BOARD OF PHARMACY

INITIAL STATEMENT OF REASONS

Subject Matter of Proposed Regulations: Self-Assessments For Pharmacies

Sections Affected: Amend Section 1715 of Article 2 of Division 17 of Title 16 of the California Code of Regulations (CCR).

Problems Addressed

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

In 1997, the California State Board of Pharmacy (board) developed via regulation a self-assessment process for pharmacies, including hospital pharmacies, to use as a tool to confirm compliance with provisions of specific state and federal law. Included in the existing regulation section is the requirement to complete the self-assessment, the frequency of completion, and some general requirements. In addition, each self-assessment form itself is incorporated by reference in the existing regulation. Because the self-assessment forms are compilations of state and federal law and regulations, modifications must be made on an annual basis to incorporate changes in those laws. This is a time-intensive process and the board has not been able to update the regulation and self-assessment form as frequently as necessary, with the last update being completed in 2014.

To remedy this, the Board is seeking to further refine the regulations to specify the forms' requirements. These requirements currently only exist in the self-assessment forms and the Board determined it is necessary to move the requirements into regulation. One example is the requirement for the form to be signed under penalty of perjury is currently established as part of the self-assessment form. Upon promulgation of this rulemaking, future updates to the self-assessments can be expedited through the streamlined rulemaking process afforded for non-substantive changes in Section 100 of CCR (Title 1).

In this rulemaking, the Board proposes to amend Section 1715 of Article 2 of Division 17 of Title 16 of the CCR to update and establish the requirements for the following self-assessment forms in regulation: Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment (Form 17M-13, Rev. 07/18) and Hospital Pharmacy Self-Assessment (Form 17M-14, Rev. 07/18).

Anticipated Benefits

Currently, a pharmacist-in-charge (PIC) goes through the process of completing the self-assessment form, at least biennially, during which the PIC is made aware of any areas where the pharmacy may be out of compliance with laws and regulations. This awareness can increase self-correction and makes the pharmacy site inspection process more meaningful by providing useful information to the PIC about controlling statutes and regulations. Self-assessment forms also serve as an easy reference guide for a PIC.

This regulatory proposal benefits the health and welfare of California residents and benefits employee safety by ensuring the pharmacy is operating consistent with pharmacy law. The proposed regulation will update the self-assessment form with current law and regulations. The revised self-assessment forms will aid licensees in assessing their compliance with federal and state pharmacy law to reflect laws and regulations adopted since 2014, and exclude laws and regulations superseded or repealed since 2014. The proposal will not impact the state's environment.

This proposal also allows for a streamlined process for updating the self-assessment form as changes to pharmacy law occur, which will provide a more effective and efficient use of board resources, by reducing the workload associated with the rulemaking process.

Specific Purpose of the Proposed Changes

The Board's proposal makes the following amendments:

Amend 16 CCR Section 1715. Self-Assessment of a Pharmacy by the PIC.

Subdivision (c) is amended in the following manner:

"A pharmacist-in-charge of a community pharmacy shall assess the pharmacy's compliance with current laws and regulations by using", is added to clarify that the pharmacist-in-charge (PIC) is the person responsible for assessing the pharmacy's compliance, and that the same person must complete the self-assessment form for a community pharmacy. The Board determined this amendment was necessary because the PIC is responsible for the pharmacy's compliance with laws and regulations, and therefore would be the person to complete the assessment and must not delegate the task to another staff member at the pharmacy. As the person completing the assessment, the PIC is also in a position to adjust the pharmacy's practices.

Delete the words “this assessment shall be on” to adjust the grammar of the sentence to match the changes made to reflect that the PIC is responsible for conducting the assessment.

Update the revision date from “10/14” to “07/18” to incorporate the newer version of the Form 17M-13 by reference, to clearly state that the current version of the form, which reflects current laws and regulations, is the one the PIC must use to complete the assessment.

Add a forward slash (“/”) in the title of Form 17M-13 after the word “Assessment” and before the word “Hospital” to reflect that the self-assessment form may be used in either setting - a traditional community pharmacy and hospital outpatient pharmacy. The addition of the forward slash grammatically delineates the two pharmacy types for which the self-assessment form may be used.

Add a period after the word “Self-Assessment” to improve grammar.

Add a new second and amend the current second, now third, sentence by adding “As used in this section, a community pharmacy means a pharmacy serving retail or outpatient consumers. A pharmacist-in-charge of a hospital pharmacy serving inpatient consumers, shall assess compliance with current laws and regulations using the components of” and the words “and on” are removed from the newly amended third sentence. The new second sentence was added to require that the components of Form 17M-13 are used for pharmacies in traditional retail and outpatient hospital pharmacies. Because traditional retail and outpatient hospital pharmacies have similar standards, the Board determined they require the use of the same form. The addition clarifies which self-assessment form is required based on the pharmacy setting. The new third sentence was amended to require a PIC of a hospital pharmacy serving inpatient consumers to complete the Hospital Pharmacy Self-Assessment Form (Form 17M-14 (Rev. 07/18). The laws and regulations that apply to an inpatient pharmacy are somewhat different than those that apply to an outpatient pharmacy; the more current form is updated to reflect the requirements of the current laws and regulations. As a result, the board developed a different form. Grammatical changes were also made to revise punctuation.

Delete the words “which are” and the words “to evaluate compliance with federal and state laws and regulations” and add “Both forms are” to begin a new sentence in front of “hereby incorporated by reference.” This change formally incorporates both current self-assessment forms by reference. The phrase “to evaluate compliance with federal and state laws and regulations” repeats a concept already explained in subparagraph (a), so it was deleted. The phrase “and contain the following components:” was added to the

sentence to explain that the self-assessment contains the specific information found in the following subdivisions.

Subdivisions (c)(1) through (7) articulate the required components of the self-assessments. The components are the same for both forms because they represent not the substantive laws the PIC will be checking for compliance with, but rather the elements that will make the assessment sufficient, mostly for the board to evaluate whether the PIC meaningfully and timely conducted the review. These components are, with a few non-substantive changes, required by the existing versions of the forms incorporated by reference.

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

- Name and any license number(s) of the pharmacy and their expiration dates;
- Address, phone number, ownership type and website address, if applicable, of the pharmacy;
- Federal Drug Enforcement Agency (DEA) registration number, expiration date and date of most recent DEA inventory;
- Hours of operation of the pharmacy; and
- Accreditation by third party, if applicable, and dates of accreditation.

This information was added based on requirements in the existing form. The identifying information makes it clear to board inspectors and the PIC which pharmacy the form pertains to and keeps all the identifying information about the pharmacy in one place. The Board requires the PIC to be aware of such information. The PIC must record the names, license numbers and expiration dates for all licenses associated with the pharmacy to ensure all licenses are current. Awareness of the expiration dates for licensed personnel can help alert the PIC when a licensee is close to or past their renewal date so that the PIC may take steps to ensure all pharmacy licensees have current licenses. This process assists the PIC with compliance with state and federal law. The PIC is required to record the address, phone number, ownership structure and website to ensure the PIC is aware of the pharmacy's current information and that this information matches Board records. The PIC must record the current DEA number, expiration date and most recent DEA inventory because the PIC is more likely to realize whether the pharmacy is out of compliance with DEA requirements due to an expired license or an out of date DEA inventory. Further, this information allows the board to confirm the DEA registration, expiration date and date of DEA inventory to ensure

compliance with federal requirements. The hours of operation are necessary for the Board to properly monitor and enforce regulations. Further, as the Board conducts random unannounced inspections, knowledge of the hours of operations facilitate inspections during business hours.

Documentation of this information further requires deliberate review by the PIC and should highlight if the pharmacy is noncompliant with either reporting required changes to the Board (for example a new address) or DEA inventory requirements. Accreditation information is relevant for similar reasons; it is relevant upon inspection because acts that may have resulted in a change or a loss of accreditation may bear on whether the pharmacy has been complying with relevant laws. These requirements exist in the versions of the self-assessment forms that are currently incorporated by reference.

Subdivision (c)(2) adds a specific requirement that the PIC list each staff person currently working in the pharmacy, the person's license type and number to provide clarity to the reader. This provision ensures that the PIC is aware and considers the status of each license and can take corrective action if necessary. This also allows for a central place for the information to be tracked for inspection by Board staff. This requirement exists in the self-assessment forms currently incorporated by reference.

Subdivision (c)(3) is amended to add a requirement that the PIC report if the pharmacy follows laws and regulations that apply to that pharmacy setting. This is added to require the PIC to respond "yes", "no" or "not applicable" (N/A) to whether the pharmacy is, at the time of the self-assessment, in compliance with each of the requirements that apply to that pharmacy setting. This change was necessary to require the PIC to acknowledge compliance and/or noncompliance with various provisions of pharmacy law. Each noted "yes", "no" or "not applicable" identifies to both the PIC as well as Board staff that this self-review and evaluation has been completed by the PIC on behalf of the pharmacy and details the areas of noncompliance noted. This element requires deliberate assessment by the PIC, evoking a review that will hopefully result in better compliance with laws. This requirement exists in the self-assessment forms that are currently incorporated by reference.

Subdivision (c)(4) adds, "For each "no" response, the PIC shall develop a written corrective action or action plan to come into compliance with the law." This change requires the PIC to create a plan for the pharmacy to remediate areas of noncompliance and makes it more likely that the pharmacy will become fully compliant. Board staff regularly inspect pharmacies for compliance with laws and regulations; the addition of (c)(4) allows for a streamlined, efficient, and effective inspection process as inspectors can monitor the development of a correction action or action plan. This requirement exists in the self-assessment forms that are currently incorporated by reference.

Subdivision (c)(5) adds a requirement that the PIC initial each original page of the self-assessment form, by hand, and in ink. This change is intended to ensure that the document is prepared by the PIC and not another member of pharmacy staff. The requirement of a handwritten initial in ink on the form may prevent other pharmacy personnel from completing the self-assessment form for the PIC. This requires deliberate action by the PIC and helps to convey the significance of the PIC's role in ensuring the pharmacy's compliance with state and federal law. This requirement exists in the self-assessment forms that are currently incorporated by reference.

Subdivision (c)(6) adds a specific requirement that the PIC certify, under penalty of perjury, that they completed the self-assessment form. This affirms the PIC has completed the self-assessment, and makes the PIC understand the significance of his or her role in ensuring compliance. The certification also requires the PIC provide a timeframe within which any deficiency identified during the self-assessment will be corrected, and to acknowledge that all responses are subject to verification by the Board. The certification that the information provided in the self-assessment form is true and correct must be made under penalty of perjury of the laws of the State of California. By requiring attestation under penalty of perjury, the Board is communicating to the PIC and all future pharmacists-in-charge, the gravity of falsifying information to the Board. Pursuant to BPC section 4301(g), the Board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Should a PIC falsely certify to the completion of the self-assessment, the PIC could be disciplined by the Board. This requirement exists in the self-assessment forms that are currently incorporated by reference.

Subdivision (c)(7) adds the requirement for a certification and acknowledgement by the pharmacy owner or hospital administrator that he or she has read and reviewed the completed self-assessment and an acknowledgement that failure to correct any deficiency identified in the self-assessment could result in the revocation of the pharmacy's license issued by the Board. This requires the pharmacy owner or hospital administrator to be aware of the contents of the assessment completed by the PIC, and to certify, under penalty of perjury, on the final page of the self-assessment and the consequences of failure to do so.

