TITLE 16. BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS

INITIAL STATEMENT OF REASONS

Hearing Date: No hearing scheduled.

Subject Matter of Proposed Regulation: Self-Assessments Forms (Pharmacy, Hospital, Wholesaler)

Sections Affected: Amend Title 16, California Code of Regulations (CCR) sections 1715 and 1784, and the respective self-assessment forms incorporated by reference in these sections.

Background and Statement of the Problem

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

Existing law requires that a pharmacy be licensed by the Board in order to operate. (BPC section 4110). There are various types of pharmacies, including hospital pharmacies and community pharmacies (See BPC sections 4029 and 4037). There are some distinctions between pharmacy settings which necessitate more specific requirements by setting type, but all pharmacies are subject to some general requirements. Each pharmacy must designate a pharmacist-in-charge (PIC), who is responsible for ensuring the pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy (BPC section 4113).

Existing law requires that wholesalers and third-party logistics providers (3PL) be licensed by the Board in order to operate (or operate into the state, as is the case for nonresident wholesalers and 3PLs). (BPC sections 4160 and 4161.) There are some distinctions between wholesalers and 3PLs, although these businesses are subject to the same general requirements. Each business must designate a designated representative-in-charge (DRIC) or responsible manager (RM) who is responsible for ensuring the business' compliance with all state and federal laws and regulations pertaining to the practice of pharmacy (BPC sections 4160(d) and 4160(e)).

All pharmacies are subject to extensive state and federal laws and regulations, including those governing scope of practice for pharmacists and other personnel working in the pharmacy; prescription and labeling requirements; record keeping requirements, including policies and procedures; cooperating with inspections; duties related to storage, handling, and security of drugs and devices; duties related to compounding sterile drug products; and duties to provide notice to the Board regarding certain

changes to staff, facilities, and operations. Existing regulations at CCR section 1715 require the PIC of a pharmacy licensed pursuant to BPC section 4029 or 4037 to complete a self-assessment, using a Board-designated form, every odd numbered year and when certain changes occur that affect the location, organization, or management of the pharmacy.

All wholesalers and 3PLs are also subject to extensive state and federal laws and regulations, including those governing the scope of practice; prescription and labeling requirements; record keeping requirements, including policies and procedures; cooperating with inspections; duties related to storage, handling, and security of drugs and devices; duties related to compounding sterile drug products; and duties to provide notice to the Board about certain changes to staff, facilities, and operations. Existing regulations at CCR section 1784 require the DRIC of a wholesaler or RM of a third-party logistics provider to complete a self-assessment every odd-numbered year, and within 30 days of certain occurrences.

Each self-assessment form is incorporated by reference in the existing regulation. The forms incorporated by reference are being updated to include questions the PIC, DRIC, or RM will answer about the respective facility's compliance with specific laws and regulations. The self-assessment forms assist the PIC, DRIC, or RM in ensuring that the licensed facility in operating in compliance with federal and state requirements. Having PICs, DRICs, and RMs complete these self-assessment forms makes the Board inspection process more meaningful and efficient because it informs the Board inspectors of each facility's compliance and any corrective measures (to be) implemented.

Because the self-assessment forms are compilations of state and federal law and regulations, modifications must be made to the forms on an annual basis to incorporate changes in those laws and regulations. In this rulemaking, the Board proposes amending section 1715 of Article 2 of Division 17 of Title 16 of the CCR and the self-assessment forms incorporated by reference therein (*Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment* [17M-13] and *Hospital Pharmacy Self-Assessment* [17M-14]) to reflect current laws and regulations. Additionally, the Board proposes amending section 1784 of Article 10 of Division 17 of Title 16 of the CCR, and the self-assessment form incorporated by reference therein *(Wholesaler/Third-Party Logistics Provider Self-Assessment* [17M-26]) following recent changes in laws and regulations.

Anticipated Benefits

Protection of the public is the Board's highest priority in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, protection of the public is paramount. This regulatory proposal benefits the health and welfare of California residents, and worker safety. This proposal does not impact the state's environment.

This proposal will update the self-assessment forms incorporated by reference so that the forms reflect current laws and regulations. Therefore, the PICs of pharmacies, DRICs of wholesalers, and RMs of third-party logistics providers throughout California will conduct self-assessments using up-to-date forms, thereby ensuring compliance with current laws and regulations. Ensuring facilities comply with current laws and regulations will better protect consumers, as it will create accountability and improve facility operations. This will benefit the health and welfare of California consumers, as well as employee safety. The proposal does not impact the state's environment.

Specific Purpose of, and Rationale for, the Proposed Changes

The Board's proposal makes the following amendments:

Factual Basis/Rationale

Sections 1715 (c)(7) and (d) and 1784 (c)(7) and (d) are updated to capitalize the "B" in "Board". This change is non-substantive because it is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for consistency throughout the Board's regulations. Inconsistent capitalization/lowercasing may result in misinterpretation and confusion.

Section 1715, subsection (c) is updated to change the revision date of self-assessment forms 17M-13 and 17M-14 from 1/22 to 1/24. The purpose of this change is to incorporate by reference the updated versions of the forms. This amendment is necessary to ensure that the regulated public is aware of the revision date of the self-assessment form so that licensees use the correct version of the form.

Community Pharmacy Self-Assessment/Hospital Outpatient Self-Assessment form (17M-13) has been updated to make the following changes:

On every page of Form 17M-13, the footer at the bottom left corner which reads "17M-13 (Rev. 1/22)" was amended to reflect the updated revision date "17M-13 (Rev. 1/24)." Conforming changes were made throughout. The purpose of this change is to label the form to indicate this is the updated version. This amendment is necessary to properly identify the form and ensure that the regulated public uses the correct version of the form.

Throughout the form, sections were renumbered as needed to address additions or deletions within 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 the beginning of each section. Conforming changes were made throughout the document. These changes are non-substantive because they are renumbering and structural changes as part of an effort to "renumber[], reorder[], or relocat[e] a regulatory

provision" within the meaning of Title 1, CCR section 100(a)(1) and to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for ease of use by the regulated public and the Board, and to avoid confusion.

