authorized to an order to initiate or adjust a Schedule II Controlled substance shall have completed an education course on the risks of addiction associated with the use of Schedule II drugs.” Non-substantively, post-adoption, the phrase “an order to” was eliminated from “…a pharmacist who is authorized to an order to initiate or adjust…” as a typographical error. The sentence does not make sense otherwise.

This requirement mirrors the language of BPC 4232.5(a) which becomes effective January 1, 2022, via Assembly Bill 1533 (Stats. 2021, Ch. 629, Sec. 25) and provides education to the PIC about the new requirement for completion of the education course.

Section 6.10 was added to include the requirement for pharmacists to join the board’s email notification list. This section is not requiring the PIC to enroll the pharmacists in the board’s email notification list; however, listing the requirement here will ensure that the PIC understands they must be enrolled and encourage them to speak with any pharmacist under their supervision about the requirements of BPC 4013.

Page 12

Section 8.3 was amended to add “or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience” to align the language on the self-assessment for with the language in BPC 4209(b). This change ensures consistency between the form and the statutory requirement.

Section 8.5 was added to include the requirement for intern pharmacists to join the board's email notification list. This section is not requiring the PIC to enroll the intern pharmacists in the board's email notification list; however, listing the requirement here will ensure that the PIC speaks with any intern pharmacist under their supervision about the requirement and will provide education to the intern pharmacist about the requirement of BPC 4013.

Page 13

Section 9.1 was amended to add "The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist's supervision." The requirement is added for education purposes for the PIC to ensure they are aware of the responsibility of the pharmacist as it relates to a pharmacy technician as specified in BPC 4115(h).

Section 9.3 was amended to change "his or her self" to "them" to use a gender-neutral pronoun.

Section 9.5 was amended to change "120" to "140" which is consistent with the changes to BPC 4115.5(c)(1), which became effective January 1, 2020.

Section 9.6 was added to include the requirement for pharmacy technicians to join the board's email notification list. This section is not requiring the PIC to enroll the pharmacy technicians in the board's email notification list; however, listing the requirement here will ensure that the PIC speaks with any pharmacy technician under their supervision about the requirement and will provide education to the pharmacy technician about the requirement of BPC 4013.

Page 14

Section 11.1.4 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Page 15

Section 12.8 was amended to add HSC section 11159.3 to the prescription requirements. HSC section 11159.3 become law effective January 1, 2020, via Senate Bill 569 (Stats. 2019, Ch. 705, Sec. 1).

Non-substantively, post-adoption, Section 12.10 was amended to add the word "parts" subsequent to "21 CFR" to correct legal citations.

Section 13.2 was amended to add "patient centered labeling requirements." This addition is to provide clarity instead of simply referring to CCR 1707.5. Reference to CCR 1707.5 was maintained as the reference for the patient centered labeling requirements.

Page 16

Section 13.4 was amended to add “and includes the statement ‘generic for _____’ where the brand name is inserted, and the name of the manufacturer. In the professional judgment of the pharmacist, if the brand name is no longer widely used, the label may list only the generic name of the drug and the manufacturer’s name may be listed outside the patient-centered area.” This language was added for clarity to the PIC as a result of changes to CCR 1707.5, which became effective July 1, 2017.

Section 13.6 was added and reads: “When a biological product is substituted with an alternative biological product, all the requirements of BPC 4073.5 are met.” Adding this information provides educational notice to the PIC about the requirements of BPC 4073.5 and substitution of biological products.

Section 13.7 was amended to add “or by recording the identity of the reviewing pharmacist in a computer system by a secure means.” This addition is consistent with the requirement of CCR 1712 and is being added for clarity on the ability for pharmacist to verify prescriptions via a computer system. Further, for purposes of clarity, the reference to a pharmacy technician trainee was moved from the end of the sentence to the beginning of the sentence, right after pharmacy technician. This change is non-substantive and does not alter the meaning of the section or the requirements within statute and regulation.

Page 17

Section 13.13 was amended to add reference to BPC 4119 as a first check box. The addition reads: “BPC 4119 to an approved service provider within an emergency medical services system for storage in a secured emergency pharmaceutical supplies container, in accordance with the policies and procedures of the local emergency medical services agency.” BPC 4119 was amended effective January 1, 2018, to allow for the furnishing of dangerous drugs to an emergency medical services agency.

Section 13.17 was reworded. Instead of identifying the exceptions in the form of a list, which was proposed in the original noticed text, the exceptions were added back into the section using the new wording of “self-administered hormonal contraception” instead of “drugs.” Including the exceptions within the specific language is for clarity and is a non-substantive change. Deleting the duplicative list is a non-substantive post-adoption change.

Page 18

Section 13.17.3 is added and reads: “When requested by the patient, the pharmacist dispenses up to a 12-month supply of an FDA-approved, self-administered hormonal contraceptive pursuant to a valid prescription that specifies an initial quantity followed by periodic refills.” Adding this information provides educational notice to the PIC about the requirements of BPC 4064.5 and the furnishing of self-administered hormonal

contraception.

Section 13.17.4 is added and reads: “When a pharmacist furnishes a self-administered hormonal contraceptive pursuant to BPC 4052.3 under protocols developed by the Board of Pharmacy, the pharmacist may furnish, at the patient’s request, up to a 12-month supply at one time.” Adding this information provides educational notice to the PIC about the requirements of BPC 4064.5 and the furnishing of self-administered hormonal contraception.

Section 13.17.1.5 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Section 13.19 is added and reads: “The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container.” Adding this information provides educational notice to the PIC about the requirements of BPC 4074 and CCR 1744 with respect to labeling requirements when taking a medication with alcohol.

Section 13.20 is added and reads: “Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.”” Adding this information provides educational notice to the PIC about the requirements of BPC 4076.7 respect to labeling requirements for opioids and overdose/addiction.

Section 13.21 is added and reads: “When requested by a patient or patient representative, the pharmacy provides translated directions for use, printed on the prescription container, label, or on a supplemental document. If the translated directions for use appear on the prescription container or label, the English-language version of the directions for use also appears on the container or label, whenever possible, and may appear on other areas of the label outside the patient-centered area. If the English-language directions is not possible to appear on the container or label, the English-language directions is provided on a supplemental document.” Adding this information provides educational notice to the PIC about the requirements of BPC 4076.7 with respect to labeling requirements for translated directions for use. The non-substantive grammatical change post-adoption moved the “is not possible” to the beginning of the second sentence for clarity.

Section 13.22 is added and reads: “When a pharmacist furnishes naloxone pursuant to the board of pharmacy’s approved protocol, the pharmacist complies to all the requirements listed in CCR 1746.3.” Adding this information provides educational notice to the PIC about the protocol requirements of CCR 1746.3 and the furnishing of naloxone hydrochloride.