By requiring attestation under penalty of perjury, the Board is communicating to the pharmacy owner or hospital administrator and all future pharmacy owners or hospital administrators, the gravity of falsifying information to the Board. Pursuant to BPC section 4301(g), the Board has the statutory authority to discipline a licensee who knowingly made or signed any certificate or document that falsely represents the existence or nonexistence of facts. Like the PIC, the pharmacy's license may be

disciplined if its pharmacy owner or administrator, provides a false certification to the board. This requirement also ensures that the owner or administrator is reviewing the completed self-assessment and is made aware of any operational deficiencies. This knowledge may increase the likelihood that any deficiencies are corrected timely, which is a benefit to consumers, workers, and board inspectors during an inspection. Currently, this requirement only exists on the self-assessment form and the requirement is being added into regulation to ease the administrative process of updating the self-assessment form.

Subdivision (d) adds "completed in its entirety and" to require that the entire form be completed – even if to indicate that it does not apply – and that such requirement is in addition to the existing requirement in the section, that the fully executed self-assessment form is kept in the pharmacy. When only portions of the self-assessment are completed, the PIC has not fully assessed the pharmacy's compliance, and a full and meaningful assessment is necessary to make it more likely the pharmacy is compliant. The requirement exists in the self-assessment forms that are currently incorporated by reference.

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

Subdivision (e) is added to require any identified areas of noncompliance to be corrected as specified in the certification. When the PIC completes the certification, they must identify a timeframe for corrections to be completed. This change is made to make ensure that the pharmacy corrects the areas of non-compliance and to ensure that the PIC is responsible to the owner or administrator, as well as to the Board. Failure to do so without a valid justification could result in administrative or disciplinary action against the license by the Board.

The reference statutes were amended to add appropriate sections. Sections 4019, 4036, 4051, 4059, 4110, 4120, 4201, and 4031 of the Business and Professions Code were added as references. These added references are included as non-substantive changes as they reference licensing definitions, requirements, and disciplinary processes as they relate to pharmacies and pharmacists.

Changes to Form 17M-13 Incorporated by Reference

As explained above in the change made to the regulation text, the title of the form Community Pharmacy Self-Assessment Hospital Outpatient Pharmacy Self-Assessment was amended to make a technical correction to the title of Form 17M-13 by inserting a forward slash between "Community Pharmacy Self-Assessment" and "Hospital Outpatient Pharmacy Self-Assessment." The change is made here for the same reason and for consistency.

Important Note: the current self-assessment form includes underline in two areas detailed below. In the proposed versions of the self-assessment forms, the currently underlined text has been double underlined for added emphasis to the reader. A legend has been added to aid the reader.

- "The assessment shall be performed before July 1 of every odd-numbered year:"
- "Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

In both cases, the text is double underlined for emphasis to the reader and in neither occurrence is the double underline intended to convey a change to the form.

The Board proposes all of the changes set forth below be made within Form 17M-13 (Rev. 07/18) *"Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment*:"

On every page of Form 17M-13, the footer at the bottom left corner which reads "17M-13 (Rev. 10/14)" was amended to reflect the updated revision date ("17M-13 (Rev. 07/18)"). Conforming changes were made throughout.

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. For consistency of abbreviations, "BPC" is now used throughout to reference Business and Professions Code sections, "HSC" is now used throughout to reference Health and Safety Code sections, and "CCR" is now used throughout to reference sections of the California Code of Regulations. These abbreviations replace other variations (e.g., B&PC is being replaced with BPC). Conforming changes were made throughout the document.

Throughout the form, the law or regulation that forms the basis for the question has been added as a reference following the question. This will foster compliance with the laws and regulations, by allowing the PIC and pharmacy to readily refer to the source for each requirement while conducting the self-assessment, but also allowing the self-

assessment form to be used as a reference for where to look for further information. In addition, the completed self-assessment will assist a board employee to better direct their attention and resources when performing an inspection.

On page 1, the second paragraph was amended to add a period punctuation after “entirety” and replaced “and” with “It” as the beginning of a second sentence. These changes were made to emphasize the self-assessment must be completed in its entirety. The word “It” was added to refer to the self-assessment and the “and” was removed so there could be two sentences. These changes were made to make the form easier to read.

On page 1, the second paragraph was amended to replace “and retained” with “, initialed, signed, and readily available.” The self-assessment will have little value if it is not initialed and signed by the person completing the assessment. Without knowing who completed the assessment, when the form is reviewed in the future, another pharmacist or a Board Inspector, will be unable to identify who completed it and who to speak to regarding noncompliance issues.

On page 1, the second paragraph was amended to add a third and fourth sentence and reads “Signatures and initials shall be an original handwritten signature or initial on the self-assessment form.” This was added to require that the PIC, owner or administrator are required to sign, initial and date on the self-assessment paper forms. These changes are made for consistency with the revised text of CCR section 1715, subdivision (d), which requires that the original self-assessment be completed, initialed, signed, and readily available during an inspection.

One page 1, under the ownership designation, a trust ownership option was added pursuant to the passage of SB 1193 (Hill, Chapter 484, Statutes of 2016). This change is consistent with the change to BPC section 4035, which was amended through SB 1193.

On page 1, the term “Permit” was changed to “License” as BPC Section 4032 defines “license” to include any license, permit, registration, certificate, or exemption issued by the board. Replacing the term allows the Board to achieve consistency with statute and clarity to the regulated public. Conforming changes were made throughout the document.

On page 1, after the words “Accredited by” the word “optional” was deleted and replaced with “if any” to provide clarity to the reader that a pharmacy with any accreditations must record the accreditations. This additionally provides clarity that this is a required field if any accreditations are held. Pharmacy accreditations are relevant

and bear on licensure for the reasons described in the changes to the text of subdivision (c) of CCR section 1715.

On page 1, a period was added after “Sat” to provide clarity to the reader that “Sat.” is an abbreviation for Saturday.

On page 1, after the words “Website address” the word “optional” was deleted and replaced with “if any” to provide clarity to the reader that a pharmacy with a website must record the website address. This additionally clarifies that this is a required field if a website exists. Identifying information like the website allows the inspectors to review the site and confirm that the pharmacy’s practices are compliant with laws and regulations governing the practice of pharmacy.

On page 2, all references to “APP” were amended to “APH” to for consistency with other frequently used board acronyms in other contexts. When it issues an advanced practice pharmacist license, the Board uses “APH” as a prefix before a number. As a result, that prefix has become known and will be recognized by PICs filling out a self-assessment form.

Changes to Sections 1 through 31

In the changes discussed below, which are organized as sections 1 through 31 in the form, each section relates directly to a specific law or regulation, which is now cited in the form, that the pharmacy is required to follow. By this regulation and updated form, a PIC is required to assess the pharmacy’s compliance and/or practice with respect to each identified law or regulation by answering “yes,” “no,” or “n/a” (not applicable), but compliance with the requirement is <u>not</u> required by the form. Rather, compliance is required by the identified underlying law or regulation. In each case where a new question is asked, it is asked because there is a new or modified section of the law, and the changes are made to ensure the PIC and pharmacy evaluate whether or not they are in compliance with those sections. As previously explained, pharmacies’ compliance with existing laws and regulations fosters public protection.

Changes made to Section 1 – Facility

On page 3, the definition of BPC was added as Business and Professions Code for clarity to the regulated public on the use of BPC in the form.

On page 3, section 1.7 was amended to add a third sentence that reads “A pharmacy may also or instead display the notice on a video screen.” This change reflects changes made to 16 CCR section 1707.6 that became effective in December 2012. This change to the form was inadvertently not included in previous revisions of this form. The section

reference was also corrected from 1707.2 to 1707.6 as the previous reference to 1707.2 was an incorrect reference on the form.

On page 3, a new section 1.8 was added to read “Point to Your Language” poster is posted in a place conspicuous to and readable by a prescription drug consumer or adjacent to each counter in a pharmacy where drugs are dispensed. (CCR 1707.6[c]).” This change reflects the requirement established in CCR 1707.6(c). This requirement took effect in December 2012 and was inadvertently not included in previous revisions of this form.

With the addition of new section 1.8 reference above, sections 1.8 – 1.15 are renumbered to 1.9 – 1.16.

Changes made to Section 2 – Delivery of Drugs

On page 5, section 2.1 was amended to remove a duplicate set of parentheses in the citation for HSC section 1120(a) for ease of reading.

On page 5, section 2.2, the following grammar changes were made for clarity. The Board found these changes make a consistent point of view for the reader as the PIC.

- In section 2.2, the word “A” was replaced with “The,” the word “may” was deleted, and the word “if” was deleted and replaced with “only when,” for grammatical consistency of the perspective of the person completing the form with other questions.
- In subsection 2.2.5, in the first sentence, the words “pursuant to this subdivision” was deleted as the form is not a subdivision and section 2 contains information from different areas of laws, so reference was removed for clarity.
- In subsection 2.2.5, the words “shall be” was replaced with the word “is” in the second and third sentences. This grammatical change was made as “shall be” is future tense and “is” is present tense, meaning the pharmacy already meets the requirement.

On page 5, new sections 2.3, 2.4 and 2.5 have been added to ensure compliance with the requirements created under the federal Drug Supply Chain Security Act (DSCSA) that was enacted by Congress in November 2013 and governs the traceability of drug products through the drug distribution supply chain. Each addition is designed to make sure the licensee is aware of the requirements in the particular provision of the federal DSCSA referenced in the question itself, and to compel the licensee to consider the pharmacy’s compliance with such provision. While these are federal drug distribution requirements, the Board is responsible for ensuring compliance with State and Federal requirements within the State of California. As such, including the federal requirements within the self-assessment form will help educate the PIC and ensure compliance.

On page 5, new section 2.3 was added to read “Prior to, or at the time of, accepting ownership of a product included in the DSCSA from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1 [d][1][A][i])” to draw the licensees’ attention to federal requirements regarding the specific information that the licensee should receive when the licensee takes ownership of drugs.

On page 5, new section 2.4 was added to read “Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the DSCSA to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee-1[d][1][A][ii])” to draw the licensee’s attention to the federal law regarding what information the pharmacy must provide upon transferring ownership of a drug product.

On page 5, new section 2.5 was added to read “The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])” to draw the licensee’s attention to federal law regarding the specific data that is required to be captured at point of sale.

Change made to Section 3 – Drug Stock

On page 6, section 3.1, references to Health and Safety Code section 111335, and 21 USC sections 331, 351, and 352 were added to provide authority relating to a question related to adulterated or misbranded drugs and devices. The added references identify the legal codes that address the maintenance of the pharmacy drug stock. These are provided as a reference tool for the PIC.

On page 6, section 3.2, BPC section 4059.5 is inserted as an additional reference. This reference is added as it identifies the restrictions on ordering and receiving dangerous drugs and devices and is provided as a reference tool for the PIC.

On page 6, section 3.2.1, the word “not” was added, the word “are” was deleted; the words “should not be” was added; and the word “not” was deleted. These changes were made to make the question easier to follow in that the PIC and pharmacy should have no reason to believe that the drug stock is adulterated.