Throughout the form, the law or regulation that forms the basis for the question has been added or amended, as appropriate, as a reference following the question. The purpose of these changes is to provide the corresponding citation along with each question. This is necessary to foster compliance with the laws and regulations, by helping the PIC and pharmacy to refer to the source for each requirement while conducting the self-assessment, as well as providing a reference for where to look for further information. In addition, the completed self-assessment will assist Board employees with better directing their attention and resources when performing inspections.

Throughout the form, typographical changes were made for grammatical consistency, including the addition of commas and periods. These changes are non-substantive because they are part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

Page 4

New number 1.16 is added for the purpose of ensuring licensees comply with the requirement for the pharmacy to provide the Board with any email address and update their email address with 30 days of any change, as required by section CCR 1704(b). It is necessary for pharmacies to provide an email address to the Board to ensure that the Board is able to communicate with licensees timely about any issues. As a result of this addition to the form, the next two items have been renumbered to 1.17 and 1.18 respectively. These changes are non-substantive because they are part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1).

Page 5

Prior number 1.18 is being stricken from the form due to the repeal of BPC section 4106.5, as such the requirement is no longer valid. This change is non-substantive because it is a change "deleting a regulatory provision for which all statutory or constitutional authority has been repealed" withing the meaning of Title 1, CCR section 100 (a)(2).

New number 1.20.1 is added for the purpose of ensuring licensees/pharmacy staff do not refuse to dispense or furnish an electronic data transmission prescription solely because the prescription was not submitted via, or is not compatible with, the proprietary software of the pharmacy. This addition is necessary due to the amendment to BPC section 688(b)(2) in 2022, which became effective January 1, 2023.

New number 1.20.2 is added for the purpose of ensuring licensees/pharmacy staff are aware that they are not required to verify that a prescription falls under one of the exceptions to BPC section 688, and that they may continue to dispense medication from a legally valid written, oral or fax prescription pursuant to BPC section 688. This addition is necessary due to the amendment to BPC section 688(i) in 2022, which became effective January 1, 2023.

Existing number 1.20.1 is renumbered to 1.20.3. This is a change without regulatory effect because it is "renumbering . . . a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1).

Existing number 1.20.2 is renumbered to 1.20.4. This is a change is non-substantive because it is part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1). New number 1.20.4 is also amended for the purpose of ensuring that, upon request from the patient or person authorized to make a request on the patient's behalf, licensees transfer or forward an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester, unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. The language is further amended for the purpose of removing the last sentence (Unfulfilled controlled substance prescriptions are transferred or forwarded in compliance with Federal Law.) as duplicative with the new language specific to the NCPDP SCRIPT standard, which is more specific than the reference to "Federal Law." The latest version of the NCPDP SCRIPT is required pursuant to Title 42, Chapter IV, Subchapter B, Part 423, Subpart D, Section 423.160. These changes are necessary to ensure compliance with these updated federal provisions.

Page 6

Existing number 1.20.3 is renumbered to 1.20.5. This is a change is non-substantive because it is part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1). New number 1.20.5 is amended to remove "the" and "or its" so that the sentence reads "If pharmacy staff is aware..." for grammatical clarity. As a pharmacy is a facility, the pharmacy itself cannot be aware of information, only the pharmacy staff can be aware. This change is non-substantive because is a grammatical change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

New number 1.22 is added for the purpose of ensuring licensees t report to the Board any disciplinary action taken by any government agency since its last license issuance or last renewal, which is required by CCR section 1702.5. This change is necessary to ensure compliance with the requirement established effective July 1, 2021.

New number 1.23 is added for the purpose of ensuring licensees, except for Correctional Pharmacies, notify the Board of any temporary closure of the facility as soon as any closure exceeds three consecutive calendar days. Additionally, a temporary closure does not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four consecutive calendar days. This addition is necessary to ensure notification to the Board, as required by CCR section 1708.1, which became effective October 1, 2022.

New number 1.24 is added for the purpose of ensuring licensees that qualify as chain stores as defined in BPC section 4001 do not establish quotas related to the duties for which pharmacists or pharmacy technicians are required. This addition is necessary to ensure compliance with the requirement of BPC section 4113.7, which became effective January 1, 2022.

New number 1.25 is added for the purpose of ensuring that a chain community pharmacy is staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy related services, unless the pharmacist on duty waives the requirement in writing during specified hours based on workload need; the pharmacy is open beyond normal business hours, which is before 8:00am and after 7:00pm; or the pharmacy's average prescription volume per day is less than 75 prescriptions a day for the past calendar year and the pharmacist is not expected to provide any ancillary services provided by law. This addition is necessary to ensure these pharmacies meet the staffing requirement of BPC section 4113.6, which became effective January 1, 2024.

Page 7

New number 1.26 is added for the purpose of ensuring that, within a chain community pharmacy, where staffing of pharmacist hours does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted and included on any outgoing telephone message. This addition is necessary to ensure compliance with the posting requirement in BPC section 4113.6(b), which became effective January 1, 2024.

Page 8

Number 3.5 is amended for the purpose of removing the date (November 27, 2023), as it has passed, and removing the term "traceability" for grammatical clarity. Removing the old date is necessary for clarity as the date has passed and the unit-level traceability is required. Additionally, removing the double use of "traceability" is necessary for sentence flow and grammatical clarity.

Page 9

Section 4 is amended and the existing language ("(If yes, complete Section 30 [donate drugs] or Section 31 [operate program] of this Self-Assessment.)") is stricken. During inspections, Board inspectors have received comments about the length of the self-assessment form. to the purpose of this amendment is to reduce the overall length of

the self-assessment form, so the existing language within this section is stricken. The number of Pharmacies that donate drugs to a voluntary county-approved drug repository and distribution program is very small, as such, the section does not apply to the majority of licensees. It is necessary to strike the reference to Sections 30 [donate drugs] and 31 [operate program] =to reduce the overall length of the self-assessment form while still meeting the intent of the self-assessment form, which is to educate and assist pharmacists/facilities with operating in compliance with the law.

New number 4.1.1 is added for the purpose of ensuring that, should the pharmacy donate to or operate a voluntary drug repository and distribution, the program meets all the requirements as specified in law, and the specific statutes are identified so that the PIC can locate the requirements and ensure the pharmacy's compliance if the pharmacy does donate to or operate a program. This addition is necessary to new number assists pharmacists/facilities that donate to a repository with assessing their compliance with law. The items provided the health and safety code sections to provide easy reference to the applicable statutes.