Section 13.23 is added and reads: “When the pharmacy furnished naloxone or another opioid antagonist to a school district, county office of education, or charter school

pursuant to Section 49414.3 of the Education Code, it is furnished exclusively for use at a school district school site, county office of education school site, or charter school, and a physician or surgeon provides a written order specifying the quantity to be furnished." Adding this information provides educational notice to the PIC about the requirements of BPC 4119.8 and the furnishing of naloxone or opioid antagonist to a school system.

Pages 18 - 19

Section 13.24 is added and reads: "The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency if the furnished exclusively for use by trained employees of the law enforcement agency and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years." Adding this information provides educational notice to the PIC about the requirements of BPC 4119.9 and the furnishing of naloxone or opioid antagonist to a law enforcement agency. Post-adoption, the language was non-substantively amended to mirror the statutory language of BPC 4119.9 to read as follows: "13.24. The pharmacy furnishes naloxone hydrochloride or other opioid antagonist to a law enforcement agency exclusively for use by employees of the law enforcement agency, who have completed training provided by the law enforcement agency, in administering naloxone hydrochloride or other opioid antagonists, and the records of acquisition and disposition of naloxone hydrochloride or other opioid antagonists furnished shall be maintained by the law enforcement agency for 3 years. (BPC 4119.9)"

Page 19

Section 13.25 is added and reads: "For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours, provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine (includes informing each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e)." Adding this information provides educational notice to the PIC about the requirements of CCR 1746.4 and the records required for administering vaccines. Post-adoption, the language was non-substantively amended to mirror the regulatory language of CCR 1746.4(e) and (f) to read as follows: "13.25. For each vaccine administered by a pharmacist, a patient vaccine administration record is maintained in an automated data processing or manual record mode such that the information required under section 300aa-25 of Title 42 of the United States Code is readily retrievable during the pharmacy's normal operating hours. A pharmacist provides each patient with a vaccine administration record, and reports to the immunization registry, in accordance with BPC 4052.8(b)(3), the information described in HSC 120440(c) within 14 days of the administration of any vaccine. A pharmacist

informs each patient or patient's guardian of immunization record sharing preferences detailed in HSC 120440(e). (CCR 1746.4[e], [f])"

Section 13.26 is added and reads: "The pharmacy furnishes epinephrine auto-injectors to an authorized entity for the purpose of rendering emergency care in accordance with HSC 1797.197(a), and is furnished exclusively for use by, or in connection with, an authorized entity and an authorized health care provider provides a prescription specifying the quantity of the epinephrine auto-injectors to be furnished to the authorized entity. A new prescription is obtained for any additional epinephrine auto-injector required for use. The pharmacy complies with the requirements for labeling and records maintained pursuant to BPC 4119.4." Adding this information provides educational notice to the PIC about the requirements of BPC 4119.4 and the records required for furnishing epinephrine auto-injectors.

Section 13.27 is added and reads: "When a pharmacist initiates and furnishes HIV preexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.02." BPC section 4052.02 authorizes a pharmacist to furnish preexposure prophylaxis (PrEP), if certain conditions are met. Adding this information provides educational notice to the PIC about the requirements of BPC 4052.02 and HIV preexposure prophylaxis.

Section 13.28 is added and reads: "When a pharmacist initiates and furnishes HIV postexposure prophylaxis, the pharmacist does so in compliance with all the requirements of BPC 4052.03." BPC section 4052.03 authorizes a pharmacist to furnish postexposure prophylaxis (PEP), if certain conditions are met. Adding this information provides educational notice to the PIC about the requirements of BPC 4052.03 and HIV postexposure prophylaxis.

Section 13.29 is added and reads: "When a pharmacist receives a prescription, which include the words 'expedited partner therapy' or the letters 'EPT' pursuant to HSC 120582, the pharmacist labels the drug without the name of the individual for whom the drug is intended." Adding this information provides educational notice to the PIC about the requirements of BPC 4076(a) and (f) and the requirements for EPT labeling. Post-adoption, "pharmacists" was changed to the singular form, "pharmacist," as a non-substantive grammatical change.

Section 13.30 is added and reads: "When a pharmacist provides EPT the pharmacist provides written notification that describes the right of an individual who receives EPT to consult with a pharmacist about the medication dispensed and additional information regarding possible drug interactions." Adding this information provides educational notice to the PIC about the requirements of BPC 4076(a) and (h) and the written notification requirements to individuals receiving EPT.

Page 20

Section 14.5 was added and reads: “Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times within 6 months, and all refills taken together do not exceed a 120-day supply.” Adding this information provides educational notice to the PIC about the restrictions on refills for Schedule III and IV controlled substances, as specified by HSC 11200.

Pages 20 - 21

Section 15 has been added to include the requirements for auto-refill programs. On July 1, 2022, the board’s regulations (CCR section 1717.5) with respect to auto-refill programs become effective. Adding this information provides educational notice to the PIC about the requirements for auto-refill programs that have not previously existed.

Sections 15.1 through 15.1.9 were added and identify the specific requirements on the form, from regulation identified above, for a pharmacy that provides auto-refill programs. These additions ensure that the PIC is aware of the regulatory requirements should the pharmacy provide this service.

Post-adoption, the language in Section 15.1.3 was non-substantively amended to mirror the language within the regulation (CCR 1717.5[a][3]) for consistency.

Page 22

Section 17.3 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Page 23

Section 18.3 was added and reads: “For electronic data transmission prescriptions, at the request of the patient or person authorized to make a request on behalf of the patient, the pharmacy immediately transfers or forwards an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester (BPC 688 (g). Unfulfilled controlled substance prescriptions received as electronic data transmission prescriptions are transferred or forwarded in compliance with Federal Law.” Adding this information provides educational notice to the PIC about the requirements for electronic data transmission established by BPC 688, effective January 1, 2022.

Page 24

Section 20.2 was amended to add “Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.” This addition provides education to the PIC

with respect to the records requirement of BPC 4105(d)(1). Post-adoption, the language was non-substantively amended to remove the duplicative text “maintained electronically.”

Section 20.2.3 was added and reads: “Purchase Invoices and sales records for non-prescription diabetic test devices dispensed pursuant to a prescription.” This addition provides education to the PIC with respect to the records requirement of BPC 4081(d). The pharmacy must maintain records for diabetic test devices for three years.

Section 20.2.9 was amended to add “and reverse distributors” to the records requirements. Reverse distributors were established by statute (BPC 4040.5) in 2018 and can accept outdated or nonsaleable dangerous drugs or dangerous devices. The pharmacy must maintain records for any items transferred or sold to another entity, per BPC 4105.