On page 6, section 3.2.2, the word “not” was added; the word “are” was deleted; the words “should not be” was added; and the word “not” was deleted. These changes were

made to make the question easier to follow in that the PIC and pharmacy should have no reason to believe that the drug stock is misbranded.

Change made to Section 4 – Voluntary Drug Repository and Distribution Program

On page 6, section 4.1 was amended to update the renumbered sections by removing "29," and adding after Section "30 [donate drugs] or Section 31 [operate program]", to cross reference that Section 30 of the self-assessment form is specific to donated drugs and Section 31 is specific to operation of a program. References to the titles of the specific sections that must be completed have been added to ensure the PIC is well advised about the need to further assess compliance in other areas detailed in the self-assessment form specific to donating to and operating a county-owned Voluntary Drug Repository and Distribution Program.

Changed made to Section 5 – Pharmacist-in-Charge (PIC)

On page 6, section 5.2 was amended to add a statutory reference to BPC § 4113(c) which requires a PIC to adhere to all state and federal pharmacy laws. This ensures the PIC has full knowledge and understanding of his or her obligations as a PIC.

On page 7, section 5.7 was removed for consistency with regulation. 16 CCR section 1709.1(d) states a PIC is not permitted to concurrently serve as a PIC of a pharmacy and a designated representative-in-charge of a wholesaler or veterinary food-animal retailer. The Board determined the phrasing of the requirement was misleading and needed to be removed for clarity.

With the removal of section 5.7, section 5.8 is renumbered to 5.7.

Changes made to Section 6 – Duties of a Pharmacist

On page 8, section 6.1 has been amended to clarify the requirements for assessing the pharmacy's practices regarding certain duties only a pharmacist can perform. By requiring the identification if a pharmacy performs these functions, it emphasizes that these duties are to be done only by a pharmacist and, if the pharmacy does do them, it provides references to the laws and regulations to make it more likely that, when done, each is more likely to be done consistent with law. It will also assist a Board employee by better directing their attention and resources when performing an inspection. The pharmacist's duties assessed include transmitting prescriptions to pharmacists; administering drugs and biological products; selling dangerous devices; providing consultation/training on drug therapy; providing professional information; furnishing medication by protocols; dispensing aid-in-dying drugs; and ordering/interpreting tests to manage drug therapies.

Section 6.1 was reformatted into a bulleted list instead of a long paragraph to allow for ease of use as well as to ensure the PIC independently assessed each of the criteria. The ability to “furnish a reasonable quantity of compounded drug products to a prescriber for office use by the prescriber” was removed because, if a pharmacy engages in compounding, that requirement is better addressed in the required compounding self-assessment form. Removal of the provision here eliminates duplication within the board’s regulation. The ability to “dispense aid-in-dying drugs” was added to reflect a pharmacist’s authority pursuant to AB 15 (Eggman, Chapter 1, Statutes of 2015-16 Second Extraordinary Session) enacting the End of Life Option Act. Finally, a citation to the specific law that supports each of the bulleted items has been added to provide a cross reference for the PIC and pharmacy, enabling both to more easily explore the relevant authority if need be.

On page 9, section 6.2 was amended to clarify the requirements for assessing the pharmacy’s practices regarding certain duties only a pharmacist can perform related to prescriptions, patients, clinical data, consultation with prescribers, supervision of packing drugs and packing procedures, supervision of pharmacy technicians, and duties authorized by state or federal law. This section was reformatted into a bulleted list instead of a long paragraph to allow for ease of use as well as ensure the PIC independently assesses each of the criteria. Further, the specific underlying statutory provision that supports each of the bulleted items has been added to provide a cross reference for the PIC.

On page 9, section 6.4 was amended to delete “are able to” and replaced with “have obtained approval to” and deleted “information on the Internet that is maintained by the California Department of Justice regarding controlled substance history of a patient who is under the care of the pharmacy based on data obtained through”. This change reflects the statutory change made by Assembly Bill 40 (Santiago, Chapter 607, Statutes of 2017), which required all California licensed pharmacists to register for access to the Controlled Substance Utilization Review and Evaluation (CURES) program. The CURES program requires pre-registration and approval of identifying documents prior to being able to access the system. Pharmacists must complete both portion and have access to the database. The Board determined this was necessary for consistency with establishing alternative methods for a pharmacist to access the CURES Prescription Drug Monitoring Program (PDMP) system. This revision of the self-assessment form will aid licensees in assessing their compliance with this new requirement.

On page 8, section 6.5 was amended to add the word “only” after the word “contraceptive” and before the word “pursuant”. This word was added to clarify the requirement that a pharmacist may provide emergency contraception exclusively

pursuant to protocol established in regulation pursuant to BPC 4052.3(a)(1). The Board determined this addition was necessary to ensure the self-assessment form was consistent with regulation.

On page 10, section 6.8 was added and reads “The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration (BPC 4052[b]).” This section has been relocated to section 6.8 from previous section 7.1 and was deleted in section 7.1, as section 7 of the self-assessment form pertains only to advanced practice pharmacy and this requirement for DEA registration is not limited to only an advanced practice pharmacist. The Board determined this was necessary to clarify that this requirement does not solely apply to advanced practice pharmacists but rather to any pharmacist authorized to initiate or adjust a controlled substance therapy.

Changes made to Section 7 – Duties of an Advanced Practice Pharmacist

On page 10, in the title of Section 7, a “d” was added to “Advance” to read “Advanced” for consistency with BPC 4016.5. The Board determined this change was necessary to ensure the reference of advanced practice pharmacist is consistent with authorizing statute.

On page 10, section 7.1 deleted and relocated to section 6.8. With the removal of section 7.1, conforming renumbering is updated to reflect the following:

- 7.2 is renumbered to 7.1; and
- 7.2.1 – 7.2.6 are renumbered to 7.1.1 – 7.1.6.

Additionally, the extra set of three check boxes, previously established for the stricken 7.1 have been deleted.

On Page 10, renumbered section 7.1, former section 7.2, the word “advance” was changed to “advanced” twice for grammatical clarity. The Board determined this change was necessary to ensure the reference of advanced practice pharmacist is consistent with statute.

On Page 10, renumbered section 7.1, former section 7.2, the words “recognition by” were changed to “license from” to accurately reflect that the advanced practice pharmacist is a license issued from the Board and not an acknowledgement or recognition by the Board. The Board determined this change was necessary to ensure the self-assessment forms clearly reference the license issued by the board consistent with statute.

Change made to Section 8 – Duties of an Intern Pharmacist

On page 11, in section 8.1, the following modifications were made to adjust the grammar of the sentence to match the changes made to reflect that the PIC is responsible for conducting the assessment.

- In the first sentence of 8.1, the word “may” has been deleted; an “s” was added to the word “perform”; and the word “all” has been deleted.
- In the second sentence, the word “A” has been deleted; the word “The” has been added; the word “may” has been deleted; an “s” was added to “supervise”; and the words “no more than” have been added before “two”.

On page 11, section 8.3 was modified to add “, when applicable.” to specify that the intern hours affidavits are not always required. As a result of legislation in SB 590 (Stone, Chapter 147, Statutes of 2015), intern hour affidavits are not required for those who graduated from a United States pharmacy school after January 1, 2016. The Board determined this change is necessary to reflect statutory changes. Further, the statutory references of subdivisions (b), (c), and (d) of BPC 4209 were updated to include the applicable subdivisions of the statute.

Changes made to Section 9 – Duties of a Pharmacy Technician

On page 11, section 9.1 was modified to remove “Registered” and capitalize the “P” in “pharmacy technician” to clarify that pharmacy technicians are not registered but licensed with the Board pursuant to BPC 4202. The words “are performing” was deleted and replaced with “only perform” to clearly state that pharmacy technicians are limited to performing the specific tasks listed. These changes are consistent with underlying statute in BPC section 4115.

On page 11, section 9.3 was modified to change “her self” to “herself” for grammatical clarity.

Changes made to Section 11 – Consultation/Patient Profile/Review of Drug Therapy

On page 12, section 11.1 BPC 4052(a)(7) was deleted and replaced with BPC 4052(a)(8) to correct the underlying statutory reference. BPC 4052(a)(8) refers to consultation, training and education to patients about drug therapy. A duplicate colon was removed for clarity as there was no grammatical purpose. The Board determined these changes were necessary to provide clarity to the reader.

On page 12, subsection 11.1.3 was modified to delete the word “and” after the semicolon because an additional subsection 11.1.5 was added. This change was made for grammatical clarity.

On page 12, subsection 11.1.4 was modified to delete the period, add a semicolon, and add the word “and” because an additional subsection 11.1.5 has been added. This change was made to alert the reader of an additional subsection after 11.1.4. The Board determined this was necessary for grammatical clarity.

On page 12, section 11.1.5 was added and reads “all of these above, unless a patient or patient’s agent declines the consultation directly to the pharmacist.” This is added for consistency with BPC 4052 and CCR 1707.2 to ensure pharmacists comply with their duty to consult. Further, this section specifies that the consultation is not required if the patient, or patient’s agent, declines the consultation directly to the pharmacist as required in the referenced regulation. The Board determined this was necessary to add to specify the circumstances where a pharmacist is not required to provide a consultation.

Change made to Section 12 – Prescription Requirements

On page 13, section 12.10 was added and reads “All controlled substance prescriptions that are e-prescribed conform to provisions of federal law. (21 CFR 1306.08, 1306.11, 1311.100).” This addition was necessary to clearly state the requirement that all controlled substance e-prescriptions must meet the provisions of federal law referenced. The addition of this element in the self-assessment is designed to make sure the licensee is aware of the requirements in the particular provisions of the federal law referenced, and to compel the licensee to consider the pharmacy’s compliance with such provision. The Board determined this was necessary to ensure PICs are adhering to federal pharmacy laws.

Changes made to Section 13 – Prescription Labeling, Furnishing and Dispensing

On page 14, sections 13.3 – 13.5 were removed as the regulations referenced were amended and as such these sections are inconsistent with current regulations. The amended regulation requires specific wording in a specific format, as such the requirements listed in the self-assessment form are no longer relevant to current law in CCR 1707.5. The Board determined these items must be removed to reflect the changes made to the referenced regulation section that became effective April 2015 specific to patient-centered prescription labels.

With the above removal and addition of items contained within this section, this section is renumbered in the following manner:

- 13.6 – 13.13 are renumbered to 13.3 – 13.10;
- 13.11 is added;
- 13.14 – 13.16 are renumbered to 13.13 – 13.14;
- 13.15 is added;
- 13.17 is renumbered to 13.16;
- 13.17.1.1 – 13.17.1.5 are renumbered to 13.16.1.1 – 13.16.5; and
- 13.18 is renumbered to 13.17.

On page 14, renumbered section 13.3, former section 13.6, was amended in the following manner to clearly state that the effective expiration date of a drug must be accurately identified on the prescription label. Previously the requirement stated that this information was required on only when required on the manufacturer's label. The board determined that these changes were necessary to reflect changes to the law made by SB 493 (Hernandez, Chapter 469, Statutes of 2013) within BPC 4076.