New number 5.8 is added for the purpose of ensuring that the PIC or pharmacist on duty, if the PIC is not available, is authorized to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. Additionally, a sentence is included that this authorization does not apply to facilities of the Department of Corrections and Rehabilitation. This staffing addition is necessary to ensure the applicable facilities are sufficiently staffed, as authorized by BPC section 4113(c)(2), which became effective January 1, 2024.

New number 5.9 is added for the purpose of ensuring that the PIC or pharmacist on duty immediately notifies the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff, and that, if the conditions are not resolved within 24 hours, the PIC or pharmacist on duty ensures the Board is timely notified. This notification addition is necessary to ensure the safety of patients, personnel, and pharmacy staff, as well as that the Board receives timely notification of the issue, and is authorized by BPC section 4113(c)(2), which became effective January 1, 2024.

Page 11

Number 6.7 is amended to add "in law" at the end of the sentence, move BPC section 4052.4 to the reference section, and add BPC section 4119.10 to the reference section. The purpose of this change is to ensure appropriate reference to all legal requirements, which go beyond BPC 4052.4. This change is necessary as BPC section 4052.4 is not the sole law section that must be adhered to for this item specifically, so adding BPC sections 4052.4 and 4119.10 to the reference section with BPC section 1206.6 ensures that all appropriate code sections are identified as references for the PIC and that the PIC confirms that the facility is operating in compliance with all the applicable code sections, not just BPC section 4052.4.

Number 6.9 is amended for the purpose of removing the date (July 1, 2022), as it has passed, and capitalizing the letter “a”, as it will now start the sentence. Removing the old date is necessary for clarity as the date has passed. Capitalizing the letter “a” is non-substantive because it is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

New number 6.11 is added for the purpose of ensuring that only a prescriber, a prescriber’s authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in BPC section 4019, into a pharmacy’s or hospital’s computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. This item is necessary to remind licensees of the restrictions established by BPC section 4071.1, which limits who may enter a prescription or order into the identified computer systems.

New number 6.12 is added for the purpose of ensuring pharmacists located and licensed in the state know they may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility’s policies and procedures. This is also added for the purpose of ensuring each health care facility maintains a record of the pharmacist’s verification of the medication chart order and that the records meet the requirements described in sections 4081 and 4105. The addition of this verification authorization and records requirement is necessary to remind licensees of the authority and the requirements for chart order verifications, , which is specified by BPC section 4071.1, and became effective September 1, 2023.

Page 13

Number 9.2 is amended for the purpose of adding the specific tasks that the pharmacy technician may perform under the direct supervision and control of a pharmacist, specifically packaging, manipulative, repetitive, or other nondiscretionary tasks. It is also amended for the purpose of adding that, if a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines via injection or intranasally, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, then a second pharmacy technician shall assist a pharmacist with performing the tasks as defined in BPC section 4115(a). Adding this information is necessary for clarity with respect to the tasks a pharmacy technician can perform under specific ratio requirements, and having a second pharmacy technician present to assist the pharmacist should the pharmacy technician be performing certain tasks is required by BPC section 4115(b)(1)(A).

Page 14

New number 9.7 is added for the purpose of reminding licensees that individuals must not act as pharmacy technicians without first being licensed by the Board as pharmacy technicians, as any staff acting as a pharmacy technician must be licensed pursuant to BPC section 4115(f). Further, this additional clarification is necessary to ensure pharmacies and PICs know that possession of a pharmacy technician certification only is not equivalent to being licensed by the Board, as Board inspectors have found unlicensed individuals working as pharmacy technicians under the belief that it was acceptable because the individual had a certification. This addition will ensure unlicensed individuals are not acting as pharmacy technicians without the appropriate licensure.

New numbers 9.8 through 9.8.4 are added to remind licensees of the following:

9.8 A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])

9.8.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist; (BPC 4115[b][1][A])

9.8.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board; (BPC 4115[b][1][B], BPC 4202[a][4])

9.8.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C]; and

9.8.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

This information is added for the purpose of listing the tasks a pharmacy technician can perform under the direct supervision and control of a pharmacist and the specific requirements that must be met for a pharmacy technician to perform these tasks, consistent with BPC sections 4115(b)(1)(A)-(D). This addition is necessary for clarity and to ensure that the pharmacist is aware of the tasks a pharmacy technician may perform, the circumstances under which the individual may perform those tasks, and the requirements that must be met in order for the pharmacy technician to perform those tasks.

Page 16

Number 12.8 is amended for the purpose of adding short descriptions of what each Health and Safety Code section references for ease of reference by licensees. Specifically, HSC section 11159.2 refers to the terminally ill exemption, 11159.3 refers to the declared emergency exemption, and 11167.5 refers to the SNF (Skilled Nursing Facilities), ICF (Intermediate Care Facilities), licensed home health agency and licensed hospice exemption). These additions provide clarity to the regulated public regarding what each code section refers to, which will aid the pharmacist in locating the requirements should they need additional information.

Page 19

Number 13.22 is amended for the purpose of updating the reference to naloxone to "federal FDA-approved opioid antagonists" pursuant to the change in BPC section 4052.01, which is also added. This change is necessary to put the requirement on the form in line with the requirement in statute, which became effective January 1, 2023.

Number 13.25 is amended for the purpose of reminding licensees that at the request of a patient, the pharmacist must notify the patient's primary care provider or enter the appropriate information in a patient record system shared with the primary care provider, as permitted by the primary care provider. The pharmacist must also notify each pregnant patient's prenatal care provider, if known, of any vaccine administered to the patient within 14 days. These additions are necessary because they are requirements under CCR 1746.4(d), which became effective in January 2022.

Page 21

Number 15.1 is amended for the purpose of removing the prior effective date (July 1, 2022), as it is in the past and is no longer needed within the form. Removing the old date is necessary for clarity as the date has passed.

Page 22

New number 16.9 is added for the purpose of including the requirement for a community pharmacy to report, either directly or through a designated third party, including a component patient safety organization as defined in Section 3.20 of Title 42 of the Code of Federal Regulations, all medication errors to an entity approved by the Board, no later than 14 days following the date of discovery of the error. This addition is necessary to ensure reporting, which is required by BPC section 4113(a), which became effective January 1, 2024.