Section 20.2.10 was added and reads: “Records of receipt and shipment.” This addition provides education to the PIC with respect to the records requirement of BPC 4081. The pharmacy must maintain records for any items received or shipped.

Section 20.3 (formerly section 19.3) was amended to change “Hypodermic needle and syringe sales by a pharmacist to a person without” to “A pharmacist may sell hypodermic needles and syringes to a person with,” which provides clarity to the PIC with respect to the requirements for selling hypodermic needles and syringes. Post-adoption, this section was non-substantively amended to correct a scrivener’s error by replacing “with” with “without” to mirror the language in the statute (BPC 4145.5).

Page 25

Section 19.3.3 was stricken due to the change in section 20.3 above. BPC 4145.5 was amended effective January 1, 2021, with respect to the furnishing of hypodermic needles and syringes. The previous language in the section no longer applies.
Section 20.6 was added and reads: “The pharmacy furnishes an epinephrine auto-injector to a school district, county office of education, or charter school pursuant to Section 49414 of the Education Code if all of the following are met.” This addition provides education to the PIC with respect to the requirement of BPC 4119.2(a) that specifies the requirements for furnishing epinephrine auto-injectors to schools.

Section 20.6.1 was added and reads: “The epinephrine auto-injectors are furnished for use at a school district site, county office or education, or charter school.” This addition provides education to the PIC with respect to the requirement of BPC 4119.2(a)(1) that specifies the requirements for furnishing epinephrine auto-injectors to schools.

Section 20.6.2 was added and reads: “A physician and surgeon provide a written order that specifies the quantity of epinephrine auto-injectors to be furnished.” This addition provides education to the PIC with respect to the requirement of BPC 4119.2(a)(2) that

specifies the requirements for a physician or surgeon to provide a written order prior to furnishing epinephrine auto-injectors to schools.

Page 26

Section 20.7 was non-substantively amended post adoption to mirror the language within the statute (BPC 4119.4) for consistency.

Page 27

Section 21.12 non-substantively amended post-adoption to mirror the language within the statute (HSC 11167(c), (d)) for consistency.

Section 21.14 was amended to change “upon” to “within one business days of” as required by 21 CFR 1301.74(c) and CCR section 1715.6.

Page 28

Section 21.17 was amended to change the term “weekly” to “within one working day from the date the controlled substance is released to be patient.” The change is consistent with the statutory amendments to HSC 11165(d) effective January 1, 2021. This amendment provides education to the PIC about the CURES reporting requirements.

Section 21.18 was amended to strike the previous language related to physician office use of controlled substances and replace the language with “Furnishing of dangerous drugs and controlled substances for physician office use is done under sales and purchase records that correctly give the date, names and addresses of supplier and buyer, the drug or device and its quantity. The prescription may not be used for obtaining dangerous drugs or controlled substances for supplying a practitioner for the purpose of dispensing to patients.” This amendment provides education to the PIC with respect to the requirements for furnishing dangerous drugs and devices for physician office use as specified by 21 CFR 1306.04.

Section 21.19 was added and reads: “The pharmacy has designed and operates a system to identify suspicious orders and ensures the system complies with applicable Federal and State privacy laws. Upon discovering a suspicious order or series of orders, notify the DEA administration and the Special Agent in charge of DEA in their area.” This addition provides education to the PIC with respect to the requirements for suspicious orders as required by 21 USC 832. This section was amended non-substantively post-adoption to delete the word “administration” as redundant, since “DEA” refers to the Drug Enforcement Administration.

Page 30

Section 23.3 was amended to add “The pharmacist shall notify the prescriber if the remaining portion of the prescription is not filled within 72 hours.” This addition provides

education to the PIC with respect to the requirement of CCR 1745(d) that specifies the partial fill notification requirements in the event the remaining portion of a partial fill is not filled within a 72-hour period.

Section 23.4 was amended to add “(in a readily retrievable form or on the original prescription)” to mirror the language in CCR 1745(c)(2). This addition provides education to the PIC with respect to the requirement of CCR 1745 that specifies the partial fill record requirements.

Section 23.5 was amended to add “The pharmacist shall report to CURES only the actual amounts of drug dispensed. The total dispensed shall not exceed the prescribed quantity.” This addition provides education to the PIC with respect to the requirements of BPC 4052.10, which became effective July 1, 2018, and which specifies the required CURES reporting for partially filled controlled substances.

Section 23.6 was relocated from 23.12. This section was relocated as it is closely associated with the requirements in sections 23.4 and 23.5, so it was appropriate to relocate the information.

Page 31

Section 23.14 was added and reads: “Controlled substance prescriptions with the 11159.3 exemption during a declared local, state, or federal emergency, noticed by the Board, may be dispensed if the following are met:

- The prescription contains the information specified in HSC 11164(a), indicates that the patient is affected by a declared emergency with the words “11159.3 exemption” or a similar statement, and is written and dispensed within the first two weeks of notice issued by the board.
- When the pharmacist fills the prescription, the pharmacist exercises appropriate professional judgment, including reviewing the patient’s activity report from the CURES PDMP before dispensing the medication.
- If the prescription is a Schedule II controlled substance, dispenses no greater than the amount needed for a seven-day supply.
- The patient first demonstrates, to the satisfaction of the pharmacist, their inability to access medications, which may include, but not limited to, verification of residency within an evacuation area.”

This addition provides education to the PIC with respect to the requirements of HSC 11159.3 for filling a prescription during a declared local, state, or federal emergency. The second bullet point under this section was amended to add an “S” to the word “CURE” post-adoption to non-substantively correct a scrivener’s error.

Pages 31 - 32

Section 23 (which was Section 22 in the original form) was renumbered to 24 and was amended to update the title of the section from “Automated Dispensing/ Delivery Devices” to “Automated Drug Delivery Systems.”

Assembly Bill 2037 (Bonta, Statutes of 2018, Chapter 647) added, among other things, BPC section 4119.11. This new statute established two separate classifications of ADDS, specifically, Automated Patient Dispensing System (ADPS) and Automated Unit Dose System (AUDS). Additionally, Senate Bill (SB) 1447 (Hernandez, Chapter 666, Statutes of 2018) added, among other things, BPC sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7, which established the board’s authority to issue an ADDS license; established ownership, placement, and operation requirements; established recordkeeping and quality assurance requirements; and established the requirement for the completion of an annual self-assessment by the pharmacy holding the ADDS license.