- In the renumbered section 13.3, former section 13.6, the word "The" was added; the word "Expiration" was changed to "expiration" as an article "The" was added to the beginning of the sentence; the "s" was removed from the word "dates"; the word "a" was added; the word "drugs'" was deleted and replaced with the word "drug's"; the words "effectiveness is accurately identified on the label" were added and the words "are consistent with those of the manufacturer if the information is required on the original manufacture's label." were deleted.

On page 14, renumbered section 13.6, former section 13.9, was amended to add "or as otherwise allowed for those filled by a pharmacy technician trainee" to the end of the section to clarify that the prescriptions filled by a technician trainee must also be checked by the pharmacist. Including this requirement in this form is necessary to ensure the protection of the consumer. Further, the section is amended to clarify that recording the initials is required on prescriptions filled by a pharmacy technician trainee as well as pharmacy technicians. The references to the underlying statutory BPC 4115.5 provision regarding technician trainees was added for consistency with the rest of the self-assessment form.

On page 15, new section 13.11 was amended and reads "Medication guides are provided on required medications. (21 CFR, Part 208, Section 208.24[e])." The addition of this element in the self-assessment form is designed to make sure the licensee is aware of the requirements in the particular provisions of the federal law referenced, and to compel the licensee to consider the pharmacy's compliance with such provision. The Board determined this was necessary to ensure PICs are adhering to federal pharmacy laws and that patients receive information deemed necessary by the federal government.

On page 15, renumbered section 13.14, former section 13.16 was amended to include the specific subsection of the relevant Health and Safety code referenced for ease of use to the reader. Including statutory references in the self-assessment form provides an easy reference for the user regarding the relevant sections of pharmacy law.

On page 15, new section 13.15 was relocated from section 14.5 and amended to read "Refills for Schedule III and IV controlled substance prescriptions are limited to a maximum of 5 times and in an amount, for all refills of that prescription taken together, not exceeding a 120-day supply. (H&SC 11200[b])". The language was amended for consistency with HSC 11200(b), which was amended 2014. This requirement regarding the furnishing of controlled substances is more appropriately placed in Section 13 of the self-assessment form, which is specific to prescription labeling, furnishing and dispensing and not limited to refills only. The Board determined specifying the subsection is necessary to correctly reference the underlying statute.

On page 15, renumbered section 13.16, former section 13.17, was amended and reformatted to ensure that the PIC assesses each exception. Listing each element independently requires the PIC to assess each requirement separately and, if needed, correct only that specific area. Additionally, former section 13.17 was amended to add a reference BPC 4064.5, which was amended by Senate Bill 999 (Pavley, Chapter 499, Statutes of 2016) and authorizes a pharmacist to dispense up to a 12-month supply at one time. Finally, self-administered hormonal contraception was added to the reference. In 2014, Pharmacists received authorization to furnish self-administered hormonal contraceptives via BPC 4052.3.

On page 16, renumbered section 13.17, former section 13.18, was amended to add a reference to CCR 1744, which addresses drug warnings label requirements as identified in section 13.17. The Board determined this was necessary for consistency with the rest of the self-assessment form and to ensure the accurate regulatory reference was available for the reader's reference.

Change made to Section 14 – Refill Authorization

On page 16, section 14.5 was moved to new section 13.15 as explained above.

Changes made to Section 16 – Erroneous or Uncertain Prescriptions/Corresponding Responsibility for Filling Controlled Substance Prescriptions

On page 18, section 16.3 was amended to include the specific Health and Safety Code section 11153, which addresses the corresponding responsibility of pharmacists to evaluate a prescription for a legitimate medical purpose. The Board determined

specifying the code section was necessary and to ensure the accurate regulatory reference was available for the reader's reference.

On page 18, section 16.4 was deleted for ease of reading as it is duplicated in section 12.7. The Board determined this duplication removal was necessary to provide clarity to the reader.

With the removal of the section, section 16.5 is renumbered to 16.4.

On page 18, section 16.6 was deleted for clarity as it is duplicated in section 6.4. The Board determined this removal was necessary to provide clarity to the reader.

Changes made to Section 19 – Record Keeping Requirements

On page 19, section 19.1 was amended in the following manner:

- The word "A" was deleted and replaced with "All"; "biennial" was deleted to specify that the completion of the self-assessment is not "A" single event but it may be required with other events such as a change in PIC as identified in CCR section 1715. An extraneous space between "self -assessment" was removed for grammatical clarity. The letter "s" was added to "self-assessment" and "is" was changed to "are" for grammatical clarity to match preceding amendments to this section.

The Board found these changes were necessary to be consistent with underlying regulations regarding record keeping.

On page 20, section 19.3.5 "30 or fewer" was deleted as this limit was removed from BPC section 4145.5 effective January 1, 2015 in Assembly Bill 1743 (Ting, Chapter 331, Statutes of 2014). The Board determined this change was necessary to ensure that the requirements stated in the self-assessment form are consistent with statute.

On page 20, section 19.4 "or hypodermic needle and exchange program" was deleted as the board does not have jurisdiction over hypodermic needle exchange programs that occur outside of a pharmacy. This change is made as a pharmacist who is completing the assessment would not have authority over a hypodermic needle and exchange program. These programs are usually operated under the authority of the Department of Public Health. The Board determined this change was necessary to clarify that when a pharmacy issues the needles without a prescription, there is a requirement for consultation; a pharmacy need not be operating a hypodermic needle exchange program in order to issue needles without a prescription and therefore the language is removed.

On page 21, section 19.5 was amended to add the following:

“Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location:
_____.”

This was added to clearly state that the waiver approval and location of records is required by CCR section 1707 and to provide a space where this information may be recorded, which will alert the PIC to whether a waiver does or does not exist for the pharmacy. The Board determined it was necessary to increase the PIC’s awareness of the record keeping requirements to increase compliance. If records are being stored off-site and the pharmacy does not have a waiver in place, the PIC can take steps correct the non-compliance. Having the PIC record this information during the self-assessment is necessary to ensure they are aware and involved in the protection of the public’s personal information.

On page 21, section 19.6 was amended in the following manner:

- delete “dispenses” and add “furnishes an”,
- delete “a prehospital emergency medical care person or lay rescuer” and replace with “an authorized entity”,
- add a reference to BPC 4119.4

These amendments are made to make this section consistent with statute in BPC 4119.4 which became law on January 1, 2017(Assembly Bill 1386 (Low, Chapter 374, Statutes of 2016)). The Board determined this change is necessary for consistency with the new statute as the law now allows auto-injectors to be provided without a prescription from a prescriber, and that this furnishing, as identified in the statute, shall only be to authorized entities. Previously, auto-injectors could only be dispensed with a valid prescription. BPC 4119.4 allows for auto-injectors to be furnished by pharmacists to specific entities without a valid prescription.

On page 21, section 19.6.1 was amended to add an “n” to the introductory “A” to create the word “An”, and a period punctuation was added at the end of the sentence after “dispensed” for grammatical clarity. “physician/surgeon” is deleted; and replaced with “authorized healthcare provider” to provide clarity that the person who may provide a written order shall be only the authorized healthcare provider and not only a physician or surgeon as previously limited by BPC 4119.3. Further, this section was amended to add the new reference to statute of the Business and Professions Code “, 4119.4[a][2]”. The Board determined these changes are necessary to highlight the new law established in BPC 4119.4 by Assembly Bill 1386 (Low, Chapter 374, Statutes of 2016).Previously, auto-injectors could only be dispensed with a valid prescription. BPC 4119.4 allows for auto-injectors to be furnished by pharmacists to specific entities without a valid prescription.

On page 21, section 19.6.2 was amended to add a reference to BPC 4119.4[b] to clearly state the statute on which this requirement of the self-assessment form is based and to be consistent with the rest of the self-assessment form.

On page 21, section 19.6.3 was amended to add a reference to BPC 4119.4[c] to clearly state the statute on which the requirement for manufacturer provided materials to be provided with furnished epinephrine auto-injectors is based and to be consistent with the rest of the self-assessment form.

Change to Section 20 – DEA Controlled Substances Inventory

On page 21, section 20.2 is amended to add "See also Section 21", as section 21 has been added to the self-assessment form and details new requirements for inventory reconciliation of controlled substances in California pharmacies. The Board determined this was necessary to notify the user that more information related to this topic may be found in section 21 and performing a self-assessment of all controlled substance inventory reconciliation at once may help streamline the self-assessment process for the PIC.

On page 21, section 20.3 "Is" is deleted and "All completed inventories are" is added to clarify the regulatory requirement that every part of the inventories is required and not just certain inventories as specified in CCR section 1718. The Board determined this change was necessary to ensure that every inventory completed for the pharmacy is available for inspection.

On page 22, section 20.11 was amended to remove a reference citing the Prescription Drug Marketing Act of 1987 which was replaced by a reference to the Drug Supply Chain Security Act for alignment with current federal law. The Board determined this change was necessary so the accurate federal laws were available for the reader's reference.

Addition of Section 21 - Inventory Reconciliation Report of Controlled Substances

On pages 23-24, Section 21 – Inventory Reconciliation Report of Controlled Substances is added. This section is added to include the provisions of recently promulgated regulations regarding inventory reconciliation reporting of controlled substances effective April 1, 2018. Additionally, regulatory references were added throughout this section to clearly state the section of regulation upon which each requirement is based. The Board determined that this additional section is necessary so that the new requirements are contained in the self-assessment form which will ensure that the PIC assesses the pharmacy for compliance with these new regulations, and allows for a streamlined, efficient, and effective inspection process as inspectors can monitor the development of a correction action or action plan if needed.

The added sections read as follows:

- On page 23, Section 21.1 was added to read “The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])”.
- On page 23, Section 21.2. was added to read “The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])”.
- On page 23, Section 21.3. was added to read “21.3. A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This report requires: (CCR 1715.65 [c])”
- Section 21.3.1 was added to read. “A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])”
- Section 21.3.2 was added to read. “A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])”
- Section 21.3.3 was added to read. “A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])”
- Section 21.3.4 was added to read. “All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])”
- Section 21.3.5 was added to read. “Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])”

On page 23, Section 21.4. was added to read “The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])”

On page 23-24, Section 21.5. was added to read “The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A

countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])".

On page 24, Section 21.6. was added to read "A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65(c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65(c). (CCR 1715.65 [f])". The Board determined this addition was necessary so that a PIC is aware of the reporting requirement and timeline for the inventory reconciliation upon being associated to the pharmacy as the PIC.

These added sections mirror existing regulation exactly and are being added to the form as the regulation was established after the previous 2014 revision of the form.

Changes to Renumbered Sections 22 – 25, Former Sections 21 – 24

With the addition of Section 21, Sections 21 – 24 are renumbered to Sections 22-25.

Changes to Renumbered Section 22, Former Section 21 – Oral/Electronic Transmission and Partial Fill of Schedule II Controlled Substance Prescriptions

On page 24, the title of renumbered section 22, former section 21, was amended to remove the word "Fractionation" and replace it with the words "Partial Fill" for clarity to the reader as the word "fractionation" is an antiquated term of industry and "partial fill" is more widely used. The Board determined this addition was necessary for ease of reading.

On page 24, renumbered section 22.1, former section 21.1, was amended to add "only" to provide clarity and ensure that Schedule II controlled substance medications are dispensed exclusively after receipt of an original prescription is received. The Board determined this change was necessary to specify that other forms of prescription may not be accepted for Schedule II controlled substances.