New number 16.10 is added for the purpose of including the exemption for an outpatient hospital pharmacy in that an outpatient hospital pharmacy is not required to report a medication error if it meets the requirements of an adverse event, and it has been reported to the State Department of Public Health pursuant to Section 1279.1 of the Health and Safety Code. This addition is necessary to ensure reporting, which is required by BPC section 4113(e), which became effective January 1, 2024.

Page 23

Number 18.3 is amended for the purpose of reminding licensees that a pharmacy shall, upon request from the patient or person authorized to make a request on the patient's behalf, transfer or forward an electronic data transmission prescription, that was received but not dispensed to the patient, to an alternative pharmacy designated by the requester, unless the action would result in a violation of any state or federal law or the action is not supported by the latest version of NCPDP SCRIPT standard. The amendment further removed the last sentence as duplicative with the new language specific to the NCPDP SCRIPT. The latest version of the NCPDP SCRIPT is required pursuant to Title 42, Chapter IV, Subchapter B, Part 423, Subpart D, Section 423.160. This change is necessary to ensure compliance with the updated federal provisions.

Page 25

New number 20.2.12 is added for the purpose of including the requirement that records demonstrating compliance with medication error reporting requirements be maintained for three years. This addition is necessary under the requirement of BPC section 4113(a), which became effective January 1, 2024.

Page 28

Number 21.14 is amended for the purpose of conforming to changes to CCR 1715.6; specifically, it reminds licensees that any loss of controlled substances in one of the added categories that follows number 21.14 (in added numbers) that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed the specifications in 21.14.1, 21.14.2, and 21.14.3 must be reported to the DEA within one business day of discovery and to the Board within 30 days after the date of discovery. This change is necessary to conform this portion to the drug loss reporting regulations within CCR section 1715.6, which were amended with an effective date of April 1, 2022.

New number 21.14.1 is added for the purpose of reminding the licensee of the requirement to report drug losses of 99 dosage units of tablets, capsules, or other oral medication. This addition is necessary to include the requirements of CCR 1715.6(a)(1)(A) on the self-assessment form and ensure compliance with the drug loss reporting requirements.

New number 21.14.2 is added for the purpose of reminding the licensee of the requirement to report drug losses of 10 dosage units of single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches. This addition is necessary to include the requirements of CCR 1715.6(a)(1)(B) on the self-assessment form and ensure compliance with the drug loss reporting requirements.

New number 21.14.3 is added for the purpose of reminding the licensee of the requirement to report drug losses of Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers. This addition is necessary to

include the requirements of CCR section 1715.6(a)(1)(C) on the self-assessment form and ensure compliance with the drug loss reporting requirements.

Number 21.17 is amended for the purpose of changing Schedule IV controlled substances to Schedule V controlled substances. This change is necessary as a result of the amendments to HSC section 11165(d), and will ensure that CURES reporting is completed for all required controlled substances.

Page 29

Numbers 22.3.6 through 22.3.9 are added for the purpose of reminding licensees of the inventory requirements of CCR section 1715.65, which was amended in 2022 and effective January 1, 2023. Specifically, the additional language is as follows:

22.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg, alprazolam 2mg, tramadol 50mg, and promethazine with codeine 6.25mg/10mg/5ml at least every 12 months. (CCR 1715.65[a][2])

*22.3.7. An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the **reportable** loss. (CCR 1715.65)*

22.3.8. Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

22.3.9. The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The individual who performs the inventory shall sign and date the inventory or report. If not personally completed by the pharmacist-in-charge or professional director, the report must also be signed by the pharmacist-in-charge or professional director. (CCR 1715.65[e], [e][1])

The inventory reconciliation regulations within CCR section 1715.65 were amended with an effective date of January 1, 2023. These additions are necessary to ensure that the requirements listed on the self-assessment form are current and complete.

Page 30

Number 22.5 has been stricken for the purpose of updating and moving it up to new number 22.3.9 so the signature requirements are all in the same number. This is necessary for clarity to the licensee, and ensures this requirement is not missed because it is separate from the other signature requirements.

Page 34

Section 27 is amended for the purpose of striking the existing language (numbers 27.1.1 through 27.2.12) and adding references to HSC sections 125286.20 and 125286.25. During inspections, Board inspectors have received comments about the length of the self-assessment form. Additionally, the number of Pharmacies that provide

blood clotting products for home use is relatively small, and as such, the section does not apply to the majority of licensees. Removing these portions is necessary to reduce the overall length of the form, while still meeting the intent of the self-assessment form, which is to educate and assist pharmacists/facilities with operating in compliance with law. The form will also provide the legal references to HSC sections 125286.20 and 125286.25. This is necessary so that licensees can easily refer to the appropriate legal references if this section applies to them.

Page 37

Number 28.4 is amended for the purpose of updating the reference to naloxone to "federal FDA-approved opioid antagonists" pursuant to the change in BPC section 4052.01. This change is necessary to put the requirement on the form in line with the requirement in statute, which became effective January 1, 2023.

Pages 39-43

Section 31 is amended for the purpose of striking the existing language starting at number 31.2 through number 31.42. In an effort to reduce the overall length of the self-assessment form, this existing language is stricken as the number of Pharmacies that provide telepharmacy and remote dispensing site pharmacies is small, and as such, the section does not apply to the majority of licensees. Removing this section is necessary to reduce the overall the length of the form, while still meeting the intent of the self-assessment form, which is to educate and assist pharmacists/facilities with operating in compliance with law.

The new additions to the section include the following:

31.2. The supervising pharmacy is not located greater than 150 road miles from the remote dispensing site pharmacy, unless otherwise approved by the board. (BPC 4131[b]).

The purpose of this number is to remind licensees of the requirement of BPC section 4131(b).

31.3. Both the supervising and remote dispensing site pharmacies operate in accordance with BPC 4130, 4131, 4132, 4133, 4134, 4135, 4044, 4044.3, 4044.6, 4044.7, 4059.5.

As the section will only apply to a small population of licensees, the purpose of this portion of the form is to provide the appropriate legal references so that licensees can easily refer to the appropriate legal references if this portion is applicable to the pharmacy.

31.4. The remote dispensing site pharmacy will cease to be a remote dispensing site pharmacy and may become a full-service pharmacy licensed under Section 4110 with a pharmacist onsite if it meets all the requirements for licensure for a pharmacy, if the remote dispensing pharmacy dispenses more than 225 prescriptions per day, calculated each calendar year. (BPC 4130[h]).