Due to these statutory changes in 2018, section 24.1 (formally 23.1) was amended to read:

> Does the pharmacy use an automated drug delivery system, automated patient dispensing system and/or automated unit dose system? (CCR 1713)
>
> If yes, complete the biennial self-assessment for automated drug delivery systems.
>
> Note: An ADDS license is not required for technology installed within the secured licensed premises area of a pharmacy, used in the selecting, counting, packaging, and labeling of dangerous drugs and devices. (BPC 4427.2[j]) or exempt AUDS operated by a licensed hospital pharmacy. (BPC 4427.2(i) As a reminder, a self-assessment form is required for an exempt AUDS.

Sections 23.2 through 23.4.2 were stricken. With the statutory changes identified above, the sections no longer apply.

Page 33

Section 25.3 was amended to add “by another pharmacy” and “and includes the name and address of both pharmacies and complies with the other requirements of” and strike “in compliance with” to mirror the requirements of BPC 4052.7. This addition provides education to the PIC with respect to the requirements of BPC 4052.7 that identifies the repacking requirements for previously dispensed drugs.

Section 25.4 was added and reads: “The pharmacy only repackages and furnishes a reasonable quantity of dangerous drugs and devices for prescriber office use.” This addition provides education to the PIC with respect to the requirement of BPC 4119.5(b) that identifies the repacking requirements for prescriber office use.

Section 26.3 was non-substantively amended post-adoption to change “both” to “the three” for clarity, as there are three questions prior to this statement.

Page 36

Section 28.1.8 (Section 27.1.8 in the proposed text and Section 26.1.8 in the original text) was stricken as it is duplicative of the reporting requirements in section 28.1.1.

Section 28.1.11 was added and reads: “Inventory reconciliation reporting requirements.” This addition provides education to the PIC with respect to the requirement of CCR 1715.65(b) that requires written policies and procedures for inventory reconciliation. This section was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Page 37

Section 28.3.7 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Section 28.3.8 was stricken post-adoption as it is duplicative of section 28.3.5. This is a nonsubstantive change to correct the duplication.

Pages 37 - 38

BPC section 4052(a)(10)(A)(3) authorizes a pharmacist to furnish travel medications without a doctor’s prescription. Additionally, 16 CCR section 1746.5 establishes standards for pharmacists who furnish travel medications. Specifically, section 1746.5 establishes the additional education pharmacists must have; the standards for evaluating a patient and the patient’s travel plans in a pre-travel consultation; the requirements for notification of the patient’s primary care provider or providing a written record of drugs and/or devices furnished to the patient; and the requirements for maintaining the documents concerning the patient medication record for three (3) years. Sections 28.7 through 28.7.5 were added and identify the requirements on the form, from the statute and regulation identified above, for a pharmacy and pharmacist that dispenses travel medication. These additions ensure that the PIC is aware of the regulatory requirements should the pharmacy provide this service.

Section 28.7.4 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Pages 38 - 39

Sections 29.1 and 30.3 were amended to remove reference to Form 17M-39, Rev. 10/12 and add “as required by CCR 1735.2(k).” The change ensures that the self-assessment form referenced within CCR 1735.2 is completed in the event that form 17M-39 is updated outside future updates to form 17M-14.

Pages 39 - 44

Section 31 has been added to include the requirements for telepharmacy systems and remote dispensing site pharmacies.

Sections 31.1 through 31.39 were added and identify the specific requirements for a pharmacy acting as a supervising pharmacy of a remote dispensing site pharmacy (RDSP), based on Assembly Bill (AB) 401 (Aguiar-Curry, Chapter 548, Statutes of 2017), which added, among other things, BPC sections 4130, 4131, 4132, 4133, 4134, 4135:

- Section 4130 – Established the board's authority to issue an RDSP license. Additionally, it established that the RDSP shall only be staffed by a pharmacist or a pharmacy technician.
- Section 4131 – Established that, if the RDSP is not staffed by a pharmacist, it shall be staffed by a pharmacy technician who meets the qualifications of BPC section 4132, with the direct supervision of a pharmacist, which can be done remotely.
- Section 4132 – Established that, in addition to BPC section 4202, a pharmacy technician working at an RDSP shall meet the qualifications promulgated by the board prior to working at an RDSP.
- Section 4133 – Established the requirement for video and audio communication to be maintained between the supervising pharmacy and the RDSP.
- Section 4134 – Established the requirement for a pharmacist from the supervising pharmacy to complete monthly inspections of the RDSP.
- Section 4135 – Established that, if the supervising pharmacy is closed, the RDSP must also be closed with an alarm or monitoring system.

These additions ensure that the PIC is aware of the regulatory requirements should the pharmacy provide this service.

Additionally, sections 31.40 through 31.42 were added to include the requirements of BPC 4059.5(g), which address the ordering, delivery, and storage of dangerous drugs and dangerous devices for an RDSP that is being operated by a pharmacy technician under the supervision of a pharmacist. Again, these additions ensure that the PIC is aware of these regulatory requirements should the pharmacy provide this service.

There were three sections mistakenly numbered 31.31. Therefore, post-adoption, two of the sections were renumbered as 31.29 and 31.30, respectively. This is a non-substantive change without regulatory effect, as it is re-numbering provisions only.

Post-adoption, Section 31.7 was non-substantively amended to replace the word "will" with "may" to mirror the permissive language within the statute (BPC 4130(h)), as this is the only legally tenable interpretation of the statutory language.

Section 31.16 was amended non-substantively post-adoption for clarity to remove reference to the regulations promulgated by the Board, as the requirements are identified in statute (BPC 4132) and not via regulation.

Pages 44 through 50

Section 32 has been added to include the requirements for prescription drug take-back services to the self-assessment form.

Title 21, Code of Federal Regulations (CFR) sections 1300 - 1317 established the federal DEA's regulations on drug take-back programs. The federal law sets forth the voluntary requirements for drug take-back programs in accordance with the Secure and Responsible Drug Disposal Act of 2010. The practice of pharmacy in California is regulated, authorized, and enforced by the board. The federal government does not regulate the practice of pharmacy in California unless the pharmacy is acting as a manufacturer. Effective, June 6, 2017, the board established, via regulation, numerous requirements for pharmacies, hospital pharmacies, and clinics to provide drug take-back services. The requirements are found in CCR 1776-1776.5. Sections 32.1 through 32.50.5 identify the requirements for drug take-back services within a pharmacy. These additions ensure that the PIC is aware of the regulatory requirements should the pharmacy provide this service.

Hospital Pharmacy Self-Assessment (17M-14)

Throughout form 17M-14, the board added "Corrective Action or Action Plan ____" at the end of each section. This is a non-substantive change and ensures that there is space at the end of each section for the PIC to make notes of improvements identified or made during the completion of the self-assessment form.