On page 25, section 22.5 was added to read "The pharmacist maintains records of each partial filling (filled within 30 days from the date of prescription issuance) of an original prescription for a Schedule II controlled substance when a partial fill is requested by the patient or practitioner. (21 USC 829[f])" to clearly state the new records retention requirements created under the federal Controlled Substances Act, 21 USC 829[f]." The Board determined this change was necessary for consistency with new federal law requiring records for partial fills of Schedule II controlled substances.

With the addition of this new section, sections 21.5 – 21.12 are renumbered to sections 22.6 – 22.13.

Changes to Renumbered Section 23, Former Section 22 – Automated Dispensing/Delivery Devices

On page 26, renumbered section 23.2, former 22.2, is amended to delete “dispensing unit” and replace with “drug delivery system” for clarity as “drug delivery system” is consistent with pharmacy law, specifically, BPC 4017.3. The Board determined this is necessary for consistency with the Board’s statute regarding terminology for ADDS.

Further, this section is amended to add references to 21 CFR Part 201.17, HSC 111355. Reference to 21 CFR Part 201.17 is added to alert the reader to the location where the requirement exists regarding the location of the expiration date on the container and/or package. Reference to HSC 111355 is added to alert the reader to the section outlining the requirement for a drug being deemed misbranded. The Board determined these references were necessary to include in the self-assessment form to provide clarity regarding where the requirements from this section of the form can be found and to make them easily accessible for the user.

On page 27, renumbered section 23.4.1, former section 22.4.1, is amended to add the words “except when statute authorizes exceptions” and the code section “, 1261.6[g]. This is added to alert the PIC that narrow exceptions exist in statute to allow other personnel to refill the machine in certain circumstances. Further, HSC 1261.6[g] was added as a reference should the PIC wish to review the exceptions provided in the statute.

Changes to Renumbered Section 25, Former Section 24 – Refill Pharmacy

On page 27, renumbered section 25.3, former section 24.3, is amended with a non-substantive change to correct the redirected section number from “23” to “26.”

Changes to Renumbered Section 26, Formerly an Unnumbered Section – Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10)

On page 28, the previously unnumbered section title entitled Standards of Service for Providers of Blood Clotting Products for Home Use (HSC 125286.10) is numbered 26. The section title was an erroneous omission in numbering of the previous version of the form. The Board determined this addition is necessary for ease of use for the reader.

Changes to Renumbered Section 27, Former Section 26 – Policies and Procedures

On page 29, former section 26.1.1 is deleted for consistency with pharmacy law as pharmacists are now permitted to administer immunizations without a prescriber’s order

of state protocol pursuant to BPC section 4052.8 and 16 CCR section 1746.4. This change of statute was made in Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013). The Board determined this change is necessary to ensure the correct laws are reflected in the self-assessment form.

With the removal of this provision, former sections 26.1.2 – 26.1.12. are renumbered 27.1.1 – 27.1.11.

On page 30, renumbered section 27.1.9, former section 26.1.10 is amended in the following manner: The phrase “Preventing the dispensing of a prescription drug that is contrary to the law;” is deleted and replaced with “A policy to establish how a patient will receive a medication when a pharmacist has a conscientious objection;” the original phrase misstated the cited statutory reference, BPC section 733. BPC 733 requires that a pharmacist take additional actions to assist a patient with receiving their medication should the pharmacist object to filling the prescription. On the previous form, the requirement only stated that the pharmacist needed to prevent filling a prescription and not that additional steps needed to be taken. Adding this information will allow the PIC to access their practice and ensure they have a plan in the event a prescription will not be filled. The Board determined this change is necessary to ensure the applicable laws are precisely stated so that the PIC may apply them correctly during the self-assessment.

On page 31, renumbered section 27.4, former section 26.4, is amended for consistency and clarity to add the corresponding regulation reference to CCR 1746.3, which establishes the protocol for furnishing naloxone hydrochloride. The Board determined this change is necessary to ensure the correct laws are referenced in the self-assessment.

On page 31, sections 27.5 and 27.6 were added to address the furnishing of nicotine replacement products and hormonal contraception provided in SB 493 and 16 CCR sections 1746.1 and 1746.2. These new form sections read as follows:

> 27.5 – “Furnishes nicotine replacement products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.9, CCR 1746.2).”
>
> 27.6 – “Furnishes hormonal contraception products in accordance with standardized procedures or protocols developed and approved by both the Board of Pharmacy and the Medical Board of California. (BPC 4052.3, CCR 1746.1).”

The Board determined these additions are necessary to add these new statutory requirements and to promote awareness and compliance among the regulated public.

Change to Renumbered Section 28, Former Section 27 - Compounding

On page 32, renumbered section 28.1, former section 27.1 is amended to correct the reference from CCR section 1735.2[j], to CCR section 1735.2[k] as the self-assessment form for compounding is incorporated be refence in 1735.2[k] and not [j]. The Board determined this change is necessary to ensure the correct references to statute are included in the self-assessment form. Ensuring accurate references allows the user to easily find applicable laws which will aid in understanding of and compliance with the rule.

Changes to Renumbered Section 31, Former Section 30 – Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program

On pages 34-35, the words “Pharmacies That Operate a Voluntary County-Approved Drug Repository and Distribution Program” were added before the three headings in the section entitled “Drug and Maintenance of Drug Stock”; “Transferring Donated Drugs From One Participating Entity to Another”; and “Dispensing to Eligible Patients” to provide clarity to the reader that the what follows applies only to pharmacies that donate drugs to a voluntary county-approved drug repository and distribution program. The Board determined this change is necessary for ease of use. This section only applies to those approved to operate a drug repository and distribution program pursuant to HSC sections 150201 and 150202.

Changes to Pharmacist-in-Charge Certification

On page 36, after the word “corrected” the following is added “by_____” to provide for clarity and allow a space where the PIC could add the date for which the deficiencies will be corrected. The Board determined this is necessary to ensure that there would be further action by the PIC to correct the deficiencies. This is being added for the PIC to provide an expected timeline for resolution of the noncompliance issues. Board staff regularly inspect pharmacies for compliance with laws and regulations; having the expected timeline for resolution will allow for a more meaningful inspection. The inspector and PIC can quickly identify possible noncompliance areas based on the resolution timeline.

Changes to Acknowledgement by Hospital Administrator

On page 36, after the word “self-assessment” in the second sentence, the words “in the timeframe identified in the PIC Certification above” were added to provide clarity to the PIC that any corrections must be made within the timeframe provided in the certification. Adding this statement to the section that the pharmacy owner must sign will increase awareness of this requirement to the highest level and ensure compliance. The Board determined this is necessary in order to ensure that the PIC would be given support by

the pharmacy owner to correct the deficiencies. Additionally, it provides an additional layer of accountability for the PIC to ensure areas of noncompliance are addressed timely.

The words “Pharmacy Owner or Hospital Administrator” are also added to the acknowledgment signature line, to clarify who may sign the acknowledgment. This addition is also stylistically consistent with the preceding acknowledgment from the pharmacist-in-charge.

Changes to Legal References

On page 36, the list of legal references has been deleted and a new list of legal references has been added as the last page of the document.

The list of legal references has been updated to maintain consistency with the cited references appearing within the self-assessment form. Outdated references have been removed and current references added. To the extent that the regulation duplicates the information from statute, such duplication is to ensure that the regulated public can readily and easily find the requirements in one place as an easy self-check, rather than having to review multiple sources.

Additionally, the contact information for various state, federal, and private agencies has been removed as it may not be the most current information at the time that the PIC completes the self-assessment form and the most accurate information is available on the Internet.

Changes to Form 17M-14 Incorporated by Reference

Important Note: The current self-assessment form includes underline in two areas detailed below. In the proposed versions of the self-assessment forms, the currently underlined text has been double underlined for added emphasis to the reader. A legend has been added to aid the reader.

- “The assessment shall be performed before July 1 of every odd-numbered year:”
- “Each self-assessment must be kept on file in the pharmacy for three years after it is performed.

In both cases, the text is underlined and double underlined for emphasis and in neither occurrence is the underline intended to convey a change to the form.

The Board proposes all of the changes set forth below be made within Form 17M-14 (Rev. 10/16) “Hospital Pharmacy Self-Assessment.”

On every page of Form 17M-14, the footer at the bottom left corner which reads “17M-14 (Rev. 10/14)” has been amended to read “17M-14 (Rev. 07/18).” to reflect the updated revision date (“17M-14 (Rev. 07/18)”). Conforming changes were made throughout.

Throughout the form sections were renumbered as needed to address additions or deletions within the document. Additionally, “Yes, No, N/A” is removed or added as needed above the check boxes to ensure the boxes are identified at the top of each page and beginning of each section. To ensure clarity and consistency of abbreviations, BPC is now used throughout to reference Business and Professions Codes, HSC is now used throughout to reference Health and Safety Codes and CCR is now used throughout to reference California Code of Regulations. These abbreviations replace other variations (e.g., B&PC is being replaced with BPC). Conforming changes were made throughout the document.

Throughout the form, the law or regulation that forms the basis for the question has been added as a reference following the question. This will foster compliance with the laws and regulations, by allowing the PIC and pharmacy to readily refer to the source for each requirement while conducting the self-assessment, but also allowing the self-assessment form to be used as a reference for where to look for further information. In addition, the completed self-assessment will assist a board employee to better direct their attention and resources when performing an inspection.

On page 1, the second paragraph is amended in the following manner: a period punctuation is added after “entirety” and replaced “and” with “It” as it is now the beginning of a second sentence. These changes were made to provide clarity to emphasize the self-assessment must be completed in its entirety. The word “It” is added to refer to the self-assessment and the “and” is removed so there could be two sentences. The phrase “and retained“ is deleted and replaced with “initialed, signed, and readily available.” The self-assessment will have little value if it is not initialed and signed by the person completing the assessment. Without knowing who completed the assessment, when the form is reviewed in the future, another pharmacist or a Board Inspector, will be unable to identify who completed it and who to speak to regarding noncompliance issues. A third sentence is added and reads “Signatures and initials shall be an original handwritten signature or initial on the self-assessment form. This is added to provide clarity that the pharmacists-in-charge are required to physically sign, initial and date on the self-assessment paper forms. The board determined this is necessary to ensure the PIC will sign, initial and date the self-assessment forms. This requirement may prevent people who are not the PIC (e.g., corporate executives/representatives, office managers, pharmacy technicians, etc.) from completing the form on behalf of the PIC.

On page 1, under “Notes:” the name of the self-assessment is changed to replace “Hospital Outpatient Pharmacy Self-Assessment” to “Community Pharmacy Self-Assessment/Hospital Outpatient Pharmacy Self-Assessment” and the revision date is revised from “(17M-13 Rev. 10/14)” to read “(17M-13 Rev. 07/18)” to provide clarity to the reader about the requirement to perform an additional self-assessment if a pharmacy is dispensing prescriptions for outpatient use. This updated is necessary to correctly reference the proper name of self-assessment form 17M-13. The Board determined clarification is necessary to alert the user to this additional requirement. Without the added forward slash, the title of the self-assessment form reads as applying to one pharmacy type. The addition of the forward slash delineates two settings for which the self-assessment form may be used. These changes are necessary to update the revision date of the forms to reflect the current versions and are necessary to confirm the board’s regulated public is clear on the version of the form that must be completed under the specified conditions. In the same section an extraneous closed parenthesis is deleted at the end of the paragraph for grammatical clarity.