The purpose of this number is to remind licensees of the requirement of BPC section 4130(h).

As the section will only apply to a small population of licensees, these changes to the form are necessary to provide the appropriate legal references to the Business and Professions Code sections so that licensees can easily refer to the appropriate legal references if these portions are applicable to the pharmacy.

Page 43

Number 32.1 is amended for the purpose of removing the referral to section 33 if the answer is "no" or "not applicable" to the question. This is necessary because sections 33 and 34 are being stricken as explained below, so referring the licensee to those sections will no longer be necessary.

Pages 49-52

The form is amended for the purpose of striking sections 33 and 34. During inspections, Board inspectors have received comments about the length of the self-assessment form. As the number of Pharmacies that donate drugs to a voluntary county-approved drug repository and distribution program is very small, the sections do not apply to the majority of licensees, so in an effort to reduce the overall length of the self-assessment form, it is necessary to strike this existing language.

All changes identified within the self-assessment form are necessary for clarity and consistency in the Board's regulations and to ensure the accuracy of the legal references on the self-assessment form, which is a tool used by licensees to evaluate the facilities' compliance with laws and regulations.

The **Hospital Pharmacy self-assessment form (17M-14)** has been updated to make the following changes:

On every page of Form 17M-14, the footer at the bottom left corner which reads "17M-14 (Rev. 1/22)" was amended to reflect the updated revision date "17M-14 (Rev. 1/24)." Conforming changes were made throughout. The purpose of this change is to label the form to indicate this is the updated version. This amendment is necessary to properly identify the form and ensure that the regulated public uses the correct version of the form.

Throughout the form, sections were renumbered as needed to address additions or deletions within 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 the beginning of each section. Conforming changes were made throughout the document. These changes are non-substantive because they are renumbering and structural changes as part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1) and to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for ease of use by the regulated public and the Board, and to avoid confusion.

Throughout the form, the law or regulation that forms the basis for the question has been added or amended, as appropriate, as a reference following the question. The purpose of these changes is to provide the corresponding citation along with each question. This is necessary to foster compliance with the laws and regulations, by helping the PIC and pharmacy to refer to the source for each requirement while conducting the self-assessment, as well as providing a reference for where to look for further information. In addition, the completed self-assessment will assist Board employees with better directing their attention and resources when performing inspections.

Throughout the form, typographical changes were made for grammatical consistency, including the addition of commas and periods. These changes are non-substantive because they are part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

Page 4

Number 1.15 is added for the purpose of reminding licensees that medicinal cannabis must be stored in locked containers within the patient's room, a designated area, or with the patient's primary care giver and retrieved, administered, handled, removed, or disposed in accordance with HSC sections 1649.1, 1649.2, 1649.3, and 1649.4. It is necessary to add this information to ensure that the PIC is aware of the storage requirements of medicinal cannabis within the hospital, as required under the Compassionate Access to Medical Cannabis Act, which became effective January 1, 2022.

Number 2.2.2 is amended for the purpose of adding "chief executive officer". This is necessary to more closely align the language within this number with the language within BPC section 4115(j)(3).

Page 6

Number 3.7 is updated for the purpose of reflecting the appropriate traceability requirements based on the effective date. Per the Drug Quality and Security Act (DQSA), lot-level traceability became effective November 27, 2020 and unit-level traceability because effective November 27, 2023. The new language reads "The pharmacy has lot-level and unit-level traceability in accordance with the Drug Quality and Security Act (DQSA)." This update is necessary to ensure clarity to the regulated public about the traceability requirements and ensure old effective dates are appropriately removed.

Pages 7-8

Section 5 is amended for the purpose of striking some of the existing language. During inspections, Board inspectors have received comments about the length of the self-assessment form. In an effort to reduce the overall length of the self-assessment form, this existing language is stricken, as the number of Pharmacies that donate drugs to a voluntary county-approved drug repository and distribution program is very small, as

such, the section does not apply to the majority of licensees. Reference to Section 30 [donate drugs] and 31 [operate program] were stricken as well. Removing these sections is necessary to reduce the overall the length of the form, while still meeting the intent of the self-assessment form, which is to educate and assist pharmacists/facilities with operating in compliance with law.

New number 5.1 is added to ask the licensee if the pharmacy donates to or operates a county-approved Voluntary Drug Repository and Distribution Program. This is necessary to remind licensees that this program does exist and ensure that the PIC is aware of the program.

New number 5.1.1 is added for the purpose of reminding that, should the pharmacy donate to or operate a voluntary drug repository and distribution, the program must meet all the requirements as specific in law and the specific statutes are identified so that the PIC can locate the requirements if the pharmacy does donate to or operate a program. This new number is necessary to assist pharmacists/facilities that donate to a repository with assessing their compliance with the law. The items are also necessary because they include the Health and Safety Code sections to provide easy reference to the applicable statutes.

New number 6.6 is added for the purpose of reminding that the PIC or pharmacist on duty, if the PIC is not available, is authorized to make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely. Additionally, a sentence is included that this authorization does not apply to facilities of the Department of Corrections and Rehabilitation. This staffing addition is necessary to help ensure the pharmacist is able to practice competently and safely, and is authorized by BPC section 4113(c)(2), which became effective January 1, 2024

Page 9

New number 6.7 is added for the purpose of reminding that the PIC or pharmacist on duty must immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or pharmacist on duty shall ensure the Board is timely notified. This notification addition is necessary to ensure the safety of patients, and of everyone working in the pharmacy, and is authorized by BPC section 4113(c)(2), which became effective January 1, 2024.

Page 10

New number 7.8 is added for the purpose of reminding licensees that only a prescriber, a prescriber's authorized agent, or a pharmacist may electronically enter a prescription or an order, as defined in BPC 4019, into a pharmacy's or hospital's computer from any location outside of the pharmacy or hospital with the permission of the pharmacy or hospital. This item is necessary to ensure licensees are aware of the restrictions

established by BPC section 4071.1, which limits who may enter a prescription or order into the identified computer systems.