Page 1

In the introductory material on page 1, the reference to Form 17M-13's revision date was changed from 10/14 to 12/21. Post-adoption, non-substantive changes were made to refer to Form 17M-14 and Form 17M-39 by the corresponding regulation that incorporates each form. Thus, in referencing Form 17M-14, "Rev. 12/21" was stricken and replaced with "pursuant to 16 CCR 1715," and, in referencing Form 17M-39, "Rev. 02/12" was stricken and replaced with "pursuant to 16 CCR 1735.2(k)." The purpose of this change was to avoid the need to pursue further regulations to update revision dates for forms merely being referenced, particularly given that, as commenter Joe Jolliff, Pharm.D. highlighted, Form 17M-39 is currently undergoing revisions.

Check boxes were added before "Sole Owner" and "Non-Licensed Owner" under the ownership section on page one. Additionally, "Trust" was added as an ownership type per the changes to BPC 4035 in 2017 which added "trust" to the definition of "person." Finally, the check box after "Other" was removed. These changes are non-substantive and done for layout purposes. Placing the checkbox before the ownership type makes the section a little clearer when a box is checked.

Page 3

Sections 1.2 and 1.4 were amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Section 1.5 was amended to remove the term “night stock” and add “a supply of” within the section to mirror the language within 22 CCR 70263(n), which does not reference the term “night stock” and makes the section consistent with regulation.

Page 4

Section 1.12 was amended to remove the reference to “Rev. 10/12” and add “required by CCR 1735.2[k].” The change ensures that the self-assessment form referenced within CCR 1735.2[k] is completed in the event that Form 17M-39 is updated outside future updates to Form 17M-14.

Pages 4 - 5

Sections 2.2 and 2.2.1 were amended to add “pharmacist” after “intern.” These changes are necessary to align the language within the self-assessment form with the license title identified in BPC section 4030.

Page 6

Section 3.7 was added and reads: “The pharmacy is aware, effective November 27, 2020, pharmacies are required by the Drug Quality and Security Act (DQSA), to have pharmacy lot-level traceability and by November 27, 2023 unit-level traceability. (Drug Supply Chain Security Act).” This addition was added to include the reference to the DQSA, which was passed in 2017 with three year and six-year implementation milestones. The DQSA established Federal medication tracing requirements.

Section 4.2 was amended to add “Records of drugs taken from the drug stock or drug supplies must be maintained and the pharmacist must be notified” to the section to mirror the language within 22 CCR 70263(n) and make the section consistent with regulation.

Pages 6 - 7

Section 4.3 was amended to add “or to any person in the occasional emergency situation where no other sources are readily available in the community to meet the emergency need” to the section to mirror the language within CCR 4380(b) and make the section consistent with statutory language.

Page 7

Section 4.6 was added and reads: “Dangerous drugs or dangerous devices are purchased, traded, sold or transferred with an entity licensed with the board as a

wholesaler, third-party logistics provider, pharmacy or a manufacturer, and provided the dangerous drugs and devices." This requirement mirrors the language of BPC 4059.5(b) and 4169(a)(1) which prohibits the purchase, trade, sale, warehousing, distribution or transfer of dangerous drugs and dangerous devices to a person or entity that is not licensed by the board.

Section 4.6.1 was added and reads: "Are not known or reasonably should not be known to the pharmacy as being adulterated." This requirement mirrors the language of BPC 4169(a)(2) and is added to provide education and a reminder to the PIC about the prohibition.

Section 4.6.2 was added and reads: "Are not known or reasonably should not be known to the pharmacy as being misbranded." This requirement mirrors the language of BPC 4169(a)(3) and is added to provide education and a reminder to the PIC about the prohibition.

Section 4.6.3 was added and reads: "Are not expired." This requirement mirrors the language of BPC 4169(a)(3) and is added to provide education and a reminder to the PIC about the prohibition. The term expired is an industry standard term and applies to the beyond use date and/or the manufacturer's expiration date and may vary depending on the drug product.

Section 4.7 was added and reads: "If the pharmacy reasonably has cause to believe a dangerous drug or dangerous device in, or having been in its possession is counterfeit or the subject of a fraudulent transaction, the pharmacy will notify the board within 72 hours of obtaining that knowledge." This requirement mirrors the language of BPC 4107.5 and is added to ensure that the PIC is aware of the 72-hour reporting requirement when counterfeit dangerous drugs or dangerous devices or fraudulent transactions are identified. Post-adoption, this section was non-substantively amended to mirror the language within the statute (BPC 4107.5) for consistency.

Section 4.8 was added and reads: "The pharmacy does not furnish dangerous drugs or dangerous devices to an unauthorized person." This requirement mirrors the language of BPC 4163 which prohibits an unauthorized person from acquiring dangerous drugs or dangerous devices.

Section 4.9 was added and reads: "An automated unit dose system (AUDS) operated by a licensed hospital pharmacy as defined by BPC 4029, and used solely to provide doses administered to patients while in a licensed general acute care hospital facility shall be exempted from the requirement of obtaining an ADDS license if the hospital pharmacy owns or leases the AUDS and owns the dangerous drugs or devices in the AUDS. The AUDS shall comply with all other requirements for an ADDS (i.e., Security, Record keeping, Self-Assessment, Quality Assurance, etc.) and maintain a list of the location of each AUDS it operates." This section mirrors the language of BPC 4427.2(i), which requires the AUDS to comply with all other requirements for an ADDS when exempt from licensure.

Page 9

Section 6.5 was added and reads: “The PIC is not concurrently serving as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailer. (CCR 1709.1[d]).” Section 6.5 was originally stricken during the 45-day comment period as the prior section suggested that a PIC could serve, concurrently, as the designated representative-in-charge for a wholesaler or veterinary food-animal drug retailed; however, this act is prohibited by CCR 1709.1(d). Section 6.5 was added to ensure that the PIC is aware of the restriction.

Page 9

Section 7.1 was amended to strike the word “Only” to mirror the language in CCR 1793.1, which allows both a pharmacist and an intern pharmacist acting under the supervision of a pharmacist to perform the listed functions; this is the only legally tenable interpretation of the regulation. For grammatical compliance, the word “a” was capitalized as a non-substantive change.

Pages 10 - 11

Section 7.2.5 was added to include information regarding the ability of a pharmacist to perform FDA-approved clinical tests as long as the pharmacist uses an authorized lab and has completed the appropriate training as specified is BPC 4052.4. Section 7.2 identifies functions that a pharmacist working at a licensed health care facility may complete; as such, adding this ability to this subsection is appropriate and consistent with statutory law.