In several places on page 1, the term “Permit” is changed to “License” as it is more accurate to refer to these items as licenses and not permits. BPC section 4032 defines “license” to include any license, permit, registration, certificate, or exemption issued by the board. Replacing the term allows the Board to achieve consistency with statute and clarify to the regulated public. Conforming changes were made throughout the document.

On page 1, after “Hours:”, a period is added after “Sat” to provide clarity to the reader that “Sat.” is an abbreviation for Saturday. The Board determined this is necessary to avoid confusion on what “Sat” without a period might be referring.

On page 2, all references to “APP” have been amended to “APH” for clarity to the reader. During computer programming for the Advanced Practice Pharmacist license, it was discovered that the Board is unable to use the APP suffix and a change was made to APH. This change is necessary to create consistency with the license prefix issued to an advanced practice pharmacist.

Change made to Section 1 - Pharmacy

On page 4, section 1.12 is amended to delete “(If yes, complete section 27 – “Compounding”)” and replace with “(If yes, complete Compounding Self-Assessment Form 17M-39, Rev. 10/12)” to provide clarity that if the pharmacy compounds sterile drugs, the Compounding Self-Assessment Form is required. The Board determined this change is necessary because the previous section for Compounding is deleted and enhanced by the Compounding Self-Assessment. This amendment is necessary to alert the PIC completing the self-assessment of this separate form requirement.

Changes made to Section 3 – Delivery of Drugs

On page 5, new sections 3.4, 3.5, and 3.6 have been added to ensure compliance with the requirements created under the federal Drug Supply Chain Security Act (DSCSA) that was enacted by Congress in November 2013 and governs the traceability of drug products through the drug distribution supply chain.

On page 5, section 3.4 is added to read, "Prior to, or at the time of, accepting ownership of a product included in the DSCSA from an authorized trading partner, the pharmacy is provided transaction history, transaction information, and a transaction statement. (21 USC 360eee-1 [d][1][A][i])" to clearly state what information must be provided by the supplier upon transfer of ownership of product in accordance with federal laws. This addition is necessary to ensure the Board's regulated public is aware of and compliant with the federal requirements established in the DSCSA.

On page 5, section 3.5 is added to read, "Prior to, or at the time of, each transaction in which the pharmacy transfers ownership of a product included in the Drug Supply Chain Security Act to an authorized trading partner, the subsequent owner is provided transaction history, transaction information, and a transaction statement for the product. This requirement does not apply to sales by a pharmacy to another pharmacy to fulfill a specific patient need. (21 USC 360eee- 1[d][1][A][ii])" for consistency with federal laws regarding what information must be provided by the supplier upon transfer of ownership of product except when a pharmacy is selling to another pharmacy for a specific patient need. This addition is necessary to ensure the Board's regulated public is compliant with the federal requirements established in the DSCSA.

On page 5, section 3.6 is added to read, "The pharmacy captures transaction information (including lot level information, if provided), transaction history, and transaction statements, as necessary to investigate a suspect product, and maintains such information, history, and statements for not less than 6 years after the transaction. (21 USC 360eee-1[d][1][A][iii])" for consistency with federal laws regarding data to be captured at the point of sale. This addition is necessary to ensure the Board's regulated public is aware of the need to comply with the federal requirements regarding data gathering and retention, established in the DSCSA.

Changes made to Section 4 – Drug Stock

On page 6, section 4.1, a reference to Health and Safety Section 111335 is added for consistency with state statute for misbranded drugs and devices. Additionally, 21 USC sections 331, 351, and 352 were added to provide a reference to federal law for adulterated or misbranded drugs and devices in interstate commerce. The Board found this addition is necessary to provide the correct law citations for the reader's reference.

Change made to Section 6 – Pharmacist-in-Charge

On page 7, section 6.1 is amended to modify an incorrect reference from CCR "709" to "1709." The Board determined this change is necessary to ensure the correct regulation citation was referenced on the self-assessment form.

On page 8, section 6.5 has been removed, as, pursuant to CCR section 1709.1(d), a PIC is not permitted to concurrently serve as a PIC of a pharmacy and a designated representative-in-charge of a wholesaler or veterinary food-animal retailer. The current phrasing makes appear as the information, whether or not a PIC is serving as both, is requested for reference, this implies that such an arrangement would be legally permissible and it is not. The Board determined that this phrasing was misleading and therefore it is removed.

Changes made to Section 7 – Duties of a Pharmacist

On page 8, section 7.1 has been amended to clarify the requirements for assessing duties that may only be performed by a pharmacist. This section is reformatted into a bulleted list instead of a long paragraph to allow for ease of use as well as to ensure the PIC independently assesses each criterion. The introductory phrase "Within the scope of inpatient pharmacy service" is replaced by "Only a pharmacist" as the entire form references hospital pharmacies. Further, the specific underlying statutory provision that supports each of the bulleted items has been added to provide a cross reference for the PIC. By requiring the identification if a pharmacy performs these functions, it emphasizes that these duties are to be done only by a pharmacist and, if the pharmacy does do them, it provides references to the laws and regulations to make it more likely that, when done, each is more likely to be done consistent with law. It will also assist a board employee by better directing their attention and resources when performing an inspection. BPC 4019, 4051, CCR 1717(c), and 1793.7 have been added as references as they define the duties of a pharmacist.

On page 9, section 7.2 has been amended to specify the duties only a pharmacist may perform related to ordering/performing drug-therapy assessments. This section is reformatted into a bulleted list instead of a long paragraph to allow for ease of use as well as to ensure the PIC independently assesses each criterion. Further, the specific underlying statutory provision that supports each of the bulleted items has been added to provide a cross reference for the PIC. BPC 4027, 4051, and 4052 have been added as references as they define the duties of a pharmacist in a health care facility.

On page 9, section 7.3 is added and reads "The pharmacist who is authorized to issue an order to initiate or adjust a controlled substance therapy is personally registered with the federal Drug Enforcement Administration (BPC 4052[b])." This section has been

relocated to section 7.3 from previous section 8.1 and is deleted in section 8.1 for clarity as the authorization created in the statute is not limited to only an advanced practice pharmacist. The Board determined this is necessary to be clear to the reader about who is authorized to perform this function.

Changes made to Section 8 – Duties of an Advanced Practice Pharmacist

On page 10, section 8.1 is deleted and relocated to section 7.3 to remove it from this section that is specific to advanced practice pharmacists, the authorization created in the statute is not limited to only an advanced practice pharmacist. The Board determined this is necessary to provide this clarity to the PIC so that they may perform an accurate assessment.

With the removal of section 8.1, 8.2.1 – 8.2.6 are renumbered to sections 8.1 and subsections 8.1.1 – 8.1.6.

On Page 10, renumbered section 8.1, former section 8.2, the word “advance” is changed to “advanced” twice to provide clarity to the reader that the section pertains to advanced practice pharmacists and not another position. The Board determined this change is necessary to ensure the reference of advanced practice pharmacist is consistent with statute, specifically, BPC 4016.5.

Further, former section 8.2, the words “recognition by” is changed to “license from” to provide clarity to the reader that the advanced practice pharmacist is a license issued by the Board and not an acknowledgement or recognition. The Board determined this change is necessary to ensure the self-assessment forms accurately reference that this is a license issued by the board, consistent with statute.

Changes made to Section 9 – Duties of an Intern Pharmacist

On page 10, section 9.1.2 was amended to add a terminal parenthesis after the statute reference BPC4119.7[c].

On page 11, section 9.4 is modified to add “, when applicable.” for consistency with statute effective January 1, 2016. As a result of legislation in SB 590 (Stone, Chapter 147, Statutes of 2015), intern hour affidavits are not required for those who graduated from a United States pharmacy school after January 1, 2016. The Board determined this change is necessary to reflect statutory changes. Further, the statutory references of subdivisions (b), (c), and (d) of BPC 4209 were updated to include the applicable subdivisions of the statute.

Changes made to Section 10 – Duties of a Pharmacy Technician

On page 11, section 10.1, an additional regulation section is added to include the reference to CCR 1793.7. The Board determined this addition is necessary for consistency with the rest of the self-assessment form and to ensure all citations are included for reference in the self-assessment form as CCR section 1793.7 specifies the duties a pharmacy technician may complete under the supervision of a pharmacist.

On page 11, sections 10.2 and 10.3 were modified in the following manner: previous section 10.2 is broken up into two different sections. Section 10.2 now reads "The ratio is not less than one pharmacist on duty for two technicians on duty. (BPC 4115[f], CCR 1793.7[f]),," which was previously reflected in section 10.3 and duplicated in previous section 10.6. Section 10.3 now reads "When prescriptions are dispensed to discharge patients with only one pharmacist, there is no more than one technician performing the tasks as defined in BPC 4115(a). The ratio of pharmacy technicians performing those tasks for additional pharmacists does not exceed 2:1. (BPC 4038, 4115[f], CCR 1793.7[f])" which is relocated from previous section 10.2. These sections were added and amended for clarity to the reader. These changes were necessary to require that the different scenarios where different ratios apply are assessed independently of one another.

With the addition of another section, sections 10.2 – 10.5 were renumbered to sections 10.3 – 10.6.

On page 11, renumbered section 10.5, former section 10.4, has been modified to change "her self" to "herself" for grammatical clarity.

On page 11, former section 10.6 was removed to eliminate duplicative text.

Change to Section 11 – Duties of Non-Licensed Personnel

On page 12, a non-substantive change was made to correct a typographical error in the abbreviations used to reference to Business and Professions Code. The letter "C" was added to "BPC".

Change to Section 14 – Labeling and Distribution

On page 14, section 14.1 is modified to remove "and parenteral admixtures" to provide clarity which medications must be properly labeled and included pursuant to BPC 4076(b), which is specific to unit dose medications and not parenteral admixtures. .

Additionally, the Board determined parenteral admixtures falls within the purview of the Compounding Self-Assessment (Form 17M-39, Rev. 2/12).

Further, subsection “[b]” to BPC 4076 is added and “CCR 1751.2” is removed as the rule upon which this section relies exists in statute. The Board determined this addition is necessary to ensure all references are correct in the self-assessment form as [b] clearly references the requirement and 1751.2 applies to compounding and not unit dose medications.

Change to Section 16 – Confidentiality of Chart Orders, Prescriptions and Patient Medical Information

On page 15, section 16.5 is added to read: “Records regarding dangerous drugs and dangerous devices stored off-site (only for pharmacies who have obtained a waiver from the Board of Pharmacy to store records off-site) are secure and retrievable within three business days. (BPC 4105, CCR 1707)”

Date Waiver Approved _____ Waiver Number _____

Address of offsite storage location:
_____.”

Further, section 16.6 is added to read: Records for non-controlled substances are maintained on the licensed premises for at least one year from the date of dispensing. Records for controlled substances are maintained on the licensed premises for at least two years from the date of dispensing.