New number 7.9 is added for the purpose of reminding that a pharmacist located and licensed in the state may, on behalf of a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code, from a location outside the facility, verify medication chart orders for appropriateness before administration consistent with federal requirements, as established in the health care facility's policies and procedures. The health care facility shall maintain a record of the pharmacist's verification of the medication chart order that meets the same requirements as those described in Sections 4081 and 4105. This item is necessary to ensure the pharmacy completes the verification authorization and records requirement that are specified by BPC section 4071.1, which became effective September 1, 2023.

Pages 12-13

Number 10.3 is amended for the purpose of adding the specific tasks that the pharmacy technician may perform under the direct supervision and control of a pharmacist, specifically, packaging, manipulative, repetitive, or other nondiscretionary tasks. It is also amended for the purpose of adding that, if a pharmacy technician, under the direct supervision and control of the pharmacist, prepares and administers influenza and COVID-19 vaccines via injection or intranasally, prepares and administers epinephrine, performs specimen collection for tests that are classified as waived under CLIA, receives prescription transfers, and accepts clarification on prescriptions, then a second pharmacy technician shall assist a pharmacist with performing the tasks as defined in BPC section 4115(a). Adding this information is necessary for clarity with respect to the tasks a pharmacy technician can perform under specific ratio requirements, and having a second pharmacy technician present to assist the pharmacist should the pharmacy technician be performing certain tasks is required by BPC section 4115(b)(1)(A).

Page 14

New number 10.11 is added for the purpose of reminding licensees that individuals must not act as pharmacy technicians without first being licensed by the Board as pharmacy technicians, as any staff acting as a pharmacy technician must be licensed pursuant to BPC section 4115(f). Further, this additional clarification is necessary to ensure pharmacies and PICs know that possession of a pharmacy technician certification only is not equivalent to being licensed by the Board, as Board inspectors have found unlicensed individuals working as pharmacy technicians under the belief that it was acceptable because the individual had a certification. This addition will ensure unlicensed individuals are not acting as pharmacy technicians without the appropriate licensure.

New numbers 10.12 through 10.12.4 are added for the purpose of reminding licensees of the following:

10.12. A pharmacy technician may, under the direct supervision and control of a pharmacist, prepare and administer influenza and COVID-19 vaccines via

injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are classified as waived under CLIA, receive prescription transfers, and accept clarification on prescriptions under the following conditions: (BPC 4115[b][1])

10.12.1. The pharmacy has scheduled another pharmacy technician to assist the pharmacist by performing the tasks as defined in BPC 4115(a), under the direct supervision of the pharmacist; (BPC 4115[b][1][A])

10.12.2. The pharmacy technician is certified and maintains the certification, by a pharmacy technician certifying organization offering a pharmacy technician certification program accredited by the National Commission for Certifying Agencies that is approved by the board; (BPC 4115[b][1][B], BPC 4202[a][4])

10.12.3. The pharmacy technician has completed at least six hours of practical training approved by the Accreditation Council for Pharmacy Education and includes hands-on injection technique, the recognition and treatment of emergency reactions to vaccines, and an assessment of the pharmacy technician's injection technique; (BPC 4115[b][1][C]; and

10.12.4. The pharmacy technician is certified in basic life support. (BPC 4115[b][1][D])

This information is added for the purpose of listing the tasks a pharmacy technician can perform under the direct supervision and control of a pharmacist and the specific requirements that must be met for a pharmacy technician to perform these tasks, consistent with BPC sections 4115(b)(1)(A)-(D). This addition is necessary for clarity and to ensure that the pharmacist is aware of the tasks a pharmacy technician may perform, the circumstances under which the individual may perform those tasks, and the requirements that must be met in order for the pharmacy technician to perform those tasks.

Page 18

New number 17.9 is added for the purpose of reminding the PIC and licensees that the PIC must report quality assurance review reports for medication errors with respect to ADDS to the Board at the time of annual review of the hospital pharmacy license. This is necessary to ensure compliance with the reporting requirement in CCR section 1711(f), which became effective July 1, 2021.

Page 19

Number 18.11 is amended for the purpose of bringing the language on the form in line with the changes in the language of CCR section 1715.6; specifically, the term "upon" was updated to "within one business day of" for consistency with the DEA requirement within 21 CFR section 1301.74(c). Additionally, the number was rewritten to relocate the phrase "within 30 days" to "within 30 days of discovery" to mirror the requirements of CCR section 1715.6(a). The drug loss reporting regulations within CCR 1715.6 were amended with an effective date of April 1, 2022, and these changes are necessary to ensure compliance with the updated federal and state regulations.

Number 18.11.1 is added for the purpose of reminding the licensee of the requirement to report drug losses of 99 dosage units of tablets, capsules, or other oral medication. This is necessary to include to ensure compliance with the requirements of CCR section 1715.6(a)(1)(A).

Number 18.11.2 is added for the purpose of reminding the licensee of the requirement to report drug losses of 10 dosage units of single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches. This is necessary to include to ensure compliance with the requirements of CCR section 1715.6(a)(1)(B).

Number 18.11.3 is added for the purpose of reminding the licensee of the requirement to report drug losses of Injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described, two or more multi-dose vials, infusion bags or other containers. This is necessary to include to ensure compliance with the requirements of CCR section 1715.6(a)(1)(C).

Pages 20-21

Numbers 19.3.6 through 19.3.10 are added to remind licensees of the requirements of CCR section 1715.65, which was amended in 2022 and effective January 1, 2023. Specifically, the additional language is as follows:

19.3.6. In addition to Schedule II controlled substance, the pharmacy is performing an inventory reconciliation of alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine 6.25mg promethazine/10mg codeine per 5ml of product at least every 12 months. (CCR 1715.65[a][2])

*19.3.7. An inventory reconciliation report must be prepared for any identified controlled substances lost no later than three months after discovery of the **reportable** loss. (CCR 1715.65)*

19.3.8. Inventory activities for all other controlled substances must be performed at least once every two years from the performance of the last inventory activities. (CCR 1715.65[a][3][B])

19.3.9. The inventory reconciliation report may use a digital or electronic signature or biometric identifier in lieu of a physical signature if, in addition, the individual physically signs a printed statement confirming the accuracy of the inventory or report. The signature shall be dated, and the signed and dated statement shall be retained on file. (CCR 1715.65[e][1])

19.3.10. Inpatient hospital pharmacy, the inventory reconciliation for all federal Schedule II-controlled substances, and alprazolam 1mg/unit, alprazolam 2mg/unit, tramadol 50mg/unit, and promethazine with codeine (6.25mg promethazine/10mg codeine/5ml) must be performed on a quarterly basis. The report or reports shall include controlled substances stored within the pharmacy, within each pharmacy satellite location, and within each drug storage area in the hospital under the pharmacy's control. (CCR 1715.65[g])

that the purpose of adding this information is to provide clarity with respect to the inventory reconciliation requirements within the CCR. The inventory reconciliation regulations within CCR section 1715.65 were amended with an effective date of January 1, 2023. This addition is necessary to ensure that the requirements listed on the self-assessment form, and that the pharmacies are in compliance with, are current.