Page 11

Section 7.4 was added and reads: “All pharmacists have submitted an application to the Department of Justice to obtain approval to access information online regarding the controlled substance history of a patient. Upon approval, the DOJ shall release to the pharmacist or their delegate the CURES information for an individual under the pharmacist’s care.” This requirement mirrors the language of HSC 111651.1. This section is not requiring the PIC to enroll the pharmacists in the CURES program with DOJ; however, listing the requirement here will ensure that the PIC understands they must apply and will encourage them to speak with any pharmacist under their supervision about the requirement. Additionally, the section is not requiring DOJ to release CURES information, that is required by statute. This information is educating the PIC that DOJ must do this, so if it is not occurring the PIC can take steps to investigate why the information is not being provided.

Section 7.5 was added to include the requirement for pharmacists to join the board’s email notification list. This section is not requiring the PIC to enroll the pharmacists in the board’s email notification list; however, listing the requirement here will ensure that the PIC understands they must be enrolled and encourage them to speak with any pharmacist under their supervision about the requirements of BPC 4013.

Section 7.6 was added and reads: “The hospital pharmacist (or pharmacy technician or an intern pharmacist if both requirements of BPC 4118.5(b) are met) shall obtain an accurate medication profile or list for each high-risk patient upon admission of the high-risk patients if the hospital has more than 100 beds, the accurate medication profile is acquired during hospital pharmacy’s hours of operation.” This section adds the medication profile requirements as specified in BPC 4118.5, which was added to statutory requirements effective January 1, 2019.

Section 7.7 was added and reads: “The pharmacist may initiate, adjust or discontinue drug therapy for a patient under a collaborative practice agreement with any health care provider with prescriptive authority. The collaborative practice agreement may be between a single or multiple pharmacists and a single or multiple health care providers with prescriptive authority.” This section adds the collaborative practice agreement requirements as specified in BPC 4052(a)(13) and (14), which was added to statutory requirements effective January 1, 2022.

Page 12

Section 8.1.3 was amended to add “adjust or discontinue” and “shall” before promptly to mirror the language is BPC 4052.6(a)(5) and (b) for consistency.

Section 9.4 was amended to add “or by the pharmacist-in-charge at the pharmacy while the intern pharmacist obtained the experience” to align the language on the self-assessment for with the language in BPC 4209(b). This change ensures consistency between the form and the statutory requirement.

Page 13

Section 9.5 was added to include the requirement for intern pharmacists to join the board’s email notification list. This section is not requiring the PIC to enroll the intern pharmacists in the board’s email notification list; however, listing the requirement here will ensure that the PIC speaks with any intern pharmacist under their supervision about the requirement and will provide education to the intern pharmacist about the requirement of BPC 4013.

Section 10.1 was amended to add “The pharmacist is responsible for the duties performed by the pharmacy technician under the pharmacist’s supervision.” The requirement is added for education purposes for the PIC to ensure they are aware of the responsibility of the pharmacist as it relates to a pharmacy technician as specified in BPC 4115(h).

Section 10.2 was amended to remove the second reference to “on duty” and add “when filling prescriptions for an inpatient of a licensed health facility.” The requirement is added for education purposes for the PIC to ensure they are aware of the requirement for a single pharmacist to be on duty with no more than two pharmacy technicians when

filling prescriptions for an inpatient of a licensed health facility as specified in CCR 1793.7(f).

Section 10.5 was amended to change “his or her self” to “them” to use a plural pronoun.

Page 14

Section 10.10 was added to include the requirement for pharmacy technicians to join the board’s email notification list. This section is not requiring the PIC to enroll the pharmacy technicians in the board’s email notification list; however, listing the requirement here will ensure that the PIC speaks with any pharmacy technician under their supervision about the requirement and will provide education to the pharmacy technician about the requirement of BPC 4013.

Page 16

Section 13.3 was amended to add “An order for controlled substance for use by a patient in a county or licensed hospital shall be in the patient’s records and the record of such orders shall be maintained as a hospital record for a minimum of seven years.” This is a statutory requirement within HSC 11159 and is added here for education purposes for the PIC as the record requirement is longer than the standard three years required by the Board for pharmacy records.

Page 17

Section 16.5 was amended to mirror the language within the regulation (CCR 1707) for consistency by changing “three” to “two.”

Page 19

Section 18.2 was amended to add “Any record maintained electronically, the pharmacist-in-charge or pharmacist on duty is able to produce a hardcopy and electronic copy of all records of acquisition and disposition or other drug or dispensing-related records maintained electronically.” This addition specifies the requirements associated with electronic records pursuant to BPC 4105(d)(1).

Section 18.2.2 was amended to add “and sales records” to include the sales records which are required by BPC 4081(a).

Section 18.2.8 was amended to add “and reverse distributors” to the records requirements. Reverse distributors were established by statute (BPC 4040.5) in 2018 and can accept outdated or nonsaleable dangerous drugs or dangerous devices. The hospital pharmacy must maintain records for any items transferred or sold to another entity, per BPC 4105.

Page 22

Section 20.1 was added and reads: “The pharmacy has a system assuring the prescribed medications are available in the hospital 24 hours a day.” As a hospital pharmacy, prescription medication must be available 24 hours a day per 22 CCR 70263(e). Adding this information provides educational notice to the PIC to ensure a system is in place.

Page 23

Section 21.4 was amended to add “The inspection can be done by a pharmacy technician or pharmacy intern as defined in the pharmacy’s written inspection policies and procedures.” This addition provided clarification to the PIC that a pharmacy technician or intern may perform the inspection consistent with the pharmacy’s written inspections policies and procedures. The additional language is consistent with the statutory requirements of BPC 4115(i)(3) and 4119.7(c).

Page 24

Section 23.1.4 was amended to add schedule V to the data requirement, the term “reports” was changed to “transmits” and “information” to “data” and, finally, “within one working day from the date the controlled substance is released to the patient” was added. These amendments are consistent with the changes to HSC 11165(d), which became effective January 1, 2022. The term changes of “transmits” and “data” were made for clarity are the data is transmitted electronically to the Department of Justice and the CURES program.

Section 23.2 was amended and reads: “The prescription label contains all the required information and is formatted in accordance with CCR 1707.5 including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order.” This language was added to include changes made to CCR 1707.5, which was amended in 2017 and identified specific requirements for drug labels.

Section 23.10 was added and reads: “Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” This addition is specified in BPC 4076.7, which was added to statutory requirements effective January 1, 2019.