These two sections have been added to clearly state the requirements of BPC 4105 and CCR 1707 which address where any records are stored off site be readily known and retrievable. Requiring the PIC to fill in the address ensures they are aware of the location of the records and makes the pharmacy site inspection process more meaningful by providing useful information to board staff. The Board determined it is necessary to add this to create a section devoted to the storage of records. The Board added a section on the form to allow the PIC a space to record the waiver approval and location of records. The Board determined it is necessary to increase the PIC’s awareness of the record keeping requirements to increase compliance and public safety through safe storage of records containing personal information. Additionally, if the PIC can take steps to correct if records are stored off-site; however, the facility does not have an approved waiver.

Changes to Section 18 – Record Keeping Requirements

On page 17, section 18.1 is amended with the following changes

- The word “A” is deleted and replaced with “All” and “biennial” is deleted to provide clarity that the completion of the self-assessment is not “A” single event but that it may be required with other events such as a new PIC.
- An extraneous space between “self -assessment” was removed for grammatical clarity.
- The letter “s” was added to “self-assessment” and “is” was changed to “are” twice for grammatical clarity to match preceding amendments to this section.

The Board found these changes were necessary to be consistent with underlying regulations regarding record keeping, specifically BPC 4105, which requires a licensed premises to maintain records for three years.

On page 17, section 18.2.9 is amended to remove duplicate parentheses for clarity to the reader.

On page 17, section 18.3, “Prescription Drug Marketing Act [PDMA] [Pub. L. 100-293, Apr. 11, 1988] 503” is deleted and replaced with “Drug Supply Chain Security Act (DSCSA)” to provide an accurate reference of the applicable federal law.

On page 17, section 18.4 was amended to remove a reference citing the “PDMA 503” and added “DSCSA” to provide an accurate reference of the applicable federal law. The Board determined this change is necessary for consistency with federal laws and regulations.

On page 17, section 18.6 is added to read: “18.6. All completed controlled substances inventories are available for inspection for three years. (CCR 1718)” to specify the existing regulatory requirement. (CCR 1718). The Board determined this change was necessary for consistency with applicable regulations. Further, this section is being added to ensure that the PIC is aware of the requirement to maintain completed controlled substance inventories.

With the addition of section 18.6, sections 18.6 – 18.12 are renumbered to sections 18.7 – 18.3.

On page 18, renumbered section 18.13, former section 18.12, is combined with 18.13 and 18.14 “Does” is deleted and replaced with “does” to provide clarity that the items are now one question. The Board determined this necessary because former sections 18.12 and 18.13 discussed the processes of labels and combining the sections is more efficient for the user.

Addition of Section 19. Inventory Reconciliation Report of Controlled Substances

On page 19, Section 19 – Inventory Reconciliation Report of Controlled Substances, is added. This also includes the addition of sections 19.1 – 19.8. This section is added to

include the provisions of recently promulgated regulations (CCR sections 1715.65) regarding inventory reconciliation reporting of controlled substances effective April 1, 2018. Additionally, regulatory references were added throughout this section to clearly state the section of regulation upon which each requirement is based. The Board determined that this additional section is necessary so that the new requirements are contained in the self-assessment form which will ensure that the PIC assesses the pharmacy for compliance with these new regulations, and allows for a streamlined, efficient, and effective inspection process as inspectors can monitor the development of a correction action or action plan if needed.

The added sections read as follows: The language mirrors the language of 1715.65(a) – (h), with minor changes. The changes consist of the removal of references to clinics and consulting pharmacist. Clinics would not complete the hospital self-assessment form as they are not a hospital. Additionally, a consulting pharmacist is specific to a clinics, as identified in BPC 4182.

On page 19, Section 19.1 was added to read “The pharmacy performs periodic inventory and inventory reconciliation functions to detect and prevent the loss of controlled substances. (CCR 1715.65 [a])”.

Section 19.2. was added to read “The pharmacist-in-charge of the pharmacy reviews all inventory and inventory reconciliation reports taken, and establishes and maintains secure methods to prevent losses of controlled drugs. Written policies and procedures are developed for performing the inventory reconciliation reports required by pharmacy law. (CCR 1715.65 [b])”

On page 19, Section 19.3. was added to read “A pharmacy compiles an inventory reconciliation report of all federal Schedule II controlled substances at least every three months. This report requires: (CCR 1715.65 [c])

- ☐ 19.3.1. A physical count, not an estimate, of all quantities of federal Schedule II controlled substances. The biennial inventory of controlled substances required by federal law may serve as one of the mandated inventories under this section in the year where the federal biennial inventory is performed, provided the biennial inventory was taken no more than three months from the last inventory required by this section; (CCR 1715.65[c][1])
- ☐ 19.3.2. A review of all acquisitions and dispositions of federal Schedule II controlled substances since the last inventory reconciliation report; (CCR 1715.65[c][2])

☐ 19.3.3. A comparison of the two above-mentioned items to determine if there are any variances; (CCR 1715.65[c][3])

☐ 19.3.4. All records used to compile each inventory reconciliation report shall be maintained in the pharmacy or clinic for at least three years in a readily retrievable form; and (CCR 1715.65[c][4])

☐ 19.3.5. Possible causes of overages shall be identified in writing and incorporated into the inventory reconciliation report. (CCR 1715.65[c][5])"

On page 19, Section 19.4. was added to read "The pharmacy reports in writing identified losses and known causes to the board within 30 days of discovery unless the cause of the loss is theft, diversion, or self-use in which case the report shall be made within 14 days of discovery. If the pharmacy is unable to identify the cause of the loss, further investigation is undertaken to identify the cause and actions necessary to prevent additional losses of controlled substances. (CCR 1715.65 [d])"

On page 19, Section 19.5. was added to read "The inventory reconciliation report is dated and signed by the individual(s) performing the inventory, and countersigned by the pharmacist-in-charge and be readily retrievable in the pharmacy for three years. A countersignature is not required if the pharmacist-in-charge personally completed the inventory reconciliation report. (CCR 1715.65 [e])" for consistency with the regulation about inventory reconciliation record keeping requirements. The Board determined this addition was necessary so that the PIC is aware of the reporting for the inventory reconciliation.

On page 19, Section 19.6. was added to read "A new pharmacist-in-charge of the pharmacy completes an inventory reconciliation report as identified in CCR 1715.65 (c) within 30 days of becoming pharmacist-in-charge. When possible, the outgoing pharmacist-in-charge also completes an inventory reconciliation report as required in CCR 1715.65 (c). (CCR 1715.65 [f])" for consistency with the regulation about inventory reconciliation requirements for new pharmacists-in-charge. The Board determined this addition was necessary so that a PIC is aware of the reporting for the inventory reconciliation upon being associated to the pharmacy as the PIC.

On page 19, Section 19.7 was added to read "A separate quarterly inventory reconciliation report shall be required for federal Schedule II controlled substances stored within the pharmacy and for each pharmacy satellite location. (CCR 1715.65 [g])" for consistency with the regulation about inventory reconciliation requirements for pharmacy satellite locations. The Board determined this addition was necessary so that a PIC is aware of the reporting for the satellite locations.

This section is added to specify the elements required in periodic inventory and reconciliation reports. The physical count and review of all acquisitions/dispositions of Schedule II drugs are required to conduct the comparison to ensure that the documented records of incoming/outgoing of Schedule II drugs matches the actual counts of Schedule II drugs. The records are required to be maintained for three years to allow for audits and to meet statutory record keeping requirements. The possible causes for overages must be documented in the report as part of the good faith effort of the pharmacist to account for all inventory received and dispensed. The Board determined this addition was necessary so that the PIC is aware of the periodic inventory and reconciliation requirements that must be completed by the pharmacy.

On page 20, Section 19.8 was added to read “The pharmacist-in-charge of an inpatient hospital pharmacy or of a pharmacy servicing onsite or offsite automated drug delivery systems shall ensure that:

- 19.8.1 All controlled substances added to an automated drug delivery system are accounted for;
- 19.8.2 Access to automated drug delivery systems is limited to authorized facility personnel;
- 19.8.3 An ongoing evaluation of discrepancies or unusual access associated with controlled substances is performed; and
- 19.8.4 Confirmed losses of controlled substances are reported to the board.”

This section delineates the requirements for the PIC when an inpatient hospital uses automated drug delivery systems. Specifically, all controlled substances must be accounted for and the authorized users are limited to authorized personnel to allow for control and tracking of controlled substances. The PIC is required to continually evaluate discrepancies and report losses to the board to allow for control and tracking of controlled substances. The Board determined this addition was necessary so that a PIC is aware of the reporting requirements for satellite locations.

Changes to Renumbered Sections 20 – 28, Former Sections 19 – 27

With the addition of Section 19, Sections 19 – 27 are renumbered to Sections 20 – 28.

Changes to Renumbered Section 21, Former Section 20 – Drug Supplies for Use in Medical Emergencies

On page 19, renumbered section 21.4 is amended to remove an erroneous space in the word “written” for grammatical clarity.

Changes to Renumbered Section 23, Former Section 22 – Emergency Room Dispensing

On page 22, renumbered section 23.5, former section 22.5 is amended to add “21” for the correct legal reference to 21 CFR 290.5. The Board determined this is necessary to ensure that all references are accurate.

On page 22, sections 23.8 and 23.9 are added to read as follows:

“23.8 – “The pharmacy provides patients with required Black Box Warning Information” (21 CFR 201.57[c].)

23.9 - Medication guides are provided on required medications. (21 CFR Part 208).”

This change is made to include a reference to federal regulations regarding black box warning and providing medication guides. When a PIC is aware of the requirement, they are more likely to comply with the law which leads to more patients receiving information about the prescriptions being taken from included Black Box Warning Information and medication guides being distributed with prescriptions. The Board determined this is necessary to ensure that the PIC is aware of specific federal requirements for emergency room dispensing of medication.

Changes to Renumbered Section 24, Former Section 23 – Discharge Medication/Consultation Services

On page 22, previous sections 23.4 and 23.5 have been removed for consistency with recent revisions to 1707.5, which requires 12 point font and removed the exemption. The Board determined this is necessary to ensure that every element in the form is a requirement in statute or regulations.

With the removal of these sections, sections 24.4 – 24.10 are renumbered to 23.6 – 23.12.

On page 23, renumbered section 24.9, former section 23.11, was updated to correct the legal reference by adding “15” in front of “USC” for accuracy. The Board determined this is necessary to ensure that the correct reference is available for the user.

On page 23, sections 24.11 and 24.12 have been added to alert the PIC to the requirements for materials to be distributed with prescriptions to consumers. When a PIC is aware of the requirement, the PIC is more likely to comply with the law which leads to more patients receiving information about the prescriptions being taken from included Black Box Warning Information and medication guides being distributed with prescriptions. The following has been added for consistency with federal regulations:

24.11 – The pharmacy provides patients with required Black Box Warning Information (21 CFR 201.57[c]).
24.12 - Medication guides are provided on required medications. (21 CFR Part 208)”

The Board determined this is necessary to ensure that the PIC is aware of specific federal requirements for discharge medication related to medication guides and warnings.

Changes to Renumbered Section 25, Former Section 24 – Central Filling of Patient Cassettes for Other Hospital Pharmacies

On page 23, renumbered section 25.2, former section 24.2, 23 is deleted and replaced with 26 to provide an accurate section number to re-direct the reader.