This form is also changed for the purpose of striking numbers 19.5, 19.7, and 19.8 through 19.8.4. This is necessary due to the regulatory change at CCR section 1715.65. The regulatory change, effective January 1, 2023, removed these requirements from CCR section 1715.65.

Page 22

New number 19.8 is added for the purpose of reminding licensees of the requirements of CCR section 1715.65(h), which was added in 2022 and became effective January 1, 2023. Specifically, the reminder ensures that licensees know that if the inpatient hospital pharmacy uses an ADDS, inventory in the ADDS may be accounted for under subdivision (c)(1) of 1715.65 using means other than a physical count. This addition is necessary to ensure that the PIC is aware of the change and ensures that the self-assessment form includes current legal requirements.

Page 23

New number 23.17 is added for the purpose of educate the PIC of the requirement for an ADDS to be licensed if the device is located in the emergency room and is used for dispensing to patients upon discharge. This is necessary to include to ensure compliance because, while ADDS used by hospitals for *administration* to patients are exempt from licensure pursuant to BPC section 4427.2(i), those devices used to *dispense* to patients are not exempt from licensure.

Page 25

Number 24.15 is amended for the purpose of removing the prior effective date (January 1, 2022) as it is in the past and is no longer needed within the form. Removing the old date is necessary for clarity as the date has passed.

Number 24.16 is added for the purpose of including the reminder to licensees that a hospital pharmacy must retain the dispensing information and, if the drug is a schedule II, III, IV or V controlled substance, transmits the dispensing data to the Department of Justice within one working day from the date the controlled substance is released to the patient, which is a requirement of HSC section 11165(d). Including the reminder on the self-assessment form is necessary to assist with ensuring that the prescription dispensing data is appropriately reported to the Department of Justice.

Page 29

Number 29.1 is amended for the purpose of including the reminder to licensees that licensure exempt AUDS devices must still comply with all other requirements for an

ADDS within Article 25 of the BPC, which is a requirement of BPC section 4427.2(i). While these devices are exempt from licensure, these devices are not exempt from the other requirements of Article 25. This is necessary to include to ensure compliance with the requirements of BPC section 4427.2(i).

All changes identified within the self-assessment form are necessary for clarity and consistency in the Board's regulation and to ensure the accuracy of the legal references on the self-assessment form, which is a tool used by licensees to evaluate the facilities' compliance with laws and regulations.

Section 1784, subsection (c) is updated to change the revision date of the self-assessment form from 12/21 to 1/24. The purpose of this change is to incorporate by reference the updated versions of the forms. This amendment is necessary to ensure that the regulated public is aware of the date that the self-assessment form was updated so that licensees use the correct version of the form. This subsection is also amended to remove a period at the beginning of the subsection. This change is non-substantive because it is a punctuation change as part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

The wholesaler/third-party logistics provider self-assessment form (17M-26) has been updated to make the following changes**:**

The revision date was amended at the bottom of each page from 12/21 to 1/24 to reflect the last update of the self-assessment of the form.. The purpose of this change is to label the form to indicate this is the updated version. This amendment is necessary to properly identify the form and ensure that the regulated public uses the correct version of the form.

Throughout the form, sections were renumbered as needed to address additions or deletions within 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 the beginning of each section. Conforming changes were made throughout the document. These changes are non-substantive because they are renumbering and structural changes as part of an effort to "renumber[], reorder[], or relocat[e] a regulatory provision" within the meaning of Title 1, CCR section 100(a)(1) and to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4). This is necessary for ease of use by the regulated public and the Board, and to avoid confusion.

Throughout the form, the law or regulation that forms the basis for the question has been added or amended, as appropriate, as a reference following the question. The purpose of these changes is to provide the corresponding citation along with each question. This is necessary to foster compliance with the laws and regulations, by helping the PIC and pharmacy to refer to the source for each requirement while

conducting the self-assessment, as well as providing a reference for where to look for further information. In addition, the completed self-assessment will assist Board employees with better directing their attention and resources when performing an inspection.

Throughout the form, typographical changes were made for grammatical consistency, including the addition of commas and periods. These changes are non-substantive because they are part of an effort to "[revise] structure, syntax, cross-reference, grammar, or punctuation" within the meaning of Title 1, CCR section 100(a)(4).

Page 1

The page number for the legal references has been changed for the purpose of updating page 20 from page 21. This change is necessary because, as the formatting and spacing was updated, the number of pages of the self-assessment form was reduced, which resulted in the need to update the page number.

A defining paragraph was added to page 1 for the purpose of providing information to the licensee about the self-assessment process, when the self-assessment must be completed, the process of the self-assessment process, and the retention of the completed self-assessment. This addition mirrors that information provided on the other self-assessment forms (17M-13 and 17M-14) and is necessary to inform licensee about the self-assessment process.

Page 2

A line was added for the purpose of providing a space for the DRIC/RM (Designated Representative-in-Charge/Responsible Manager) to list their email address. Listing this contact information is necessary for the inspector/Board staff should the DRIC/RM not be present during the inspection of the facility or should Board staff need to communicate with the DRIC/RM about the self-assessment or the facility.

Page 3

The title of the self-assessment form has been duplicated at the top of the third page for the purpose of providing a reminder to those completing the form or reviewing the form. Additionally, to ensure an understanding of the legal references used within the self-assessment form, identification of the CCR and BPC is added to page three under the title of the form. These additions mirror the other self-assessment forms and are necessary to provide clarity to everyone using the form (whether they are completing the form or reviewing a completed form).