Pages 24 - 25

Section 23.11 was added and reads: “A pharmacist may dispense a drug prescribed pursuant to HSC Section 120582 and label the drug without the name of an individual for whom the drug is intended if the prescription includes the words “expedited partner therapy” or the letters “EPT” and shall provide written notification that describes the right of an individual who received EPT to consult with a pharmacist about the medication dispensed and possible drug interactions.” This addition is specified in BPC 4076(f) and

(h), which was established in law on January 1, 2022, per SB 306, Statutes of 2016, Chapter 486.

Page 25

Section 23.12 is added to include the licensing requirement for AUDS utilized by emergency departments for patient dispensing, as required by BPC 4427.2(i). This section provides clarity to the PIC on the licensure requirement for these devices.

Section 24.3 was amended to add “including Patient Centered Labels in at least 12-point sans serif typeface for the four required items in the required order.” This language was added to include changes made to CCR 1707.5, which was amended in 2017.

Prior (renumbered) Section 24.4 was stricken and new sections 24.4 and 24.5 were added to update the drug warning requirements within CCR 1744 that were amended in 2017.

New Section 24.4 was added and reads: “The pharmacist includes a written label on the drug container indicating that the drug may impair a person’s ability to operate a vehicle or vessel. The label may be printed on an auxiliary label affixed to the prescription container.” This is added to include changes made to CCR 1744(a), which was amended in 2017.

Section 24.5 was added and reads: “The pharmacist includes a written label on the drug container to alert the patient about possible potentiating effects when taken in combination with alcohol. The label may be printed on an auxiliary label affixed to the prescription container.” This is added to include changes made to CCR 1744(b), which was amended in 2017.

Page 26

Section 24.6 was amended to change “on the label and” to “in the” as the requirements for the label are specified in section 24.3 on page 25. Including the information again here is duplicative and does not add to the education of the PIC.

Section 24.8 was amended to add “or can be satisfied by recording the identity of the reviewing pharmacist in a computer system by a secure means and is immediately retrievable in the pharmacy.” This addition is consistent with the requirement of CCR 1712 and is being added for clarity on the ability for pharmacist to verify prescriptions via a computer system.

Section 24.14 was added and reads: “Whenever an opioid prescription drug is dispensed to patient for outpatient use, the pharmacy prominently displays on the label or container or by a flag or other notification to the container, a notice that states, “Caution: Opioid. Risk of overdose and addiction.” This addition is specified in BPC 4076.7, which was added to statutory requirements effective January 1, 2019.

Section 24.15 was added and reads: “Effective January 1, 2022, the pharmacy has the capability to receive electronic data transmission prescriptions on behalf of patients.” This addition is specified in BPC 688, which was added to statutory requirements effective January 1, 2022.

Section 25.1 was amended to add “within this state” for clarity that filling patient cassettes can only be completed for another hospital or pharmacy within California, as specified in CCR 1710(b).

Section 26.1 is added to include the requirement for a hospital pharmacy to obtain a Centralized Hospital Packaging (CHP) license before engaging in centralized hospital packaging. This addition provides education to the PIC with respect to centralized hospital packaging and ensure that the hospital pharmacy is not performing these functions without first obtaining a license. Additionally, a space to include the license number is provided for confirmation purposes.

Page 27

Section 26.2.6 was non-substantively amended post adoption to mirror the language within the statute (BPC 4128.4) for consistency.

Page 29

Section 27.1.1 was amended to include the requirement to provide oral consultation to an inpatient of a health care facility licensed pursuant to HSC 1250 are required by CCR 1707.2(b)(2). This requirement was previously included in section 27.1.6; however, has been moved to 27.1.1 for clarity with the discharge information.

Section 27.1.6 was stricken as it was added to section 27.1.1 and is no longer needed here.

Section 27.1.2 was amended non-substantively post-adoption to replace gendered terms with gender-neutral terms consistent with ACR 260.

Page 30

Section 27.1.9 was added and reads: “Inventory reconciliation reporting requirements.” This addition provides education to the PIC with respect to the requirement of CCR 1715.65(b) that requires written policies and procedures for inventory reconciliation.

Section 27.1.10 was added and reads: “Pharmacy technician performing monthly checks of the drug supplies stored throughout the health care facility and reporting irregularities within 24 hours to the pharmacist-in-charge and the director or chief executive officer of the health care facility.” This addition provides education to the PIC

with respect to the requirement of BPC 4115(i)(3) that requires written policies and procedures for reporting irregularities.

Section 27.1.11 was added and reads: “Intern pharmacist, under the direct supervision and control of a pharmacist, may inspect the drugs maintained in the health care facility at least once per month.” This addition provides education to the PIC with respect to the requirement of BPC 4119.7(c) that requires written policies and procedures for inspections completed by intern pharmacists.

Section 27.1.12 was added and reads: “Furnishing dangerous drug or dangerous device pursuant to preprinted or electronic standing orders, order sets, and protocol, if the order is dated, timed, and authenticated in the medical record of the patient to whom the dangerous drug or dangerous device is provided.” This addition provides education to the PIC with respect to the requirement of BPC 4119.7(a) that requires written policies and procedures for furnishing drugs or devices per an electronic or standing order.

Section 27.1.13 was added and reads: “Storing and maintaining drugs in accordance with national standards regarding storage areas, refrigerator or freezer temperature, and otherwise pursuant to the manufacturer’s guidelines.” This addition provides education to the PIC with respect to the requirement of BPC 4119.7(b) that requires written policies and procedures for the storage and maintenance of drugs.

Section 27.1.14 was added and reads: “Establishing the supply contents, procedure for use, restocking and sealing of emergency drug supply.” This addition provides education to the PIC with respect to the requirement of 22 CCR 70263(f)(1) that requires written policies and procedures for restocking and sealing of emergency drug supply.

Section 27.1.15 was added and reads: “If applicable, r dispensing, storage and records of use if bedside medications are allowed. No controlled substances shall be left at bedside.” This addition provides education to the PIC with respect to the requirement of 22 CCR 70262(l) that requires written policies and procedures for the use of bedside medication.

Section 27.1.16 was added and reads: “The use of investigational drugs. Basic information concerning the dosage form, route of administration, strength, actions, uses, side effects, adverse effects, interaction and symptoms of toxicity shall be available in the pharmacy and the nursing station. The pharmacist is responsible for the proper labeling, storage and distribution of such drug pursuant to the investigator’s written orders.” This addition provides education to the PIC with respect to the requirement of 22 CCR 70262(o) that requires written policies and procedures for the use of investigational drugs.

Section 28 was amended to remove reference to Form 17M-39, Rev. 10/12 and add “as required by CCR 1735.2.” The change ensures that the self-assessment form referenced within CCR 1735.2 is completed in the event that form 17M-39 is updated outside future updates to form 17M-14.