On page 23, renumbered section 25.3, former section 24.3, was amended to add a period at the end of the sentence for grammatical clarity.

On page 24, renumbered section 25.6, former section 24.6, was amended to add a non-substantive period at the end of the requirement before the citation and closed parentheses has been added at the end of the citation. These changes were made for clarity to the reader about where the sentence ends and the ending of the parentheses.

Changes to Renumbered Section 26, Former Section 25 – Centralized Hospital Packaging Pharmacy

On page 24, renumbered section 26.1, former section 25.1, was amended to read as follows “The pharmacy prepares medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals under common ownership and located within a 75-mile radius: (BPC 4128).” This section was amended to more closely align the language within the self-assessment form with the requirements in BPC 4128. For ease of reference by the PIC, the revisions also provide sections 25.1.1 through 25.1.4 in which the PIC can delineate the hospital and distances to which centralized packaged unit dose medication are provided.

On page 22, section 26.1.5 was added to read “Prepares unit dose packages for single administration to inpatients from bulk containers, if each unit dose package is barcoded pursuant to section 4128.4. This section is amended to include the changes made by AB 486, which established the requirement for machine readable barcodes on unit dose

medication produced by centralized hospital packaging pharmacies. The Board determined this was necessary to reflect the changes in the law.

On page 22, section 26.1.6 was added to read “Prepares sterile compounded unit dose drugs for administration to inpatients, if each unit dose drug is barcoded pursuant to Section 4128.4.” This section is amended to include the changes made by AB 486, which established the requirement for machine readable barcodes on unit dose medication produced by centralized hospital packaging pharmacies. The Board determined this was necessary to reflect the changes in the law.

On page 24, section 26.1.7 was added to read “Prepares compounded unit dose drugs for administration to inpatients, if each unit dose package is barcoded pursuant to Section 4128.4.” This section is amended to include the changes made by AB 486, which established the requirement for machine readable barcodes on unit dose medication produced by centralized hospital packaging pharmacies. The Board determined this was necessary to reflect the changes in the law.

On pages 24 and 25, renumbered section 26.3, former section 25.3, the following changes were made to provide clarity to the reader. The Board found these changes were necessary for grammatical consistency reflecting the PIC as the user.

- The word “All” was replaced with “Any” as the Board is specifying any part of the unit dose is required to be barcoded as required by BPC 4128.4(a).
- The words “and readable” were deleted and “to be machine readable” to ensure unit doses that are barcoded are able to be read by a machine as required by BPC 4128.4(a).
- The words “using barcode medication administrative software” were added and the words “The barcode information contains” to specify medication software must contain certain elements as required by BPC 4128.4(b).
- Former sections 25.3.1 – 25.3.6 were deleted and replaced with “The barcode medication administration software permits health care practitioners to ensure that before a medication is administered to an inpatient, it is the right medication, for the right inpatient, in the right dose, and via the right route of administration. The software verifies that the medication satisfies the above criteria by reading the barcode on the medication and comparing the information retrieved to the electronic medical record of the inpatient.” to be consistent with statute regarding barcode medication administration as required by BPC 4128.4.

On page 25, renumbered section 26.4, former section 25.4, was added for consistency with recent statutory changes under AB 486, which established the requirement for human-readable labels on unit dose medication produced by centralized hospital

packaging pharmacies, with regard to requirements for unit dose medications produced by a centralized hospital packaging pharmacy. This section was broken into a bulleted list instead of a long paragraph to allow ease of use and includes the following:

26.4.1 The date the medication was prepared.
26.4.2 The beyond-use date
26.4.3 The established name of the drug.
26.4.4 The quantity of each active ingredient.
26.4.5 The lot number or control number assigned by the centralized hospital packaging pharmacy.
26.4.6 Special storage or handling requirements.
26.4.7 The name of the centralized hospital packaging pharmacy.

Additionally, sections 26.4.1, 26.4.2, 26.4.6 and 26.4.7 were added to the bulleted list to further clarify the requirements in BPC 4128.5, which established the requirement for human-readable labels on unit dose medication produced by centralized hospital packaging pharmacies. The Board determined this addition was necessary because the PIC must ensure that the centralized hospital packaging pharmacy is labeling unit dose medications prepared by the pharmacy to ensure patient safety.

On page 25, section 26.5 was added for consistency with recent statutory changes in AB 486 regarding lot or control numbers used in a centralized hospital packaging to read as follows:

26.5 – "The pharmacist is able to retrieve all of the following information using the lot number or control number: (BPC 4128.5 [b])

26.5.1 The components used in the drug product.

26.5.2 The expiration date of each of the drug's components.

26.5.3 The National Drug Code Directory number."

This section was added to incorporate the new statutory requirements in AB 486 and to ensure that the appropriate information is retrievable using the lot number as required in BPC 4128.5. The Board determined this addition of mirrored statutory language was necessary because it is the Board's expectation that a PIC at a centralized hospital packaging pharmacy will be aware of the requirements to retrieve by lot or control number all components used in the drug products; expiration date of drug components and the National Drug Code Director for all drug preparations prepared by the pharmacy, which ensures patient safety.

With the addition of these sections, section 25.5 was renumbered to 26.6.

On page 27, renumbered section 28, former section 27, has been amended to correct the reference to CCR section 1735.2 by deleting [j] for consistency with current regulation.

Changes to Pharmacist-in-Charge Certification

On page 27, after the word “corrected” the following was added “by_____” to provide to allow a space where the PIC could add the date for which the deficiencies will be corrected. The Board determined this was necessary to ensure that there would be further action by the PIC to correct the deficiencies. This is being added for the PIC to provide an expected timeline for resolution of the noncompliance issues. Board staff regularly inspect pharmacies for compliance with laws and regulations; having the expected timeline for resolution will allow for a more meaningful inspection. The inspector and PIC can quickly identify possible noncompliance areas based on the resolution timeline.

Changes to Acknowledgment by Hospital Administrator

A correction to the word ‘acknowledgement’ has been made, deleting an ‘e’ to correct spelling. On page 27, after the word “assessment” in the second sentence, the words “in the timeframe identified in the Pharmacist-in-Charge Certification above” are added to provide clarity to the PIC that any corrections must be made within the timeframe provided in the certification. Adding this statement to the section that the hospital administrator must sign will increase awareness of this requirement to the highest level and ensure compliance. The Board determined this was necessary in order to ensure the PIC would be given support by the hospital administrator to complete the deficiencies. Additionally, it provides an additional layer of accountability for the PIC to ensure areas of noncompliance are addressed timely. Finally, “Hospital Administrator” was added under the signature line for consistency with the PIC certification above it.

Changes to Legal References

On page 27, the list of legal references has been deleted and a new list of legal references has been added as the last page of the document.

The list of legal references has been updated to maintain consistency with the cited references appearing within the self-assessment form. Outdated references have been removed and current references added. To the extent that the regulation duplicates the information from statute, such duplication is to ensure that the regulated public can readily and easily find the requirements in one place as an easy self-check, rather than having to review multiple sources.

Additionally, the contact information for various state, federal, and private agencies has been removed as it may not be the most current information at the time that the PIC completes the self-assessment form and the most accurate information is available on the Internet..

Factual Basis/Rationale

The self-assessment form assists the PICs for the pharmacy in increasing compliance with federal and state requirements and also streamlines the pharmacy inspection process by providing relevant information to the Board inspectors. As the self-assessment forms are incorporated by reference in the regulation 16 CCR section 1715, as laws change, the self-assessment form must be modified by completing the rulemaking process which is generally at least a 12-month processes. Inherent in this process is a 12-month period where the self-assessment forms are inconsistent with statute and regulations because the forms contain statutory and regulatory references that are outdated. As a result, Board licensees may be completing the self-assessment for their operations with outdated information.

To remedy this, the Board is seeking to further define the regulations to clearly and directly state requirements that, until this proposal, were established, only, in the self-assessment form. For example, the requirement for the form to be signed under penalty of perjury is currently established by the self-assessment form.

Underlying Data:

1. Relevant Meeting Materials and Minutes from Legislation and Regulation Committee Meeting held October 26, 2016;
2. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held October 26-27, 2016;
3. Relevant Meeting Materials and Minutes from Board of Pharmacy Meeting held November 8-9, 2107; and
4. Board of Pharmacy Total Licensees from www.pharmacy.ca.gov retrieved December 16, 2017.
5. Drug Quality and Security Act (DQSA)
6. Assembly Bill 15 (Eggman, Chapter 1, Statutes of 2015-16 Second Extraordinary Session)
7. Assembly Bill 40 (Santiago, Chapter 607, Statutes of 2017)
8. Senate Bill 590 (Stone, Chapter 147, Statues of 2015)
9. Senate Bill 999 (Pavley, Chapter 499, Statutes of 2016)
10. Assembly Bill 1743 (Ting, Chapter 331, Statues of 2014)
11. Assembly Bill 1386 (Low, Chapter 374, Statutes of 2016)
12. Senate Bill 1193 (Hill, Chapter 484, Statutes of 2016).

13. Senate Bill 493 (Hernandez, Chapter 469, Statutes of 2013)
14. AB 486 (Bonilla, Chapter 241, Statutes of 2015)
15. Compounding Self-Assessment (Form 17M39, Rev. 2/12)
16. 21 CFR Sections 1306.08, 1306.11, and 1311.100
17. 21 CFR, Part 208, Section 208.24[e]
18. California Health and Safety Code Section 11200
19. California Health and Safety Code Section 11053
20. 21 USC Section 829
21. 21 CFR Section 201.17
22. 21 CFR Section 201.57[c]
23. 21 CFR Part 208

Business Impact

This regulation will not have a significant adverse economic impact on businesses. This initial determination is based on the fact that the proposed regulation affects the Board's administrative processing of updating self-assessment forms that reflect pharmacy law. Pharmacists-in-charge are already required by current pharmacy law to complete and maintain these self-assessments by July 1 of every odd-numbered year.

Economic Impact Assessment Results:

The board concludes that this regulatory proposal will have the following effects:

(1) It is unlikely that the proposal will create or eliminate any jobs within California;
(2) It is unlikely that the proposal will create new, or eliminate existing, businesses in California;
(3) It is unlikely that the proposal will expand businesses currently doing business within the state

The Board does not anticipate an impact to jobs or businesses because these proposed regulations simply change the way in which the Board updates the required self-assessment forms to reflect current pharmacy law.

This regulatory proposal benefits the health and welfare of California residents, as well as, benefiting employee safety. The proposed regulation will update the self-assessment form with current law and regulations. The revised self-assessment forms will aid licensees in assessing their compliance with federal and state pharmacy law to reflect laws and regulations adopted since 2014, and exclude laws and regulations superseded or repealed since 2014. Additionally, this proposal allows for a streamlined and more timely process for updating the self-assessment form, thereby increasing compliance among the regulated public, which will ensure pharmacies are operating in compliance with pharmacy law. Employee safety is benefited by employees operating in

a safe manner, consistent with pharmacy law. 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 requirements. This alternative was rejected because this would require the Board to spend unnecessary time in updating regulations that can be updated using the changes without regulatory effect rulemaking process.