Number 1.3 is added for the purpose of reminding licensees of the requirement that written notification be submitted to the Board with 30 days of a transfer of the management or control over the WLS/3PL to a person or entity who did not have management or control over the license at the time the original license was issued, pursuant to CCR section 1709(b). This change is necessary to ensure compliance with

the requirement, which became effective on April 1, 2022 after the change to CCR section 1709, which was updated to include management and control of the facility.

Number 1.4 is added for the purpose of reminding licensees that a copy of trust documents must be readily available to inspectors if any beneficial interest of the facility is held in a trust, pursuant to CCR section 1709(d). This change is necessary to ensure compliance with the requirement, which became effective on April 1, 2022 after the change to CCR section 1709, which was updated to include trust ownership of businesses.

Page 6

Number 3.6 is added for the purpose of reminding licensees of the requirement for the designated representative-in-charge/responsible manager to update their email address with 30 days of any change. This is necessary to ensure compliance with the required in CCR section 1704(b), which became effective on April 1, 2022.

The note at the end of Section 5 has been amended to add the word “of” between “wholesaling” and “controlled substances”, so the sentence reads “wholesaling of controlled substances”. This is a non-substantive grammatical change that is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Page 7

The note at the end of Section 6 has been amended to add the word “of” between “wholesaling” and “controlled substances”, so the sentence reads “wholesaling of controlled substances”. This is a non-substantive grammatical change that is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Number 7.2 is updated to remove the second reference to “BPC”, as it is duplicative. This is a non-substantive change that is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Page 8

Number 7.5.3 is updated for the purpose of adding “your business only furnishes” to mirror the language within BPC section 4126.5(a)(4). This addition is necessary to provide clarity to the regulated public on the limitations placed on wholesalers with respect to the receipt of drugs from a pharmacy.

Page 9

The note at the end of Section 7 has been amended to add the word “of” between “wholesaling” and “controlled substances”, so the sentence reads “wholesaling of controlled substances”. This is a non-substantive grammatical change that is part of an

effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Page 10

The note at the end of Section 9 has been amended to add the word “of” between “wholesaling” and “controlled substances”, so the sentence reads “wholesaling of controlled substances”. This is a non-substantive grammatical change that is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Page 13

Number 11.29 is amended for the purpose of including the updated reporting requirements for drug losses following changes to CCR section 1715.6, which became effective on April 1, 2022. The language now reads:

“Does the owner of your business notify the board within 30 days of discovering the loss of the following:

Any loss of a controlled substance, in one of the following categories that causes the aggregate amount of unreported losses discovered in that category, on or after the same day of the previous year, to equal or exceed:

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

(B) For single-dose injectable medications, lozenges, film, such as oral, buccal and sublingual, suppositories, or patches, 10 dosage units.

(C) For injectable multi-dose medications, medications administered by continuous infusion, or any other multi-dose unit not described in subparagraph (A), two or more multi-dose vials, infusion bags, or other containers. (CCR 1715.6)”

This information is being added for the purpose of providing clarity with respect to the drug loss reporting requirements within the CCR. The drug loss reporting regulations within CCR 1715.6 were amended with an effective date of April 1, 2022. This addition is necessary to ensure that the requirements listed on the self-assessment form are current.

Page 16

The note at the end of Section 15 has been amended to add the word “of” between “wholesaling” and “controlled substances”, so the sentence reads “wholesaling of controlled substances”. This is a non-substantive grammatical change that is part of an effort to “[revise] structure, syntax, cross-reference, grammar, or punctuation” within the meaning of Title 1, CCR section 100(a)(4).

Page 18

Number 16.13 is added for the purpose of reminding licensees that, if a wholesaler/third-party logistics provider temporarily closes, the facility shall notify the Board of any temporary closure of the facility as soon as any closure exceeds three consecutive calendar days. A temporary closure does not include a routine closure (including weekends or state and federal holidays), unless that closure exceeds four

consecutive calendar days. This change is necessary to ensure prompt notification to the Board, as is required by CCR section 1708.1, which became effective October 1, 2022.

Underlying Data:

1. Relevant Meeting Materials and Minutes from Enforcement and Compounding Committee Meeting held January 23, 2024
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held February 8, 2024

Business Impact

The Board has made an initial determination that the proposed regulatory action would have no significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states because, as discussed below under Effect of Small Business, the requirement to complete these self-assessments already exists and these regulations are updating the contents of the self-assessment forms (i.e. updating the statutes and regulations listed within the self-assessment forms) incorporated by reference. Because the Board currently requires PICs, DRICs, and RMs to complete the self-assessment forms, the proposed regulations do not increase the workload or costs for these licensees to comply.

Economic Impact Assessment:

The Board has determined that this proposal will not:

(1) create jobs within California;
(2) eliminate jobs within California;
(3) create new businesses within California;
(4) eliminate existing businesses within California;
(5) expand businesses currently doing business in the State of California.

The Board determined that this proposal will not create or eliminate jobs or businesses. This proposal removes old, out-of-date legal references and adds citations to new laws and regulations. Using a current version of the self-assessment form will help educate PICs, DRICs, and RMs, which helps ensure that facilities are operating in compliance with current state and federal laws and regulations.

The regulatory proposal will benefit the health and welfare of California residents because licensed facilities in California will be conducting self-assessments based on current laws, rather than outdated laws. This will make it more likely that the facilities will follow current laws and regulations. When PICs, DRICs, and RMs are actively engaged in reviewing the current laws and regulations, they are more likely to identify and remedy any violations of pharmacy laws and regulations, which exist primarily for consumer safety and worker safety. Additionally, this proposal will allow for a more

efficient use of Board resources during inspections, since facility compliance should be better and the Board's inspectors will be reviewing forms indicating compliance with current laws and regulations. The proposal does not impact the state's environment.

Specific Technologies or Equipment

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

Consideration of Alternatives

The Board has made an initial determination that no reasonable alternative to the regulatory proposal would either be more effective in carrying out the purpose for which the action is proposed or would be as effective or less burdensome to affected private persons and equally effective in achieving the purposes of the regulation in a manner that ensures full compliance with the law being implemented or made specific.
The only alternative to this proposal is to not amend the form to update if following changes in the laws and regulations. This alternative was rejected because licensees would be using forms with out-of-date legal requirements.

Description of reasonable alternatives to the regulation that would lessen any adverse impact on small business:

No such alternatives have been proposed, however, the Board welcomes comments from the public.