Page 31

Section 29 has been added to include the requirements for “Automated Drug Delivery Systems” to the self-assessment form.

Senate Bill (SB) 1447 (Hernandez, Chapter 666, Statutes of 2018) added, among other things, BPC Sections 4427.2, 4427.3, 4427.4, 4427.6, and 4427.7. These new statutes established the board’s authority to issue an ADDS license; established ownership, placement, and operation requirements; established recordkeeping and quality assurance requirements; and established the requirement for the completion of an annual self-assessment by the pharmacy holding the ADDS license. Sections 29.1, 29.2 (originally misnumbered as 29.6), and 29.3 identify the requirements for automated drug delivery systems within a hospital pharmacy. These additions ensure that a hospital PIC is aware of the statutory requirements should they utilize one or more of these systems.

Pages 30 through 37

Section 30 has been added to include the requirements for prescription drug take-back services to the self-assessment form.

Title 21, Code of Federal Regulations (CFR) sections 1300 - 1317 established the federal DEA’s regulations on drug take-back programs. The federal law sets forth the voluntary requirements for drug take-back programs in accordance with the Secure and Responsible Drug Disposal Act of 2010. The practice of pharmacy in California is regulated, authorized, and enforced by the board. The federal government does not regulate the practice of pharmacy in California unless the pharmacy is acting as a manufacturer. Effective June 6, 2017, the board established, via regulation, numerous requirements for pharmacies, hospital pharmacies, and clinics to provide drug take-back services. The requirements are found in CCR 1776-1776.5. Sections 30.1 through 30.49.5 identify the requirements for drug take-back services within a hospital pharmacy. These additions ensure that a hospital PIC is aware of the regulatory requirements should they provide this service.

Section 30.28 was non-substantively amended post adoption to strike the term “following” as the specific liner records are not being identified on the form so removing the term provides clarity to the PIC.
Section 30.30 was non-substantively amended post adoption to mirror the language within the regulation (CCR 1776.1 and 1776.3) for consistency.

Section 30.38 was non-substantively amended post adoption to mirror the language within the regulation (CCR 1776.4) for consistency.

During post-adoption review, additional edits were made to correct underline and strikeout errors within the self-assessment forms. These edits were non-substantive as they do not have regulatory effect.

Incorporation by Reference

Existing regulation incorporates these forms (17M-13 and 17M-14) by reference. This rulemaking continues the incorporation by reference of those forms. Continued incorporation is appropriate because the 20-plus page forms are cumbersome and contain formatting that would not be publishable in the CCR.

Nonduplication Statement - 1 CCR § 12

As stated throughout the Initial and Final Statements of Reasons, the proposed forms being incorporated by reference in these regulations partially duplicate or overlap federal and state statutes and regulations. By the very nature of the incorporated forms being "Self-Assessments," which are essentially compliance checklists, references to applicable law are essential. By repeating (and citing to) key language from these statutes or regulations within these forms, the forms themselves become significantly clearer, and enable a user to find the area of law for further research if questions arise.

To ensure accuracy, duplication or overlap is necessary to effectively implement the self-assessment forms in a way that satisfies the "clarity" standard of Government Code section 11349.1, subdivision (a)(3).

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. While the board does not have specific data to determine if its licensees are a "small business" as defined in Government Code section 11342.610, a smaller community retail pharmacy may fall into that definition.

Completion of a self-assessment form is required by existing regulation biennially and based on certain events; the completed forms are also required to be maintained. The updates will change some of the questions on the forms, but do not ask significantly more questions. It is therefore not anticipated that the pharmacy will use more time completing, or more space storing, the self-assessment form. As the requirement to complete and maintain these forms already exists in regulations, this proposal will not have an impact on businesses.

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 alternative of not updating the self-assessment forms specified within the regulation and not updating the specific requirements 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.

Objections or Recommendations/Responses to Comments

45-Day Public Comment Period

During the public comment period on November 12, 2021, and ended on December 27, 2021, the board received one comment. The comment was provided in the meeting materials for the January 27, 2022 board meeting. The board amended the regulation text to address changes in pharmacy law and voted to initiate a 15-day comment period.

Summary and Response to 45-day Comments:

Written Comments from Joe Jolliff, Pharm.D.

Comment 1: The commenter recommended that form 17M-39 be amended to change the title from “Community Pharmacy & Hospital Outpatient Pharmacy Compounding Self-Assessment” to “Pharmacy Compounding Self-Assessment” as it would apply to inpatient hospitals as well.

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. The board noted that the compounding self-assessment form was not undergoing public comment. The board noted that the title of the compounding self-assessment form can be reviewed during the rulemaking process for that form.

Comment 2: The commenter recommended that form 17M-14 be amended to identify the 2021 draft of the compounding self-assessment and not the 2012 version.

Response to Comment 2: The board reviewed this comment and did not make any changes to the text based thereon. The board acknowledged that the self-assessment form references an old version of the compounding self-assessment form; however, the form cannot reference the draft version as it has not been formally adopted in regulation at this time. In order to remedy this issue, and account for any future changes to the forms, Form 17M-13 and Form 17M-14 will reference the regulation, 16 CCR 1735.2(k), in which the form is incorporated by reference, and which has the most current revision date

15-Day Public Comment Period

During the public comment period from February 15, 2022, to March 2, 2022, the board received one comment. The comment was provided in the meeting materials for the March 16, 2022 board meeting.

Summary and Response to 15-day Comments:

Written Comments from John Gray, Kaiser Permanente,

Comment 1: The commenter stated that they do not believe a hospital with an ADDS that is exempt from licensure should be required to complete the ADDS self-assessment as they state that BPC section 4427.7(a) only requires the ADDS self-assessment to be completed for licensed ADDSs. The commenter does not believe the requirement within BPC 4427.2(i), that requires the licensed hospital pharmacy to comply with all other requirements for an ADDS in the article 25, applies to the self-assessment form. Further, commenter states that the board's policy discussion in November 2021 states "should" instead of "shall" and therefore is only encouraging the completion of the ADDS self-assessment form. The commenter requests that self-assessment forms 17M-13 and 17M-14 be amended to remove the requirement.

Response to Comment 1: The board reviewed this comment and did not make any changes to the text based thereon. BPC 4427.2(i) explicitly states, where an ADDS is exempt from licensure, it MUST comply with all other requirements within Article 25, which includes completion of the ADDS self-assessment. The board noted that it has had several policy discussions on this issue since 2019, including most recently at the January 2022 Licensing Committee and the January 2022 Board meeting (the meeting materials are available on the Board website and the meeting minutes will be posted to the same location once approved by the Committee and Board: https://www.pharmacy.ca.gov/about/meetings.shtml).